
United States Court of Appeals

for the

Fifth Circuit

Case No. 26-30203

STATE OF LOUISIANA, by & through its Attorney General,
LIZ MURRILL; ROSALIE MARKEZICH,

Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, Acting Commissioner,
U.S. Food and Drug Administration; MICHAEL DAVIS, in his official capacity as
Acting Director, Center for Drug Evaluation & Research, U S Food & Drug
Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES; ROBERT F. KENNEDY, JR., Secretary, U.S. Department of Health and
Human Services,

Defendants-Appellees,

GENBIOPRO, INCORPORATED,

Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellee/Cross-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR
THE WESTERN DISTRICT OF LOUISIANA, LAFAYETTE IN NO. 6:25-CV-1491,
HONORABLE DAVID CLEVELAND JOSEPH, U.S. DISTRICT JUDGE

**BRIEF FOR 259 MEMBERS OF CONGRESS AS *AMICI CURIAE* IN SUPPORT OF
INTERVENORS-APPELLEES/CROSS-APPELLANTS**

ABBY F. RUDZIN
Counsel of Record
O'MELVENY & MYERS LLP
1301 Avenue of the Americas
New York, NY 10019
202-326-2061
arudzin@omm.com

NANCY L. SCHROEDER
O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071
213-430-6000
nschroeder@omm.com

KEITH S. OSENTOSKI
O'MELVENY & MYERS LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
310-553-6700
kosentoski@omm.com

Attorneys for Lead Amici 259 Members of Congress

A complete list of the 47 United States Senators and the 212 Members of the United States House of Representatives participating as *amici curiae* is provided as an appendix. The Lead *Amici Curiae* are:

SEN. CHARLES E. SCHUMER

SEN. PATTY MURRAY

SEN. RICHARD J. DURBIN

SEN. RON WYDEN

REP. HAKEEM JEFFRIES

REP. KATHERINE CLARK

REP. FRANK PALLONE, JR.

REP. JAMIE RASKIN

REP. DIANA DEGETTE

REP. AYANNA PRESSLEY

CERTIFICATE OF INTERESTED PERSONS

State of Louisiana et al. v. Food & Drug Administration et al.

Case No. 26-30203

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

Lead *Amici*

Sen. Charles E. Schumer
Sen. Patty Murray
Sen. Richard J. Durbin
Sen. Ron Wyden
Rep. Hakeem Jeffries
Rep. Katherine Clark
Rep. Frank Pallone, Jr.
Rep. Jamie Raskin
Rep. Diana DeGette
Rep. Ayanna Pressley

Counsel for Lead *Amici*

O'MELVENY & MYERS LLP
ABBY F. RUDZIN
1301 Avenue of the Americas
New York, NY 10019
202-326-2061
arudzin@omm.com

NANCY L. SCHROEDER
400 S. Hope Street
Los Angeles, CA 90071
213-430-6000
nschroeder@omm.com

KEITH S. OSENTOSKI
1999 Avenue of the Stars
Los Angeles, CA 90067
310-553-6700
kosentoski@omm.com

Dated: July 22, 2026

Respectfully submitted,

/s/ Abby F. Rudzin

ABBY F. RUDZIN
O'MELVENY & MYERS LLP
Counsel for Lead Amici 259 Members of Congress

TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PERSONS	i
TABLE OF CITED AUTHORITIES	iv
INTEREST OF <i>AMICI CURIAE</i>	1
SUMMARY OF ARGUMENT	2
ARGUMENT	4
I. FDA’S DECISION TO ELIMINATE THE IN-PERSON DISPENSING REQUIREMENT WAS BASED ON THE HIGH-QUALITY SCIENTIFIC EVIDENCE THE ACT REQUIRES	4
A. Through the Act, Congress directed that FDA’s decisions be science- and evidence-based	4
B. FDA’s repeated determination that mifepristone is safe is supported by peer-reviewed research and years of real patient experience	7
C. FDA’s decision to eliminate the in-person dispensing requirement is supported by substantial evidence that mifepristone remains safe when dispensed by mail or pharmacy	10
II. THE ACT REQUIRES THAT A REMS NOT UNDULY BURDEN PATIENT ACCESS.....	15
A. In removing the in-person dispensing requirement, FDA complied with its congressional mandate not to unduly burden patient access	15
B. The in-person dispensing requirement unduly burdens patient access to mifepristone	16
C. This Court should not permit Louisiana to unduly burden nationwide patient access to medication.....	21
III. LOUISIANA’S CRITICISM OF FDA’S DECISION TO ELIMINATE THE IN-PERSON DISPENSING REQUIREMENT LACKS SCIENTIFIC MERIT AND IS THEREFORE FORECLOSED BY THE ACT	23
A. The Act requires FDA to make decisions based on science, not flawed, ideological publications	23

B. FDA’s use of FAERS data was appropriate under the Act.	24
C. Louisiana should not be able to hijack the science-based REMS system Congress designed to force its policy choices onto others.....	27
CONCLUSION	29
CERTIFICATE OF SERVICE	31
CERTIFICATE OF COMPLIANCE.....	32
APPENDIX: LIST OF <i>AMICI CURIAE</i> 259 MEMBERS OF CONGRESS.....	33
47 United States Senators	33
212 Members of the United States House of Representatives	36

TABLE OF CITED AUTHORITIES

Cases

<i>Am. Coll. of Obstetricians & Gynecologists v. FDA</i> , 472 F. Supp. 3d 183 (D. Md. 2020), <i>order clarified sub nom.</i> , 2020 WL 8167535 (D. Md. Aug. 19, 2020).....	10
<i>Benisek v. Lamone</i> , 585 U.S. 155 (2018)	22
<i>Dobbs v. Jackson Women’s Health Org.</i> , 597 U.S. 215 (2022)	3, 28, 29
<i>Farmland Dairies v. Barber</i> , 65 N.Y.2d 51 (1985).....	29
<i>FCC v. Prometheus Radio Project</i> , 592 U.S. 414 (2021)	26
<i>Purcell v. Kennedy</i> , 2025 WL 3101785 (D. Haw. Oct. 30, 2025).....	14, 15, 18
<i>S. Bay United Pentecostal Church v. Newsom</i> , 590 U.S. 965 (2020)	23
<i>Washington v. FDA</i> , 108 F.4th 1163 (9th Cir. 2024).....	15

Statutes

21 U.S.C. § 355(b)	5
21 U.S.C. § 355(c)	8
21 U.S.C. § 355(d)	5, 6, 8
21 U.S.C. § 355-1(a)	6, 28
21 U.S.C. § 355-1(b)	6
21 U.S.C. § 355-1(f).....	<i>passim</i>
21 U.S.C. § 355-1(g)	7, 12
21 U.S.C. § 393(b)	5
21 U.S.C. § 393(c)	5

Regulations

21 C.F.R. § 312.32	25
21 C.F.R. § 314.520	8
21 C.F.R. § 314.80	26
21 C.F.R. § 314.81	26

Other Authorities

2000 FDA Approval Letter	8
2011 REMS for NDA 020687 Mifeprex (mifepristone) Tablets, 200 mg, (June 2011)	8
Alexa Delbosc & Rahman Shafi, <i>What Do We Know About Immigrants’ Travel Behaviour? A Systematic Literature Review and Proposed Conceptual Framework</i> , 43 Transport Revs. 914 (2023)	18
Am. College of Obstetricians and Gynecologists, <i>Medication Abortion Up to 70 Days of Gestation</i> , Practice Bulletin No. 225 (Oct. 2020)	21
<i>Analysis of Medication Abortion Risk and the FDA Report “Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2024”, Advancing New Standards in Reproductive Health</i> (May 15, 2025)	10
Andrés Argüello & Andrea Ducas, <i>The Big, ‘Beautiful’ Bill’s Health Care Cuts Would Drive Up Uncompensated Care and Threaten Vulnerable Hospitals</i> , Center for American Progress (May 23, 2025), https://www.americanprogress.org/article/the-big-beautiful-bills-health- care-cuts-would-drive-up-uncompensated-care-and-threaten-vulnerable- hospitals/	21
Ann P. Bartel <i>et al.</i> , <i>Racial and Ethnic Disparities in Access to and Use of Paid Family and Medical Leave: Evidence from Four Nationally Representative Datasets</i> , U.S. Bureau of Labor Statistics (Jan. 2019)	20
Ashley Stoneburner, <i>et al.</i> , <i>Nowhere to Go: Maternity Care Deserts Across the US</i> , March of Dimes (2024)	22
Caitlin Myers <i>et al.</i> , <i>Abortion Access Dashboard</i> , https://experience.arcgis.com/experience/6e360741bfd84db79d5db774a11 47815 (last updated Oct. 1, 2025)	17
Citizen Petition from American College of Obstetricians and Gynecologists, https://www.regulations.gov/document/FDA-2025-P-0377-0001	10

<i>FDA Adverse Event Monitoring System (AEMS)</i> , FDA (Mar. 11, 2026), https://www.fda.gov/drugs/surveillance/fda-adverse-event-monitoring-system-aems	24
<i>FDA Adverse Event Reporting System (FAERS) Public Dashboard FAQs</i> , FDA, https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html#_Toc514144622	25
<i>FDA Ctr. For Drug Eval. & Rsch., Application No. 020687Orig1s020 Summary Review</i> (Jan. 3, 2023)	12
FDA Letter re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA #020687 (Apr. 12, 2021)	11
FDA Letter Regarding Citizen Petition Denial (Mar. 29, 2016), https://www.regulations.gov/document/FDA-2002-P-0364-0002	13
FDA Letter to Am. Ass’n of Pro-Life Obstetricians & Gynecologists (Dec. 16, 2021)	25, 27
FDA REMS Modification Rationale Review, NDA No. 020687 & ANDA No. 91178 (Dec. 16, 2021)	11, 12
FDA REMS Modification Review, NDA No. 020687/S-020 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf	9, 10
Jason M. Lindo <i>et al.</i> , <i>How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions</i> , 55 J. Human Resources 1137 (2020).....	17
Jillian McKoy, <i>Travel Times to Abortion Facilities Have Increased Drastically in Post-Roe Era</i> , Bos. Univ. Sch. of Pub. Health (Nov. 23, 2022).....	18
Laura Schummers <i>et al.</i> , <i>Abortion Safety and Use with Normally Prescribed Mifepristone in Canada</i> , 386 New Eng. J. Med. 57 (2022)	10
Lauren J. Ralph <i>et al.</i> , <i>Comparison of No-Test Telehealth and In-Person Medication Abortion</i> , 332 JAMA 898 (2024)	14
Lauren Van Schilfgaarde <i>et al.</i> , <i>Tribal Nations and Abortion Access: A Path Forward</i> , 46 Harv. J.L. & Gender 1 (2023)	18
Leonardo Cely-Andrade <i>et al.</i> , <i>Telemedicine for the Provision of Medication Abortion to Pregnant People at Up to Twelve Weeks of Pregnancy: A Systematic Literature Review And Meta-Analysis</i> , 21 Reproductive Health 136 (2024).....	14

Letter from Dr. Graham Chelius of The Society of Family Planning to FDA (Sept. 29, 2021)	16, 19
Liza Fuentes & Jenna Jerman, <i>Distance Traveled for Abortion in the United States and Reasons for Clinic Choice</i> , 28 J. Women's Health 1623 (2019).....	18
M. Antonia Biggs <i>et al.</i> , <i>Access to Reproductive Health Services Among People with Disabilities</i> , JAMA Network Open, Vol. 6, No. 11 (Nov. 29, 2023).....	17
Margot Sanger-Katz, <i>et al.</i> , <i>Who Gets Abortions in America?</i> , New York Times (Dec. 14, 2021), <a href="https://www.nytimes.com/interactive/2021/12/14/upshot/who-gets-
abortions-in-america.html">https://www.nytimes.com/interactive/2021/12/14/upshot/who-gets- abortions-in-america.html	20
Mifepristone 2023 Labeling and Medication Guide.....	13
<i>Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024</i> , FDA (2025), https://fda.gov/media/185245/download	10, 12, 13
Nat'l P'ship for Women & Families, <i>Paid Sick Days Enhance Women's Abortion Access and Economic Security</i> 3 (May 2019).....	20
<i>Office Memorandum to Population Council</i> (Sept. 28, 2000), FDA, <a href="https://wayback.archiveit.org/7993/20161024033545/http://www.fda.gov/
downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatien
tsandProviders/ucm111366.pdf">https://wayback.archiveit.org/7993/20161024033545/http://www.fda.gov/ downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatien tsandProviders/ucm111366.pdf	8
<i>Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation</i> , FDA (Feb. 8, 2026), <a href="https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-
and-providers/questions-and-answers-mifepristone-medical-termination-
pregnancy-through-ten-weeks-gestation">https://www.fda.gov/drugs/postmarket-drug-safety-information-patients- and-providers/questions-and-answers-mifepristone-medical-termination- pregnancy-through-ten-weeks-gestation	8
Reproductive Health Researches Comment Letter to FDA, UCLA Law (Aug. 27, 2025), <a href="https://law.ucla.edu/reproductive-health-researchers-
comment-letter-fda">https://law.ucla.edu/reproductive-health-researchers- comment-letter-fda	24
<i>Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg</i> , FDA (Jan. 2023), <a href="https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023
_01_03_REMS_Full.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023 _01_03_REMS_Full.pdf	12
Selena Simmons-Duffin & Shelly Cheng, <i>How Many Miles Do You Have to Travel to Get Abortion Care? One Professor Maps It</i> , NPR (June 21, 2023)	17

U.S. Gov’t Accountability Off., GAO-08-751, FDA Approval and Oversight
of the Drug Mifeprex (2008)8

Ushma D. Upadhyay, et al., *Outcomes and Safety of History-Based
Screening for Medication Abortion A Retrospective Multicenter Cohort
Study*, 182 JAMA 482 (2022)..... 10, 14

Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth
Medication Abortion in the United States*, 30 Nature Med. 1191 (2024).....13

What is a Serious Adverse Event?, FDA (May 18, 2023),
[https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-
adverse-event](https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event)26

INTEREST OF *AMICI CURIAE*

Amici curiae are 259 Members of Congress—47 United States Senators and 212 Members of the United States House of Representatives.¹ *Amici* have a special interest in upholding the Constitution’s separation of powers—including by ensuring that administrative agencies faithfully exercise the authorities Congress delegated to them in accordance with statutory limits—and protecting the health and safety of their constituents.

Amici believe that this Court should not enter a Section 705 stay of the 2023 mifepristone a Risk Evaluation and Mitigation Strategy (“REMS”) to require the nationwide reinstatement—after five years—of the in-person dispensing requirement. Louisiana’s requested relief has no basis in law, threatens the congressionally mandated evidence-based process for drug-regulatory decisions, and poses a serious health risk to pregnant individuals. Mifepristone, which patients have used for more than 25 years as part of the most common and recommended regimen for medication abortion, should not be made more difficult to access across the entire country simply because Louisiana has struggled to enforce the abortion restrictions it desires to inflict on its own citizens. Louisiana’s request for a

¹ Under FRAP 29(a)(2), counsel for *Lead Amici* certify that all parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. The complete list of *amici* is located in the Appendix.

nationwide stay—which the Supreme Court has already rejected once—is particularly egregious before the merits have been litigated.

Accordingly, *Amici* respectfully urge this Court to deny Louisiana’s request for a nationwide Section 705 stay of mifepristone’s 2023 REMS.

SUMMARY OF ARGUMENT

Congress designed a regulatory scheme to ensure Americans’ access to safe and effective medications by requiring expert-led, evidence-based scientific decision-making. In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (the “Act”), which established the standards for the modern regulation of our drug supply and designated the U.S. Food and Drug Administration (“FDA”) as the expert federal agency responsible for regulating access to new drugs. While Congress permitted judicial review of FDA’s approval decisions, it did not invite federal courts to short-circuit the statutorily mandated expert process, weigh scientific evidence in the first instance, or unduly burden access to FDA-approved medications.

FDA’s decision to eliminate the in-person dispensing requirement for mifepristone complied with Congress’s mandate that any restrictions FDA imposes on access to an approved medication must (a) be rooted in sound scientific evidence and (b) not impose unnecessary access burdens. For more than a quarter century, FDA has repeatedly and consistently affirmed that mifepristone is safe. Over seven

million patients in the U.S. have safely used mifepristone. And as with other drugs, FDA continues to monitor the post-marketing safety data on mifepristone—data confirming that mifepristone is safe without regard to how it is dispensed.

FDA’s decision to lift the in-person dispensing requirement was an evidence-based exercise of its congressionally mandated responsibility to avoid unnecessary burdens on patient access to medication. Louisiana’s accusation (Br. at 1) that FDA was motivated by a desire “to undermine” *Dobbs v. Jackson Women’s Health Organization*, 597 U.S. 215 (2022), is belied by the timeline: The in-person dispensing requirement was first suspended by a court in 2020 and later eliminated altogether by the FDA in 2021, *before Dobbs* came down. Louisiana knows these facts but continues to make this spurious claim in its attempt to reimpose an unnecessary burden on all Americans, even residents of states that protect abortion.

Decades after FDA’s initial approval of mifepristone and years after the in-person dispensing requirement was eliminated, Louisiana now seeks to re-impose this onerous nationwide restriction on all Americans. Granting such relief would undermine the science-based statutory framework Congress requires and threatens patient access to reproductive health care. As has been well documented, many Americans in states where abortion is legal live far from any reproductive health care provider. Reinstating an in-person dispensing requirement for mifepristone

exacerbates an already significant reproductive health crisis by limiting access to the most common method of early abortion.

Preserving evidence-based access to mifepristone, including when dispensed by mail or retail pharmacy, is necessary to mitigate this harm. Women deserve access to mifepristone for reproductive health care, and all Americans deserve integrity in the congressionally mandated, evidence-based process for FDA’s drug regulatory decisions. Congress commanded that FDA’s drug regulatory decisions be rooted in sound scientific evidence and prioritize patient access to essential medications, and *Amici* call on this Court to give due weight to Congress’s mandate.

ARGUMENT

I. FDA’S DECISION TO ELIMINATE THE IN-PERSON DISPENSING REQUIREMENT WAS BASED ON THE HIGH-QUALITY SCIENTIFIC EVIDENCE THE ACT REQUIRES.

A. Through the Act, Congress directed that FDA’s decisions be science- and evidence-based.

Congress required FDA to review new drugs and regulate existing drugs in accordance with established scientific principles. The centrality of sound science is evident throughout the Act, including in FDA’s mission statement: To “promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products” and ensuring that “drugs

are safe and effective.”² The Act directs FDA to carry out this mission by “consult[ing] with experts in science, medicine, and public health” and collaborating with “science-based Federal agencies.”³ In short, Congress designed the Act to ensure that drug regulatory decisions are based on robust evidence.

The Act makes clear that science- and evidence-based determinations are requisite elements of FDA’s complex drug approval and regulation processes. An approval of a New Drug Application, for example, requires a team of FDA experts with specialized scientific expertise—including physicians, statisticians, chemists, pharmacologists, and other scientists—to review “full reports of investigations” and determine that there is “substantial evidence” of safety and efficacy.⁴ And Congress defined “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.”⁵ When science-based standards provide substantial evidence of a drug’s

² 21 U.S.C. §§ 393(b)(1)-(2).

³ 21 U.S.C. §§ 393(b)(4), (c).

⁴ 21 U.S.C. § 355(d); *see also* 21 U.S.C. § 355(b)(5)(A) (explaining that all individuals who review new drug applications should have “technical excellence . . . and knowledge of regulatory and scientific standards”).

⁵ 21 U.S.C. § 355(d).

safety and efficacy, and none of the limited other grounds under the statute exist to refuse approval, FDA “shall” approve it.⁶

Congress requires that any decision by FDA to impose a Risk Evaluation and Mitigation Strategy (“REMS”) must also follow the science. Congress authorized FDA to impose REMS restrictions only after a determination that such restrictions are “*necessary* to ensure that the benefits of the drug outweigh the risks of the drug,” considering specified, evidence-based factors including the seriousness of the condition to be treated, the expected benefit of the drug, and the seriousness of any known or potential adverse events related to the drug.⁷ A post-approval REMS is authorized only if there is “new safety information” or a “signal of a serious risk,” established by “scientific data,” such as “information derived from a clinical trial,” or “peer-reviewed biomedical literature.”⁸ And Congress limited FDA’s authority to impose “elements to assure safe use,” the most onerous kind of REMS—such as the in-person dispensing requirement (“IPDR”) at issue here—to only those drugs

⁶ *Id.* The statute provides only seven narrow grounds for refusing approval: five focus on lack of sufficient safety or efficacy evidence, one concerns patent information, and one concerns misleading labeling.

⁷ 21 U.S.C. § 355-1(a)(1) (initial approval REMS) (emphasis added); 21 U.S.C. § 355-1(a)(2) (post-approval REMS).

⁸ 21 U.S.C. § 355-1(b)(3) (defining “new safety information”); 21 U.S.C. § 355-1(b)(6) (defining what evidence is permissible to show a “signal of a serious risk”).

for which it is so necessary that FDA would otherwise need to withdraw its approval of the drug.⁹

Even after a REMS has been imposed, FDA may—and in some circumstances must—continually assess the REMS strategies and goals and modify the REMS if necessary.¹⁰ The Act requires that, in assessing a REMS, FDA must evaluate whether each REMS and each REMS element continues to meet its goals.¹¹ The Act also specifically contemplates modification of a drug’s REMS, including removal of specific elements such as an IPDR, to, among other things, “minimize the burden on the health care delivery system of complying with the strategy.”¹²

In short, Congress has mandated a rigorous, science-based system for drug approvals and regulation. Neither FDA nor the federal courts have authority to impose restrictions that are not grounded in sound scientific evidence.

B. FDA’s repeated determination that mifepristone is safe is supported by peer-reviewed research and years of real patient experience.

Substantial evidence establishes that mifepristone is a safe drug. FDA first approved mifepristone in September 2000, based on peer-reviewed research and

⁹ 21 U.S.C. § 355-1(f)(1)(A).

¹⁰ 21 U.S.C. § 355-1(g)(2).

¹¹ 21 U.S.C. § 355-1(g)(3).

¹² 21 U.S.C. § 355-1(g)(4).

extensive clinical trials showing that mifepristone is safe and effective and that its health benefits outweighed its risks.¹³ That approval process took four years, involved three separate clinical trials with more than 4,000 patients, and yielded unanimous approval.¹⁴ As FDA put it, its approval of mifepristone was “based on a thorough and comprehensive review of the scientific evidence presented” that found mifepristone was “safe and effective for its indicated use.”¹⁵ The Act therefore required FDA to approve it.¹⁶

FDA initially approved mifepristone with certain restrictions.¹⁷ After fifteen years of data from millions of patient uses showing that serious adverse events are

¹³ See 2000 FDA Approval Letter (ROA.604-06); *see also* U.S. Gov’t Accountability Off., GAO-08-751, FDA Approval and Oversight of the Drug Mifeprex at 15–16, 26 (2008) (hereinafter referenced by ROA cite) (ROA.4483-84, 4494).

¹⁴ See *Office Memorandum to Population Council* (Sept. 28, 2000), FDA, <https://wayback.archiveit.org/7993/20161024033545/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf>; *see also* ROA.4483-84, 4494.

¹⁵ *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 8, 2026), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation>.

¹⁶ See 21 U.S.C. §§ 355(d) and 355(c)(1) (without specified ground for denial, FDA “shall” approve a drug application).

¹⁷ These restrictions, originally adopted under Subpart H (21 C.F.R. § 314.520), were later incorporated into FDA’s 2011 REMS. See 2011 REMS for NDA 020687 Mifeprex (mifepristone) Tablets, 200 mg, (June 2011) (ROA.640-49).

“extremely rare” and additional scientific evidence further demonstrating mifepristone’s safety, FDA began, consistent with the Act’s requirements, to eliminate some unnecessary REMS restrictions. Specifically, in 2016, FDA modified the REMS to permit qualified non-physician practitioners to become certified prescribers and to remove a REMS requirement that prescribers report non-fatal adverse events potentially associated with mifepristone.¹⁸

In making these modifications, FDA’s scientific and medical reviewers examined numerous articles “published widely in peer-reviewed medical journals,” independent clinical studies on “well over 30,000 patients,” and adverse event reporting across more than 2.5 million patient uses in the U.S. between 2000 and 2016.¹⁹ FDA relied on mifepristone’s stable risk profile over fifteen years of mandatory serious-adverse-event prescriber reporting to conclude that such reporting was no longer necessary. FDA explained that “the safety profile of [mifepristone] is well-characterized,” “no new safety concerns” had arisen in recent

¹⁸ FDA REMS Modification Review, NDA No. 020687/S-020, at 6, 8, 88 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

¹⁹ *Id.* at 13, 62, 84.

years, and “the known serious risks occur rarely.”²⁰ That decision was supported by the weight of scientific evidence, as the Act requires.²¹

C. FDA’s decision to eliminate the in-person dispensing requirement is supported by substantial evidence that mifepristone remains safe when dispensed by mail or pharmacy.

The volumes of high-quality research and real-world data amassed over the past 25 years establish that mifepristone is a safe treatment whether it is dispensed in person or not.²² Decades of reliable science and data confirming mifepristone’s safety and efficacy supported FDA’s 2021 and 2023 decisions to first suspend and then eliminate the IPDR.

In July 2020, a federal court suspended enforcement of the IPDR due to the COVID-19 pandemic.²³ In April 2021, based in part on real-world experience of

²⁰ *Id.* at 8.

²¹ See Citizen Petition from American College of Obstetricians and Gynecologists, <https://www.regulations.gov/document/FDA-2025-P-0377-0001> (explaining evidence demonstrating safety of mifepristone).

²² See, e.g., NDA No. 020687 & ANDA No. 091178, *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2024*, FDA (2025), <https://fda.gov/media/185245/download>; Laura Schummers *et al.*, *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57, 57 (2022); *Analysis of Medication Abortion Risk and the FDA Report “Mifepristone US Post-Marketing Adverse Events Summary Through 12/31/2024”*, Advancing New Standards in Reproductive Health (May 15, 2025); Ushma D. Upadhyay, *et al.*, *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study*, 182 JAMA 482, 487 (2022).

²³ *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 218 (D. Md. 2020), *order clarified sub nom.*, 2020 WL 8167535 (D. Md. Aug. 19, 2020) (relying on, *inter alia*, a “comprehensive report on the safety of abortion by the

mifepristone's continued safety while that injunction was in place, and consistent with FDA's obligation under the Act to consider burdens on patient access, FDA announced that it would suspend enforcement of mifepristone's IPDR for the duration of the pandemic.²⁴ This decision was based on substantial evidence, including adverse-event and clinical outcome data showing that mifepristone remained safe without the IPDR.²⁵

In December 2021, after reviewing additional published literature, safety information, and adverse-event data, FDA announced that it would remove the IPDR altogether.²⁶ Consistent with the Act, this decision was based on large amounts of high-quality scientific data, including REMS assessment data; data from the FDA Adverse Event Reporting System ("FAERS") during the non-enforcement period,

National Academies of Sciences, Engineering, and Medicine, an independent, nonpartisan group, which found that there is no evidence that the dispensing or taking of [medication abortion pills] requires the physical presence of a clinician.") (internal quotation marks omitted).

²⁴ FDA Letter re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA #020687 (Apr. 12, 2021) (ROA.6567-68).

²⁵ *Id.*

²⁶ See FDA REMS Modification Rationale Review, NDA No. 020687 & ANDA No. 91178, at 4 (Dec. 16, 2021) (hereinafter referenced by ROA cite) (ROA.1058) (noting that FDA would remove the IPDR following FDA's "comprehensive review" of scientific data, including published literature, safety information collected during pandemic, one-year REMS assessment report of the Mifepristone REMS Program, adverse event data, and information provided by advocacy groups, individuals, and applicants).

which showed no increase in adverse events; and numerous published studies assessing safety outcomes for thousands of patients using different mifepristone distribution systems, including at pharmacies and by mail.²⁷ This body of scientific data “generally support[ed] a conclusion that dispensing by mail is safe” and that “mifepristone will remain safe, and efficacy will be maintained if the [IPDR] is removed.”²⁸

In January 2023, FDA amended the mifepristone REMS to formally remove the IPDR and add a new pharmacy certification requirement.²⁹ Decades of data continue to confirm mifepristone’s safety and the rarity of serious complications. A recent FDA summary report, for example, found that among the patients who used mifepristone in the United States between 2000 and 2024, only 0.008% experienced blood loss requiring transfusions, 0.006% experienced an infection, most of which were not severe.³⁰ That same report shows that death after ingestion of mifepristone

²⁷ ROA.1064.

²⁸ ROA.1077, 1093.

²⁹ FDA Ctr. For Drug Eval. & Rsch., Application No. 020687Orig1s020 Summary Review (Jan. 3, 2023) (ROA.964-1053); *see also Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg*, FDA (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_REMS_Full.pdf. The January 2023 REMS modifications followed additional statutorily-required consultation with the drug sponsors. *See* 21 U.S.C. § 355-1(g)(4)(B).

³⁰ *Mifepristone U.S. Post-Marketing Adverse Events Summary*, *supra* n.22.

are incredibly low (0.00048%), and FDA has repeatedly made clear that there is no evidence showing that mifepristone caused any of these deaths.³¹ Indeed, “[n]o causal relationship between [mifepristone] and misoprostol use and an increased risk of infection or death has been established.”³²

Nor is there any evidence that serious adverse events have increased since FDA eliminated the IPDR. To the contrary, recent research continues to demonstrate that mifepristone is safe and effective without the IPDR, including when it is prescribed via telemedicine and dispensed by mail or pharmacy.³³ One study demonstrated that the rate of serious adverse events for patients who obtained mifepristone by mail after a telemedicine visit, rather than in person, is comparable

³¹ *Id.* (summary report included fatalities “regardless of causal attribution to mifepristone”).

³² Mifepristone 2023 Labeling and Medication Guide, at 2, 5 (hereinafter referenced by ROA cite) (ROA.329, 332). *See also* FDA Letter Regarding Citizen Petition Denial, at 25-26 n.69 (Mar. 29, 2016), <https://www.regulations.gov/document/FDA-2002-P-0364-0002> (FDA concluding that the “critical risk factor” for certain rare serious infections after mifepristone use “[wa]s pregnancy itself,” not mifepristone); ROA.328, 341, 343 (mifepristone label noting that “serious and sometimes fatal infections or bleeding” can arise whenever the pregnant uterus is evacuated, whether by “miscarriage, surgical abortion, medical abortion, or childbirth”).

³³ Ushma D. Upadhyay *et al.*, *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 *Nature Med.* 1191, 1191 (2024) (“[M]edication abortion [delivered through telemedicine care] is effective, safe, and comparable to published rates of in-person medication abortion care.”).

and, for either method of dispensing, extremely low.³⁴ Numerous other studies on telemedicine medication abortions have confirmed that safety rates are similar whether mifepristone was dispensed in person or by mail.³⁵

Evidence of mifepristone’s safety and efficacy is so well established that a federal court recently found that FDA acted arbitrarily and capriciously in deciding to maintain other REMS requirements for mifepristone in 2023 when it eliminated the IPDR. In other words, the court found that ***FDA continues to subject mifepristone today to more stringent REMS restrictions*** than are justified by the scientific evidence.³⁶ The court recognized that a wealth of high-quality evidence demonstrates that mifepristone remains extremely safe when regulated as other prescription drugs are (i.e., without special REMS restrictions). The court highlighted “statements from preeminent medical societies urging elimination of the mifepristone REMS” and a Canadian study finding that adverse events and

³⁴ See, e.g., Lauren J. Ralph *et al.*, *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 902 (2024).

³⁵ Upadhyay, *supra* n.22 at 482-91 (finding “similarly high effectiveness and safety rates comparing patients who received medications in-person vs by mail” and concluding that “mifepristone can be dispensed safely either in person or by mail”); Leonardo Cely-Andrade *et al.*, *Telemedicine for the Provision of Medication Abortion to Pregnant People at Up to Twelve Weeks of Pregnancy: A Systematic Literature Review And Meta-Analysis*, 21 Reproductive Health 136, at 18 (2024) (analyzing nearly two dozen published articles and concluding that there are no significant safety differences between telehealth and in-person abortion care).

³⁶ *Purcell v. Kennedy*, 2025 WL 3101785, at *23–27 (D. Haw. Oct. 30, 2025).

complications did not increase after Canada eliminated all of its special restrictions on mifepristone.³⁷

II. THE ACT REQUIRES THAT A REMS NOT UNDULY BURDEN PATIENT ACCESS.

A. In removing the in-person dispensing requirement, FDA complied with its congressional mandate not to unduly burden patient access.

Through the Act, Congress commanded that FDA cannot impose burdensome restrictions (such as an IPDR requirement) unless that restriction is “commensurate with the specific serious risk and [does] not unduly burden patient access.”³⁸ FDA must “consider[] in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and patients with functional limitations.”³⁹ Patient access is paramount: if FDA imposes such restrictions, it must “periodically reevaluate them to ensure the restrictions are well calibrated to balance safety, access, and the burden on the health care delivery system.”⁴⁰

³⁷ *Id.* at *23 (internal quotation marks omitted).

³⁸ *Washington v. FDA*, 108 F.4th 1163, 1169 (9th Cir. 2024) (internal quotation marks omitted); 21 U.S.C. § 355-1(f)(2).

³⁹ 21 U.S.C. § 355-1(f)(2)(C)(ii)–(iii).

⁴⁰ *Washington*, 108 F.4th at 1169 (internal quotation marks omitted); 21 U.S.C. § 355-1(f)(5)(B).

FDA's consideration of patient burden when eliminating the IPDR was thus mandatory, not discretionary. FDA would have violated its statutory obligation if it had failed to consider the burdens the IPDR imposes on patient access and to modify the REMS accordingly. Its decision to do so was appropriate.

B. The in-person dispensing requirement unduly burdens patient access to mifepristone.

Requiring a patient to obtain a medication at a hospital or medical office rather than by mail or at a pharmacy significantly burdens access to that medication. The Act therefore prohibits FDA from imposing such a requirement without substantial justification, and here no such justification exists. Not surprisingly, IPDRs are extremely rare: applying to “fewer than 0.1% of FDA-approved drugs.”⁴¹ Louisiana's request is untethered to any legitimate safety concern and would impose onerous burdens on pregnant women nationwide—the exact opposite of what Congress commands FDA to do.

Even within one's own state, traveling to and from a provider to obtain mifepristone requires time and imposes costs, such as gas or transportation fares, childcare, and lost wages. This reality is true regardless of where the patient lives,

⁴¹ See Letter from Dr. Graham Chelius of The Society of Family Planning to FDA, at 4 (Sept. 29, 2021).

but the burden grows with distance—potentially requiring more expensive travel, such as airfare or overnight lodging.

Distance from an in-person provider is a significant barrier to accessing abortion care.⁴² Research shows that even moderate increases in distance to a provider negatively impacts abortion access—e.g., traveling just 50-100 miles decreases abortion rates by 16%, and greater distances yielded even further declines (28% at 100-150 miles, 38% at 150-200 miles, and 44% beyond 200 miles).⁴³ And as of April 2023, one study had found that “the average American is 86 miles from a provider.”⁴⁴ Another study found that 50.7% of people with disabilities experienced logistical barriers to accessing reproductive health care, compared to 29.7% of people without disabilities.⁴⁵ Eliminating the IPDR minimizes burdens in accessing mifepristone and is thus consistent with the Act’s statutory command that FDA consider “in particular . . . patients who have difficulty accessing health care

⁴² See Caitlin Myers *et al.*, *Abortion Access Dashboard*, <https://experience.arcgis.com/experience/6e360741bfd84db79d5db774a1147815> (last updated Oct. 1, 2025).

⁴³ Jason M. Lindo *et al.*, *How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions*, 55 J. Human Resources 1137, 1152–53 (2020).

⁴⁴ Selena Simmons-Duffin & Shelly Cheng, *How Many Miles Do You Have to Travel to Get Abortion Care? One Professor Maps It*, NPR (June 21, 2023).

⁴⁵ M. Antonia Biggs *et al.*, *Access to Reproductive Health Services Among People with Disabilities*, JAMA Network Open, Vol. 6, No. 11 at 6–7 (Nov. 29, 2023).

(such as patients in rural or medically underserved areas)” and “patients with functional limitations.”^{46,47} Indeed, studies show that patients in rural areas are eight times more likely than patients living in urban areas to have to travel more than 100 miles to access abortion care (36% to 4%).⁴⁸ Louisiana’s request for a nationwide order—a federal requirement that every mifepristone patient in the country travel to a hospital or medical office just to be handed a pill—would impose exactly the kind of burden on patients that Congress prohibited, particularly for patients in rural or medically underserved areas.⁴⁹

Patients suffer from these financial burdens, but so does the health care delivery system, which Congress also mandates FDA to consider in its burden analysis.⁵⁰ The IPDR reduces the quantity of mifepristone providers, making it even harder to find and reach one. This is because the IPDR imposes an “extremely

⁴⁶ 21 U.S.C. § 355-1(f)(2)(C)(ii)–(iii).

⁴⁷ See *Purcell*, 2025 WL 3101785, at *18–19 (discussing need to address burdens of in-person dispensing and related requirements).

⁴⁸ Liza Fuentes & Jenna Jerman, *Distance Traveled for Abortion in the United States and Reasons for Clinic Choice*, 28 J. Women’s Health 1623, 1627 (2019).

⁴⁹ See, e.g., Lauren Van Schilfgaarde *et al.*, *Tribal Nations and Abortion Access: A Path Forward*, 46 Harv. J.L. & Gender 1 (2023); Jillian McKoy, *Travel Times to Abortion Facilities Have Increased Drastically in Post-Roe Era*, Bos. Univ. Sch. of Pub. Health (Nov. 23, 2022); Alexa Delbosc & Rahman Shafi, *What Do We Know About Immigrants’ Travel Behaviour? A Systematic Literature Review and Proposed Conceptual Framework*, 43 Transport Revs. 914 (2023); Fuentes, *supra* n.48.

⁵⁰ 21 U.S.C. § 355-1(f)(2)(D).

unusual” burden on providers “to serve as, in effect, both prescribers and pharmacists” by stocking and dispensing mifepristone onsite at their health center, rather than issuing a prescription to be filled at a pharmacy.⁵¹ As FDA recognized, these burdens significantly decreased the number of qualified providers offering mifepristone, with evidence showing that provider volume would “potentially doubl[e]” with elimination of the IPDR.⁵² The IPDR thus “burdens the health care delivery system and severely reduces patient access because of the challenges of obtaining institutional approval to dispense mifepristone onsite and the complicated logistics necessary to do so.”⁵³ Eliminating the IPDR is thus consistent with the Act’s statutory command that FDA “minimize the burden on the health care delivery system” and ensure that a REMS “not be unduly burdensome on patient access.”⁵⁴

The IPDR also imposes other real-world economic burdens. A majority of women seeking abortion care already have children, meaning the IPDR forces them to incur additional child care and family accommodation costs while traveling to

⁵¹ Letter from Dr. Graham Chelius of The Society of Family Planning to FDA, at 4 (Sept. 29, 2021).

⁵² *See id.* (noting that “the proportion of medication abortion providers would likely double if clinicians were permitted to prescribe mifepristone through a pharmacy”).

⁵³ *Id.*

⁵⁴ 21 U.S.C. § 355-1(f)(2)(C)–(D).

access mifepristone.⁵⁵ Additionally, many people seeking abortion care lack paid time off, meaning the IPDR forces them to lose wages and employment opportunities to access this care.⁵⁶ And the unduly burdensome consequences of Louisiana’s nationwide request will disproportionately burden people of color and low-income Americans. Black and Hispanic employees, for example, are less likely to have paid parental leave and paid sick leave benefits than white employees.⁵⁷ For people residing in states that permit telemedicine abortion care, ensuring access to this safe, effective, and legal medication without requiring in-office dispensing alleviates these burdens.

These burdens are not just economic—they can make the difference in whether a patient can access an abortion at all. Navigating travel-related costs and logistical barriers can delay patients past the point in pregnancy when medication abortion is available. This might force them into a more invasive, resource-

⁵⁵ Margot Sanger-Katz, *et al.*, *Who Gets Abortions in America?*, New York Times (Dec. 14, 2021), <https://www.nytimes.com/interactive/2021/12/14/upshot/who-gets-abortion-in-america.html>.

⁵⁶ See Nat’l P’ship for Women & Families, *Paid Sick Days Enhance Women’s Abortion Access and Economic Security* 3, 5 (May 2019) (finding that “people without paid sick days are three times more likely than people with paid sick days to delay or go without medical care for themselves” and that women lacking paid sick days face “lost wages and possibly job loss”).

⁵⁷ See Ann P. Bartel *et al.*, *Racial and Ethnic Disparities in Access to and Use of Paid Family and Medical Leave: Evidence from Four Nationally Representative Datasets*, U.S. Bureau of Labor Statistics (Jan. 2019).

intensive, and expensive procedure, which may itself only be available at an even greater distance.⁵⁸ This has dramatic consequences on the lives of everyday Americans seeking to make important reproductive health care decisions for their families and dire consequences on health care systems nationwide—both of which are already strained.⁵⁹

C. This Court should not permit Louisiana to unduly burden nationwide patient access to medication.

Reinstating the IPDR would needlessly force patients—even for those residing in states that have chosen to permit telemedicine abortion—to travel farther and spend more time and money to access a safe medication in person. FDA carefully evaluated extensive real-world evidence and determined that in-person dispensing of mifepristone does not enhance patient safety, while removing the requirement reduces burdens on patients and the health care system. This Court should reject Louisiana’s request for a nationwide stay because doing so would

⁵⁸ See, e.g., Am. College of Obstetricians and Gynecologists, *Medication Abortion Up to 70 Days of Gestation*, Practice Bulletin No. 225 (Oct. 2020).

⁵⁹ See Andrés Argüello & Andrea Ducas, *The Big, ‘Beautiful’ Bill’s Health Care Cuts Would Drive Up Uncompensated Care and Threaten Vulnerable Hospitals*, Center for American Progress (May 23, 2025), <https://www.americanprogress.org/article/the-big-beautiful-bills-health-care-cuts-would-drive-up-uncompensated-care-and-threaten-vulnerable-hospitals/> (estimating that recent Republican policy will result in 13.7 million Americans losing health insurance and providers to face an estimated \$31 billion in uncompensated care costs).

undermine Congress’s mandate and unduly burden patient access to this medication all across the United States.

Reinstating the IPDR severely limits access to mifepristone and denies medically appropriate care to patients far beyond Louisiana’s borders, exacerbating existing inequities in maternal health for patients of color, patients with low income, patients with disabilities, and patients living in rural areas—the populations most likely to rely on telemedicine care.⁶⁰ Indeed, more than half of U.S. counties do not have a hospital that provides obstetric care; 35% do not even have a single birthing facility or obstetric clinician.⁶¹

Mifepristone has been used as part of the most common and recommended regimen for medication abortion for more than 25 years and has been available without FDA’s IPDR for more than five years. Health care delivery systems have adapted and created new infrastructure in reliance on that evidence-based decision. Allowing Louisiana to force a nationwide rollback of this status quo would have a “needlessly chaotic and disruptive effect.”⁶² The impact would be acute in states with legal protections for abortion under state law. Such an injunction would further

⁶⁰ See generally Ashley Stoneburner, *et al.*, *Nowhere to Go: Maternity Care Deserts Across the US*, March of Dimes (2024).

⁶¹ *Id.* at 8 (noting that approximately 6 in 10 of these counties are rural, less populated areas).

⁶² *Benisek v. Lamone*, 585 U.S. 155, 161 (2018) (internal quotation marks omitted).

burden already taxed health care systems, harm residents of those States, and undermine their sovereign policy choices. Many states and private providers have invested in infrastructure to deliver medication abortion via telemedicine—investments that would be undermined by the reinstatement of in-person dispensing.

FDA’s decision to eliminate the IPDR complied with the Congressionally-mandated requirement to minimize burdens on the healthcare system and patients using it, and Louisiana’s request would force FDA to reimpose restrictions that violate the Act.

III. LOUISIANA’S CRITICISM OF FDA’S DECISION TO ELIMINATE THE IN-PERSON DISPENSING REQUIREMENT LACKS SCIENTIFIC MERIT AND IS THEREFORE FORECLOSED BY THE ACT.

A. The Act requires FDA to make decisions based on science, not flawed, ideological publications.

Congress created FDA to ensure that subject-matter experts review the safety of drugs and medical devices, relying on scientifically sound evidence.⁶³ As detailed above, FDA eliminated the IPDR because the evidence showed that patient health and safety will be protected while “assur[ing] access and minimiz[ing] burden” on “the health care delivery system,” thus complying with Congress’s requirements.⁶⁴

⁶³ *S. Bay United Pentecostal Church v. Newsom*, 590 U.S. 965, 967 (2020) (Roberts, C.J., concurring).

⁶⁴ 21 U.S.C. § 355-1(f)(2).

Unlike the sound scientific evidence supporting FDA’s decision to remove the IPDR, Louisiana’s attacks on mifepristone’s safety are based on so-called studies that lack scientific rigor and appear driven by a political agenda rather than science, as has been amply explained by numerous expert researchers.⁶⁵

Congress tasked FDA with making evidence-based decisions about drug safety and ensuring that any restrictions, including limits on how drugs can be prescribed and dispensed, are justified by the science and account for patients’ ability to access necessary care. Decades of data confirming mifepristone’s safety supported FDA’s decision to eliminate the IPDR. This Court should reject Louisiana’s invitation to use self-serving and flawed publications as an excuse to override sound, science-backed conclusions.

B. FDA’s use of FAERS data was appropriate under the Act.

FDA appropriately considered FAERS data in making its determination to eliminate the IPDR. Louisiana’s claims otherwise are baseless and ignore that FDA’s reliance on FAERS data is standard practice for FDA’s post-marketing surveillance of *all* approved drugs.⁶⁶

⁶⁵ See Reproductive Health Researches Comment Letter to FDA at 7–19, UCLA Law (Aug. 27, 2025), <https://law.ucla.edu/reproductive-health-researchers-comment-letter-fda>.

⁶⁶ See, e.g., *FDA Adverse Event Monitoring System (AEMS)*, FDA (Mar. 11, 2026), <https://www.fda.gov/drugs/surveillance/fda-adverse-event-monitoring-system-aems> (“The [FAERS] database is designed to support the FDA’s post-marketing safety surveillance program for drug and therapeutic biologic products.”);

When FDA was reviewing whether it could safely remove the IPDR for mifepristone, it analyzed FAERS data for the period January 27, 2020, through September 30, 2021; for more than half of that period, the IPDR was not enforced.⁶⁷ Over that nearly-two-year period, there were about a million mifepristone prescriptions written, yet only eight adverse events reported in FAERS for patients who had taken the medication, with no difference in safety outcome based on where the medication was dispensed.⁶⁸ The FAERS data provided strong support for FDA's conclusion that there had not been an uptick in the rate of adverse events or other emerging safety trends when the IPDR was not being enforced.⁶⁹

Louisiana has suggested that the FAERS data supporting removal of the IPDR was unreliable because FDA does not require prescribing clinicians to report all potentially associated adverse events in patients taking mifepristone. But again, that

see also FDA Adverse Event Reporting System (FAERS) Public Dashboard FAQs, FDA, https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html#_Toc514144622 (“FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to reporting regulations and responding to outside requests for information.”).

⁶⁷ FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists (Dec. 16, 2021) (hereinafter referenced by ROA cite) (ROA.374).

⁶⁸ *Id.* FDA defines “adverse event” as “any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.” 21 C.F.R. § 312.32(a). That definition makes clear that an adverse event need not necessarily be caused by the drug, but simply that the event occurred. *Id.*

⁶⁹ ROA.375.

is the case for nearly every drug—as a general practice, FDA requires *manufacturers, not individual physicians*, to report any serious adverse events, though prescribing physicians can still voluntarily report adverse events.⁷⁰ And unlike nearly every other drug it regulates, FDA still requires prescribers to report fatalities when a patient takes mifepristone—even where there is no evidence of causation.

Louisiana has also latched onto FDA’s previous acknowledgements that FAERS data is not comprehensive or perfect to argue that such data cannot be used to support safety determinations for regulated drugs. But FAERS data does not have to be perfect to have value.⁷¹ And while it is true that FAERS is not designed to capture every adverse event related to a drug, FDA takes that fact into account when reviewing the data. Here, FDA corroborated the FAERS data by cross-referencing it with adverse event summaries that were submitted by mifepristone’s manufacturers, which included the same eight events that were reflected in

⁷⁰ See, e.g., 21 C.F.R. §§ 314.80 and 314.81 (requiring drug manufacturers collect and report to FDA information about adverse drug experiences). An adverse event is considered serious if it results in death, a substantial risk of death, a prolonged hospital stay, a congenital anomaly or birth defect, or permanent impairment or damage, or requires medical intervention to prevent such damage. See *What is a Serious Adverse Event?*, FDA (May 18, 2023), <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>.

⁷¹ See, e.g., *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021) (explaining that agency need not have perfect data to support its decisions).

FAERS.⁷² FDA then conducted a review of published medical literature to search for additional adverse event reports across the relevant period and found none, confirming the reasonableness of relying on the FAERS data.⁷³ This information, combined with *decades* of data showing that mifepristone is a safe medication and that adverse events are very rare, was sufficient to support FDA's decision to remove the IPDR.

A finding that it is arbitrary and capricious for FDA to rely on FAERS data would have far-reaching consequences on the agency's practices for monitoring drug safety beyond just mifepristone. FDA uses FAERS as the primary source of adverse event reporting for virtually *all drugs* that it regulates. FDA has determined that manufacturer-reporting generates sufficient data to keep the agency informed about whether there have been changes to a drug's safety profile. This Court should not allow litigants to exploit alleged limitations of FAERS data as a path to challenging FDA decisions and undermine the system Congress and FDA established.

C. Louisiana should not be able to hijack the science-based REMS system Congress designed to force its policy choices onto others.

The obvious flaws in Louisiana's criticism of the 2023 REMS reflect a larger problem with its case: it seeks a nationwide order making a policy determination for

⁷² ROA.375.

⁷³ ROA.374.

the entire country. But that is not up to Louisiana. The efforts of other states to protect and expand access to abortion generally, and to medication abortion specifically, within their borders are a result of the “constitutional processes of democratic self-government.”⁷⁴ Louisiana is free to make its own laws governing its citizens, but should not be permitted to undermine the FDA’s process.

Louisiana argues that the 2023 REMS “undermines” *Dobbs v. Jackson Women’s Health Organization* by rendering Louisiana’s abortion laws “practically unenforceable.” (Br. at 1, 52). But FDA’s REMS authority is limited to assessing whether a restriction “is necessary to ensure that the benefits of the drug outweigh the risks of the drug.”⁷⁵ FDA does not—and under the system Congress designed, is not authorized to—consider the regulatory or enforcement priorities of individual States when assessing whether to impose or modify a REMS.

Moreover, the timeline demonstrates that FDA did not remove the IPDR to undermine *Dobbs* and frustrate state abortion prohibitions. The requirement was first suspended by court order in 2020 during the pandemic and then was subject to FDA’s April 2021 non-enforcement determination—both occurring *well before* *Dobbs* was handed down. FDA likewise reached its evidence-based decision to

⁷⁴ *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. 215, 346 (2022) (Kavanaugh, J., concurring).

⁷⁵ 21 U.S.C. § 355-1(a)(1).

eliminate the IPDR altogether in December 2021, *before Dobbs* was decided. There is simply no evidence supporting Louisiana’s claims that the agency’s scientific evaluation of the IPDR was motivated by state abortion bans.

Finally, FDA’s decision to eliminate the IPDR does not prevent Louisiana or similarly situated States from enforcing their own laws restricting abortion (though the undersigned disagree with those laws). Louisiana’s principal objection is that other States have made different policy choices. But “each sovereignty is free to determine what conduct shall be proscribed within its jurisdiction,” and the “wrong committed by violating such proscription” does not automatically cross state lines.⁷⁶ This Court should not permit Louisiana to weaponize its policy disagreements with sister States to force FDA to violate its statutory obligation not to unduly burden patient access to medication nationwide.

CONCLUSION

For the foregoing reasons, *Amici* Members of Congress respectfully request that this Court deny Louisiana’s request for a nationwide stay of the 2023 mifepristone REMS.

⁷⁶ *Farmland Dairies v. Barber*, 65 N.Y.2d 51, 56-57 (1985); *see also Dobbs*, 597 U.S. at 346 (Kavanaugh J. concurring).

Dated: July 22, 2026

Respectfully submitted,

/s/ Abby F. Rudzin

ABBY F. RUDZIN

O'MELVENY & MYERS LLP

*Counsel for Lead Amici 259 Members of
Congress*

CERTIFICATE OF SERVICE

I hereby certify that on July 22, 2026, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

Dated: July 22, 2026

Respectfully submitted,

/s/ Abby F. Rudzin

ABBY F. RUDZIN

O'MELVENY & MYERS LLP

Counsel for Lead Amici 259 Members of Congress

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,491 words.

This brief also complies with the type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Times New Roman 14-point font, a proportionally spaced typeface.

Dated: July 22, 2026

Respectfully submitted,

/s/ Abby F. Rudzin

ABBY F. RUDZIN

O'MELVENY & MYERS LLP

Counsel for Lead Amici 259 Members of Congress

APPENDIX: LIST OF *AMICI CURIAE* 259 MEMBERS OF CONGRESS**47 United States Senators**

Majority Leader Charles E. Schumer

Sen. Patty Murray

Sen. Richard J. Durbin

Sen. Ron Wyden

Sen. Angela D. Alsobrooks

Sen. Tammy Baldwin

Sen. Michael F. Bennet

Sen. Richard Blumenthal

Sen. Lisa Blunt Rochester

Sen. Cory A. Booker

Sen. Maria Cantwell

Sen. Christopher A. Coons

Sen. Catherine Cortez Masto

Sen. Tammy Duckworth

Sen. John Fetterman

Sen. Ruben Gallego

Sen. Kirsten Gillibrand

Sen. Margaret Wood Hassan

Sen. Martin Heinrich

Sen. John W. Hickenlooper

Sen. Mazie Hirono

Sen. Tim Kaine

Sen. Mark Kelly

Sen. Andy Kim

Sen. Angus S. King, Jr.

Sen. Amy Klobuchar

Sen. Ben Ray Luján

Sen. Edward J. Markey

Sen. Jeffrey A. Merkley

Sen. Christopher S. Murphy

Sen. Jon Ossoff

Sen. Alex Padilla

Sen. Gary C. Peters

Sen. Jack Reed

Sen. Jacky Rosen

Sen. Bernard Sanders

Sen. Brian Schatz

Sen. Adam B. Schiff

Sen. Jeanne Shaheen

Sen. Elissa Slotkin

Sen. Tina Smith

Sen. Chris Van Hollen

Sen. Mark Warner

Sen. Raphael Warnock

Sen. Elizabeth Warren

Sen. Peter Welch

Sen. Sheldon Whitehouse

212 Members of the United States House of Representatives

Minority Leader Hakeem Jeffries

Rep. Katherine Clark

Rep. Frank Pallone, Jr.

Rep. Jamie Raskin

Rep. Diana DeGette

Rep. Ayanna Pressley

Rep. Alma S. Adams

Rep. Pete Aguilar

Rep. Gabe Amo

Rep. Yassamin Ansari

Rep. Jake Auchincloss

Rep. Becca Balint

Rep. Nanette Barragán

Rep. Joyce Beatty

Rep. Wesley Bell

Rep. Ami Bera, M.D.

Rep. Donald S. Beyer Jr.

Rep. Sanford D. Bishop, Jr.

Rep. Suzanne Bonamici

Rep. Brendan F. Boyle

Rep. Shontel Brown

Rep. Julia Brownley

Rep. Nikki Budzinski

Rep. Janelle S. Bynum

Rep. Salud Carbajal

Rep. André Carson

Rep. Troy A. Carter Sr.

Rep. Greg Casar

Rep. Ed Case

Rep. Sean Casten

Rep. Kathy Castor

Rep. Joaquin Castro

Rep. Judy Chu

Rep. Gilbert R. Cisneros, Jr.

Rep. Yvette D. Clarke

Rep. Emanuel Cleaver, II

Rep. James E. Clyburn

Rep. Steve Cohen

Rep. Dr. Herb Conaway

Rep. J. Luis Correa

Rep. Jim Costa

Rep. Joe Courtney

Rep. Angie Craig

Rep. Jasmine Crockett

Rep. Jason Crow

Rep. Sharice L. Davids

Rep. Danny K. Davis

Rep. Donald G. Davis

Rep. Madeleine Dean

Rep. Rosa L. DeLauro

Rep. Suzan K. DelBene

Rep. Chris Deluzio

Rep. Mark DeSaulnier

Rep. Dr. Maxine Dexter

Rep. Debbie Dingell

Rep. Lloyd Doggett

Rep. Sarah Elfreth

Rep. Veronica Escobar

Rep. Adriano Espaillat

Rep. Dwight Evans

Rep. Cleo Fields

Rep. Shomari C. Figures

Rep. Lizzie Fletcher

Rep. Bill Foster

Rep. Valerie P. Foushee

Rep. Lois Frankel

Rep. Laura Friedman

Rep. Maxwell Alejandro Frost

Rep. John Garamendi

Rep. Sylvia R. Garcia

Rep. Robert Garcia

Rep. Jesús “Chuy” García

Rep. Laura Gillen

Rep. Marie Gluesenkamp Perez

Rep. Jared Golden

Rep. Dan Goldman

Rep. Jimmy Gomez

Rep. Maggie Goodlander

Rep. Josh Gottheimer

Rep. Adam Gray

Rep. Al Green

Rep. Adelita S. Grijalva

Rep. Josh Harder

Rep. Jahana Hayes

Rep. Jim Himes

Rep. Eleanor Holmes Norton

Rep. Steven A. Horsford

Rep. Chrissy Houlahan

Rep. Steny H. Hoyer

Rep. Val Hoyle

Rep. Jared Huffman

Rep. Glenn F. Ivey

Rep. Jonathan L. Jackson

Rep. Sara Jacobs

Rep. Pramila Jayapal

Rep. Julie E. Johnson

Rep. Henry C. (“Hank”) Johnson, Jr.

Rep. Sydney Kamlager-Dove

Rep. Marcy Kaptur

Rep. William R. Keating

Rep. Robin L. Kelly

Rep. Timothy M. Kennedy

Rep. Ro Khanna

Rep. Raja Krishnamoorthi

Rep. Greg Landsman

Rep. Rick Larsen

Rep. John B. Larson

Rep. George Latimer

Rep. Summer L. Lee

Rep. Susie Lee

Rep. Teresa Leger Fernández

Rep. Mike Levin

Rep. Sam T. Liccardo

Rep. Ted W. Lieu

Rep. Zoe Lofgren
Rep. Stephen F. Lynch
Rep. Seth Magaziner
Rep. John Mannion
Rep. Doris Matsui
Rep. Lucy McBath
Rep. Sarah McBride
Rep. April McClain Delaney
Rep. Jennifer McClellan
Rep. Betty McCollum
Rep. Kristen McDonald Rivet
Rep. Morgan McGarvey
Rep. James P. McGovern
Rep. LaMonica McIver
Rep. Gregory W. Meeks
Rep. Analilia Mejia
Rep. Christian Menefee
Rep. Rob Menendez
Rep. Grace Meng
Rep. Kweisi Mfume
Rep. Dave Min
Rep. Gwen Moore
Rep. Joseph D. Morelle

Rep. Kelly Morrison

Rep. Jared Moskowitz

Rep. Seth Moulton

Rep. Frank J. Mrvan

Rep. Kevin Mullin

Rep. Jerrold Nadler

Rep. Richard E. Neal

Rep. Joe Neguse

Rep. Donald Norcross

Rep. Alexandria Ocasio-Cortez

Rep. Johnny Olszewski

Rep. Ilhan Omar

Rep. Jimmy Panetta

Rep. Chris Pappas

Rep. Nancy Pelosi

Rep. Scott H. Peters

Rep. Brittany Pettersen

Rep. Chellie Pingree

Rep. Stacey E. Plaskett

Rep. Mark Pocan

Rep. Nellie Pou

Rep. Mike Quigley

Rep. Delia C. Ramirez

Rep. Emily Randall

Rep. Josh Riley

Rep. Luz Rivas

Rep. Deborah K. Ross

Rep. Raul Ruiz

Rep. Patrick Ryan

Rep. Andrea Salinas

Rep. Linda T. Sanchez

Rep. Mary Gay Scanlon

Rep. Jan Schakowsky

Rep. Bradley Scott Schneider

Rep. Hillary Scholten

Rep. Kim Schrier, M.D.

Rep. Robert C. “Bobby” Scott

Rep. Terri A. Sewell

Rep. Brad Sherman

Rep. Lateefah Simon

Rep. Adam Smith

Rep. Eric Sorensen

Rep. Darren Soto

Rep. Melanie Stansbury

Rep. Greg Stanton

Rep. Haley Stevens

Rep. Marilyn Strickland

Rep. Suhas Subramanyam

Rep. Thomas R. Suozzi

Rep. Emilia Sykes

Rep. Mark Takano

Rep. Shri Thanedar

Rep. Mike Thompson

Rep. Bennie G. Thompson

Rep. Dina Titus

Rep. Rashida Tlaib

Rep. Jill N. Tokuda

Rep. Paul Tonko

Rep. Norma J. Torres

Rep. Ritchie Torres

Rep. Lori Trahan

Rep. Derek Tran

Rep. Lauren Underwood

Rep. Juan Vargas

Rep. Gabe Vasquez

Rep. Marc A. Veasey

Rep. Nydia M. Velázquez

Rep. Eugene Simon Vindman

Rep. James R. Walkinshaw

Rep. Debbie Wasserman Schultz

Rep. Maxine Waters

Rep. Bonnie Watson Coleman

Rep. George Whitesides

Rep. Nikema Williams

Rep. Frederica S. Wilson

*United States Court of Appeals*FIFTH CIRCUIT
OFFICE OF THE CLERKLYLE W. CAYCE
CLERKTEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

July 22, 2026

Ms. Abby Rudzin
O'Melveny & Myers, L.L.P.
1301 Avenue of the Americas
Suite 1700
New York, NY 10019-6022No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

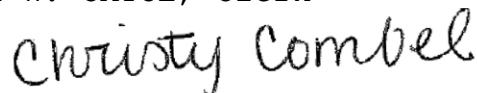
Dear Ms. Rudzin,

You must submit the 6 paper copies of your brief required by 5th Cir. R. 31.1 within 5 days of the date of this notice pursuant to 5th Cir. ECF Filing Standard E.1.

If your brief was insufficient and required corrections, the paper copies of your brief must **not** contain a header noting "RESTRICTED". Therefore, please be sure that you print your paper copies **from this notice of docket activity** and not the proposed sufficient brief filed event so that it will contain the proper filing header. Alternatively, you may print the sufficient brief directly from your original file without any header.

Sincerely,

LYLE W. CAYCE, Clerk

By: _____
Christy M. Combel, Deputy Clerk
504-310-7651

cc:

Mr. John N. Adcock
Mr. Jorge Benjamin Aguinaga
Mr. Erik Baptist
Mr. Cody S. Barnett
Mr. Andrew Marshall Bernie
Ms. Julie Marie Blake
Mr. Brennan Tyler Brooks
Ms. Mary J. Browning
Ms. Yael Hannah Caplan
Mr. Charles Cicero III
Ms. Chelsea Corey
Ms. Deborah Jane Dewart
Ms. Margaret Dotzel

Ms. Jessica Lynn Ellsworth
Mr. John Patrick Elwood
Ms. Carrie Yvette Flaxman
Mr. Eugene M. Gelernter
Ms. Heather Gebelin Hacker
Ms. Erin Morrow Hawley
Ms. Jillian Horowitz
Ms. Alyssa Howard
Ms. Caitlin Ann Huettemann
Mr. Michael T. Johnson
Mr. Robert J. Katerberg
Mr. Noah T. Katzen
Mr. Thomas S. Leatherbury
Mr. Robert Bradley Lewis
Ms. Meghan K. Matt
Ms. Gabriella McIntyre
Ms. Katherine McKay
Ms. Hilarie M. Meyers
Mr. Horatio Gabriel Mihet
Mr. Christopher Ernest Mills
Ms. Rachel N. Morrison
Mr. William Brock Most
Ms. Ester Murdukhayeva
Ms. Lisa Newman
Ms. Daphne O'Connor
Mr. Allan Edward Parker Jr.
Ms. Kimberly A. Parker
Ms. Dana A. Raphael
Ms. Jo-Ann Tamila Sagar
Mr. Max Sarinsky
Ms. Linda Boston Schlueter
Mr. Alan E. Schoenfeld
Mr. William B. Schultz
Ms. Clara Simone Spera
Mr. Mathew D. Staver
Ms. Danielle Desaulniers Stempel
Ms. Olivia F. Summers
Mr. David H. Thompson
Ms. Maria Michelle Uzeta
Mr. John Marc Wheat
Mrs. Hadiya Williams
Mr. Daniel Winik
Ms. Megan Marie Wold
Mr. Daniel W. Wolff