Nos. 25A1207, 25A1208

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C., *et al.*

Applicant,

v.

STATE OF LOUISIANA, *et al.*,

Respondents.

GENBIOPRO, INC., *et al.*

Applicant,

v.

STATE OF LOUISIANA, *et al.*,

Respondents.

BRIEF FOR 259 MEMBERS OF CONGRESS AS *AMICI CURIAE* IN SUPPORT OF APPLICATIONS BY DANCO AND GENBIOPRO TO STAY OR VACATE THE FIFTH CIRCUIT'S STAY PENDING APPEAL

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

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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 both upholding the Constitution's separation of powers—including by ensuring that federal administrative agencies faithfully exercise the authorities Congress delegated to them in accordance with statutory limits—and protecting the physical health and safety of their constituents.

Amici believe that this Court should grant an emergency stay of or vacate the Fifth Circuit's Order, which requires the nationwide reinstatement of the in-person dispensing requirement for mifepristone that has not been enforced in more than five years. The Fifth Circuit's Order should be stayed because the relief it granted 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. The Fifth Circuit's decision to do so now—before the merits have even been litigated—is particularly egregious.

Accordingly, *Amici* respectfully urge this Court to grant an emergency stay of or vacate the Fifth Circuit's erroneous order.

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[1] The complete list of *amici* is located in the Appendix. Under Rule 37.6 of the Rules of this Court, *amici* state that no counsel for a party wrote this brief in whole or in part. No party, party's counsel, or any person other than the *amicus curiae*, their members, or their counsel contributed money that was intended to finance the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The regulatory scheme Congress designed aims to ensure patient access to safe and effective medications in the United States by requiring expert-led, evidence-based regulatory decisions. 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 impose sweeping burdens on access to FDA-approved medications, as the Fifth Circuit's Order does.

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 unduly burden patient access. 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 safe and effective drugs. Louisiana's assertion that FDA

was motivated by a desire to undermine state abortion restrictions after *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), is baseless and belied by the timeline: The in-person dispensing requirement was first suspended by court order in 2020 in the context of the COVID-19 pandemic. In April 2021, based on real-world evidence of mifepristone's continued safe use during the injunction period, as well as scientific literature further confirming the medication's safety when dispensed by mail, FDA suspended the in-person requirement for the duration of the COVID-19 Public Health Emergency. In December 2021, based on its continued monitoring of mifepristone's safety under the COVID-19 nonenforcement policy, and consistent with additional peer-reviewed studies, FDA determined that it would permanently lift this unnecessary and burdensome requirement. All of these regulatory decisions occurred well before *Dobbs* came down—and were grounded in the new body of evidence confirming mifepristone's safety when dispensed by mail that arose during the pandemic. Louisiana's chronological error cannot justify its attempt to reimpose an unnecessary burden on all of America, even in sovereign states that protect abortion.

Decades after FDA's initial approval of mifepristone and years after the in-person dispensing requirement was eliminated, the Fifth Circuit on an "emergency" basis ordered FDA to re-impose this onerous nationwide restriction on all Americans. Allowing that decision to remain in place undermines the science-based statutory framework Congress commands and threatens patient access to reproductive health care. As has been well publicized, many U.S. residents 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 the imminent harm facing members of the public. 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 safety and efficacy,

[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 C.F.R. §§ 314.50, 314.105(c); *Development & Approval Process: Drugs*, FDA (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs; *New Drug Application (NDA)*, FDA (Jan. 21, 2022), https://www.fda.gov/drugs/types-applications/new-drug-application-nda; 21 U.S.C. § 355(b)(5)(A) (noting that all individuals who review new drug applications should have "technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards").

[5] 21 U.S.C. § 355(d).

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 for which it is so necessary that the drug's approval must otherwise be "withdrawn."[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

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[6] *See 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) (describing initial approval REMS); 21 U.S.C. § 355-1(a)(2) (describing 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").

[9] 21 U.S.C. 355-1(f)(1)(A).

necessary.[10] The statutory requirements include 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, in order 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 and effective drug. FDA first approved mifepristone in September 2000, based on peer-reviewed research and extensive clinical trials showing that mifepristone is safe and effective and that its health benefits outweighed its risks.[13] That approval came after a four-year review process with three separate clinical trials involving more than 4,000 patients and a unanimous advisory committee vote in favor of approval.[14] As FDA put it, its

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[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).

[13] *See* 2000 FDA Approval Letter, Compl. Ex. 24, ECF No. 1-24; *see also Development & Approval Process: Drugs*, FDA (Aug. 8, 2022), https://www.fda.gov/drugs/development-approval-process-drugs; U.S. Gov't Accountability Off., GAO-08-751, FDA Approval and Oversight of the Drug Mifeprex at 15–16, 26 (2008) [hereinafter, "GAO-08-751"].

[14] *See Office Memorandum to Population Council* (Sept. 28, 2000), FDA, https://wayback.archive-it.org/7993/20161024033545/http://www.fda.gov/downloads/Drugs/DrugSafety/

initial 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] FDA was required 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 "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

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PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf; *see also* GAO-08-751 at 15–16, 26.

[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) (in the absence of a specified ground for denial, FDA "shall" approve a drug application).

[17] These restrictions, original 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).

[18] FDA REMS Modification Review, NDA No. 020687/S-020, at 6, 8, 88 (Mar. 29, 2016).

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 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 permanently eliminate the IPDR.

A federal court suspended enforcement of the IPDR from July 2020 through

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[19] *Id.* at 13, 62, 84.

[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. Upadhay, et al., *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study,* 182 JAMA 482, 487 (2022).

January 2021, due to the COVID-19 pandemic.[23] In April 2021, based in part on real-world experience of 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 permanently remove the IPDR.[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, which showed no increase in adverse events; and numerous published studies encompassing tens of thousands of patients that assessed safety outcomes with

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[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 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), Ex. 1 to Brief of Former and Acting Commissioners of the U.S. Food and Drug Admin. as *Amici Curiae* Opposing Plaintiffs' Motion For Preliminary Injunction, ECF No. 208-1.

[25] *Id.*

[26] *See* FDA REMS Modification Rationale Review, NDA No. 020687 & ANDA No. 91178, at 4 (Dec. 16, 2021) (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).

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, and 0.001% experienced a severe infection.[30] That same report shows that mifepristone-associated deaths 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]

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[27] *Id.* at 10.

[28] *Id.* at 23, 39.

[29] *FDA Ctr. For Drug Eval. & Rsch., Application No. 020687Orig1s020 Summary Review* (Jan. 3, 2023), Compl. Ex. 50, ECF No. 1-50; *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/rems/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. It is important to note that this report does not purport to establish a causal link between the recorded deaths and mifepristone, explaining that fatalities were included in the summary report "regardless of causal attribution to mifepristone." *Id.*

[31] *See, e.g.*, 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); Mifepristone 2023 Labeling and Medication Guide, at 1, 14, 16 (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").

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, research published since the 2023 decision 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 and, for either method of dispensing, extremely low.[34] Numerous other studies on telemedicine medication abortions have confirmed that safety and effectiveness 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 in *Purcell v. Kennedy* that FDA acted arbitrarily and

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[32] Mifepristone 2023 Labeling and Medication Guide, at 2, 5.

[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.").

[34] *See, e.g.*, Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 902 (2024) (finding that the rate of serious adverse events for patients who used telehealth and were sent mifepristone by mail was 1.5%, compared to 1.4% for the group with in-person pickup).

[35] Upadhay, *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).

capriciously in deciding to maintain other REMS requirements for mifepristone in 2023, even after lifting 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 examining the effects of [Canada's] removal of REMS-like restrictions on mifepristone," which found that adverse events and complications did not increase when Canada eliminated its special restrictions on mifepristone altogether.[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 the most burdensome restrictions (such as an IPDR requirement) unless that restriction is "commensurate with the specific serious risk and [does] not unduly burden patient

[36] *Purcell v. Kennedy*, 2025 WL 3101785, at *23–27 (D. Haw. Oct. 30, 2025). Notably, another federal court has also recently recognized that the Department of Health and Human Services must adhere to evidence-based science in public health decision-making. *See Am. Acad. of Pediatrics v. Kennedy*, 2026 WL 733828, at *1–2 (D. Mass. Mar. 16, 2026) (staying revisions to childhood immunization schedule because the decision-maker had disregarded scientific methods).

[37] *Purcell*, 2025 WL 3101785, at *23 (internal quotation marks omitted).

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]

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 demanding it without substantial justification, and here no such justification exists. The Fifth Circuit's Order 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,

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[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).

childcare, and lost wages. This reality is true regardless of where the patient lives, but the burden grows with distance—potentially requiring more expensive travel, such as airfare or lodging to stay overnight.

Distance from an in-person provider is a significant barrier to accessing abortion care.[41] 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 rates declined further with greater distances (28% at 100-150 miles, 38% at 150-200 miles, and 44% beyond 200 miles).[42] And as of April 2023, one study had found that "the average American is 86 miles from a provider."[43] Another study found that 50.7% of people with disabilities experienced logistical barriers to accessing reproductive health care, which included transportation burdens, compared to 29.7% of people without disabilities.[44] Eliminating the IPDR minimizes serious 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 (such as patients in rural or medically underserved areas)" and "patients with functional limitations."[45,46]

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[41] *See* Caitlin Myers et al., *Abortion Access Dashboard*, https://experience.arcgis.com/experience/6e360741bfd84db79d5db774a1147815 (last updated Mar. 16, 2026).

[42] 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).

[43] 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).

[44] 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).

[45] 21 U.S.C. § 355-1(f)(2)(C)(ii)–(iii).

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

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%).[47] The Fifth Circuit's 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—imposes exactly the kind of burden on patients that Congress prohibited, particularly for patients in rural or medically underserved areas.[48]

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.[49] 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 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.[50] 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.[51] The IPDR also "burdens the health care

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[47] 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).

[48] *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.47.

[49] 21 U.S.C. § 355-1(f)(2)(D).

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

[51] *See id.* (noting that "the proportion of medication abortion providers would likely double if clinicians were permitted to prescribe mifepristone through a pharmacy").

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."[52] 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."[53]

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 access mifepristone.[54] 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.[55] And the unduly burdensome consequences of the Fifth Circuit's Order 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.[56] For people residing in states that permit telemedicine abortion care, ensuring access to this safe, effective, and

[52] *Id.* (noting that "fewer than 0.1% of FDA-approved drugs must be dispensed in a hospital, medical office, or clinic").

[53] 21 U.S.C. § 355-1(f)(2)(C)-(D).

[54] 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-abortions-in-america.html.

[55] *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").

[56] *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).

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-intensive, and expensive procedure, which may itself only be available at a greater distance.[57] 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.[58]

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

Reinstating the IPDR would needlessly force patients to travel farther and spend more time and money to access a safe medication in person where telemedicine abortion care is legally protected by state law. 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 stay the Fifth Circuit's Order

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

[58] *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, 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).

because it undermines Congress's mandate and unduly burdens patient access to this medication all across America.

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.[59] 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.[60]

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."[61] The impact would be acute in states with legal protections for abortion under state law. Such an injunction would further burden already taxed health care systems, harm residents of those States, and undermine their sovereign policy choices. Many states and private providers have

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

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

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

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, and Louisiana's request would force FDA to reimpose restrictions that violate the statute.

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.[62] 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.[63]

Unlike the sound scientific evidence supporting FDA's decision to remove the IPDR, Respondents' 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.[64]

Congress tasked FDA with making evidence-based decisions about drug safety

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

[63] 21 U.S.C. § 355-1(f)(2).

[64] *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.

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 Respondents' 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. Respondents' 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.[65]

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.[66] Over that nearly-two-year period, there were only eight adverse events reported in FAERS for patients who had taken mifepristone, with no difference in safety outcome

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[65] *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."); *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.").

[66] FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologist (Dec. 16, 2021), Compl. Ex. 10, ECF No. 1-10 at 27 [hereinafter "ECF No. 1-10"].

based on where the medication was dispensed.[67] 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.[68]

Respondents have 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 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.[69] And unlike nearly every other drug it regulates, FDA still requires prescribers to report fatalities when a patient takes mifepristone—without any evidence of causation.

Respondents have 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.[70] And while it is true that FAERS is not designed to

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[67] *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.*

[68] ECF No. 1-10 at 28.

[69] *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.

[70] *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).

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 FAERS.[71] 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.[72] 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 Respondents' criticism of the 2023 REMS reflect a larger problem with its case: Louisiana sought—and the Fifth Circuit granted—an order

[71] ECF No. 1-10 at 28.

[72] *Id.* at 27.

that contradicts congressional mandates, overrides FDA's well-reasoned, data-backed decision to remove the IPDR, and imposes unnecessary barriers to essential care—nationwide. 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."[73] The Fifth Circuit's Order would undermine those processes by forcing FDA to reinstate—against scientific evidence and statutory requirements—the IPDR for mifepristone.

Louisiana relies on *Dobbs v. Jackson Women's Health Organization* to argue that FDA's regulations cannot override state-level prohibitions on abortion. That reliance is misplaced for several reasons. First, 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."[74] 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.

Second, the timeline demonstrates that FDA did not remove the IPDR to frustrate state abortion prohibitions. The requirement was first suspended by court order in 2020 during the pandemic and then was subject to an April 2021 non-enforcement determination—both occurring ***well before*** *Dobbs* was handed down. FDA likewise initiated its 2021 review of mifepristone's REMS, and reached its

[73] *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 346 (2022) (Kavanaugh, J., concurring).

[74] 21 U.S.C. § 355-1(a)(1).

evidence-based decision to permanently remove the IPDR, ***well 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.

Third, 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). Respondents' principal objection is that other States have made different policy choices than Louisiana. 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.[75] 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 grant an emergency stay of the Fifth Circuit's erroneous Order.

Dated: May 4, 2026

Respectfully submitted,

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

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Sen. Cory A. Booker

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