UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
Layfette Division

THE STATE OF LOUISIANA, by and through its Attorney General, LIZ MURRILL, and ROSALIE MARKEZICH,	)	
Plaintiffs	)	Case No.: 6:25-cv-01491-DCJ-DJA
v.	)	Judge David C. Joseph
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	)	Magistrate Judge David J. Ayo
Defendants.	)	

BRIEF OF HEARTBEAT INTERNATIONAL AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY RELIEF UNDER 5 U.S.C. § 705

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INTEREST OF THE *AMICUS CURIAE*[1]

Amicus Heartbeat International ("Heartbeat") is an IRC § 501(c)(3) non-profit, Christian organization whose mission is to serve women and children through an effective network of life-affirming pregnancy help centers. Heartbeat serves approximately 4,000 pregnancy help centers, maternity homes, and non-profit adoption agencies (collectively, "pregnancy help organizations") in over 100 countries, including more than 2,300 in the United States—making Heartbeat the world's largest such affiliate network.

In addition, Heartbeat owns and operates the Abortion Pill Rescue Network (the "APRN"), which provides help for women who have started, but not yet completed, the chemical abortion process and wish to continue their pregnancies. The APRN answers more than 200 calls per month from women in the midst of a chemical abortion who quickly regretted their decision to abort and are now seeking to carry their pregnancies to term. Statistics show that more than 7,000 lives have been saved through the Abortion Pill Rescue Network. Given its regular interactions with women who have obtained abortion drugs they later regret ingesting as well as women who were coerced, such as Plaintiff Markezich, or even physically forced into taking abortion drugs obtained by others, Heartbeat is uniquely positioned to provide relevant factual background on the impact of removing certain health safeguards for

[1] *Amicus* states that no counsel for a party wrote this brief in whole or in part, and no counsel, person, or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than the *amicus* and its counsel, has made a monetary contribution to this brief's preparation or submission.

mifepristone and misoprostol.[2]

INTRODUCTION AND SUMMARY OF ARGUMENT

Starting from the flawed premise that pregnancy is an illness to be cured, rather than the natural procreative process, the U.S. Food and Drug Administration ("FDA") has undertaken changes in recent years that make abortion-inducing drugs, including mifepristone, more readily available, culminating in the 2023 REMS.[3] The FDA's actions enable individuals to obtain mifepristone without ever having an in-person appointment and do not even require the drug to be prescribed by a licensed physician. This means that individuals may obtain abortion drugs without ever being physically examined by a medical provider.

Besides violating the Comstock Act, which prohibits interstate mailing and shipping of abortion-inducing drugs, the FDA's relaxed rules undermine state protections for unborn lives—a state interest that was recognized even under *Roe* and *Casey*. This action by the FDA thwarts the return of the abortion issue to the people and their representatives that *Dobbs v. Jackson Women's Health Organization* signaled.

The FDA's actions, though, are not merely a threat to principles of federalism. They facilitate increased risk of psychological and emotional injury to women if they later suffer abortion regret. Because the FDA has removed the requirement for an in-person visit, pregnant women now obtain abortion drugs without ever being

[2] Two drugs work in tandem to produce an abortion. Under this regimen, mifepristone (also known as "RU-486" and "Mifeprex") blocks nutrition to the unborn baby in order to terminate its life, while misoprostol induces contractions to expel the child, dead or alive.

evaluated in person by a medical professional to determine the gestational age of the unborn child and screen for abnormalities or complications that would make it dangerous for a pregnant woman to take those drugs. Moreover, there is a documented risk for medical errors if the mother presents in an emergency department for post-abortion care, and these emergency providers are unaware of the abortion.

In addition to the physical dangers, under the 2023 REMS, pregnant women are vulnerable to bad actors who coerce or force an unwanted abortion. The Abortion Pill Rescue Network regularly takes calls from women who report that they were coerced or forced into taking abortion pills, and these women are urgently desiring to stop the abortion process begun without their consent. Therefore, *amicus* Heartbeat respectfully urges the Court to grant Plaintiffs' motion.

ARGUMENT

I. THE FDA'S 2023 REMS LOWERED THE STANDARD OF CARE FOR TREATING A PREGNANT MOTHER, PLACING HER HEALTH AT GREATER RISK.

The 2023 REMS challenged by the Plaintiffs lowers the standard of care for women and increases the likelihood of health complications to pregnant mothers who have an abortion, despite what protections state law might otherwise have provided.[4] The Fifth Circuit was correct to conclude that the FDA's prior approval of this permissive route to a mail-order chemical abortion violated the APA. *All. for*

[4] "[S]tandards of reasonable medical care" are "quintessentially state-law" issues. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (citing *Pegram v. Herdrich*, 530 U.S. 211, 236 (2000)).

Hippocratic Med. v. United States Food & Drug Admin., No. 23-10362, 2023 WL 2913725, at *8 (5th Cir. Apr. 12, 2023) (unpublished). These alterations in the regulations weakened safeguards for maternal health and resulted in a requirement for fewer interactions between a mother and her medical provider.

A. Increased Risk of Medical Complications and Harm to Physical Health

1. The number of women receiving ultrasounds prior to beginning a chemical abortion has dropped precipitously, representing a significant risk to women's health and safety.

When Heartbeat began operating the Abortion Pill Rescue Network in 2018, nearly 100% of mission-critical contacts (women seeking help in the midst of an abortion) reported having received an ultrasound prior to beginning the abortion pill regimen. By 2023, that percentage had plummeted to 62%. Ultrasound is critical prior to a chemical abortion for at least three reasons: (1) to determine the viability of the pregnancy; (2) to determine the gestational age of the unborn child; and (3) to determine the placement of the pregnancy. Each of these pieces of information is critical for safeguarding the woman's health and avoiding unnecessary risks posed by the abortion pill regimen.

First, in the absence of an ultrasound to confirm the viability of the pregnancy, the woman may be exposed unnecessarily to the risks of mifepristone and misoprostol. It is estimated that at least ten to twenty percent of known pregnancies end in miscarriage. *See* "Miscarriage: Overview" The Mayo Clinic, *available at* https://www.mayoclinic.org/diseases-conditions/pregnancy-lossmiscarriage/symptoms-causes/syc-20354298?p=1 (last visited Feb. 3, 2026). If the

ultrasound reveals that the baby does not have a heartbeat, the woman's body may already be in the midst of a natural miscarriage, and she can be referred to her physician for treatment. Often, no medications are needed to complete the miscarriage. It was wholly arbitrary for the FDA to conclude that it was unnecessary to determine whether a pregnancy exists before administering risky drugs to terminate it.

Second, without an ultrasound to confirm the gestational age of the unborn child, there is an increased risk in attempting an abortion on a woman whose pregnancy is more advanced than she realizes. Practitioners with no access to ultrasound dating of a pregnancy must necessarily rely on the self-reported Last Menstrual Period ("LMP") of the patient. But, as the American College of Obstetricians and Gynecologists ("ACOG"), the American Institute in Medicine ("AIUM") and the Society for Maternal-Fetal Medicine ("SFMF") have recognized, a reported LMP is not the "best obstetric estimate" of the gestational age of the unborn child. Committee on Obstetric Practice, Am. Coll. of Obstetricians and Gynecologists, *Methods for Estimating the Due Date*, Committee Op. No. 700 (May 2017), *available at* https://www.acog.org/ clinical/clinical-guidance/committee-opinion/articles/ 2017/05/methods-for-estimating-the-due-date (last visited Feb. 13, 2026). Studies show that about half of women inaccurately recall their LMP dates. *Id.* Even when women accurately recall their LMP dates, estimating gestational age based on the LMP fails to account for irregularities in the woman's cycle length or changes in her ovulation patterns from month to month. *Id.* In one study, 40% of participants who

received first trimester ultrasounds had the estimated gestational age of their unborn child adjusted by more than five days due to discrepancies between the reported LMP and the ultrasound findings. *Id.* Thus, ACOG, AIUM, and SMFM released a committee opinion declaring that "ultrasound measurement of the embryo or fetus in the first trimester . . . is the most accurate method to establish or confirm gestational age" and that "[a] pregnancy without an ultrasound examination that confirms or revises the EDD before 22 0/7 weeks of gestational age should be considered suboptimally dated." Committee on Obstetric Practice, Am. Coll. of Obstetricians and Gynecologists, *Management of Suboptimally Dated Pregnancies*, Committee Op. No. 688 (March 2017), *available at* https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/ 03/management-of-suboptimally-dated pregnancies#:~:text=recommendations%20 and %20conclusions%3A,Pregnancies%20without%20an%20ultrasonographic %20examination%20confirming%20or%20revising%20the%20estimated,clinical%20 estimate%20of%20gestational%20age (last visited Feb. 13, 2026).

The FDA has apparently concluded that optimal dating of the pregnancy is not necessary, even as a woman is prescribed a drug whose risks the FDA admits *increase* with gestational age. This arbitrary determination represents a significant risk to women's health.

Third, without an ultrasound to confirm the placement of the pregnancy, the practitioner will have no opportunity to diagnose a dangerous ectopic pregnancy or a previously undiagnosed adnexal mass. Abortion drugs do not resolve an ectopic

pregnancy, but they produce symptoms similar to an ectopic pregnancy (pain and bleeding), making it very difficult for a woman to determine whether her pain is an expected effect of the abortion drug or an indication of a life-threatening ectopic pregnancy. Importantly, abortion drugs are *contraindicated* for women experiencing ectopic pregnancies. 2023 Mifeprex Label, at 1, https://bit.ly/46Zix63 (last visited Feb. 13, 2026). The FDA has not shown how it is safe to prescribe to a woman who may have an ectopic pregnancy the very drug it has contraindicated for ectopic pregnancies.

The overall result of these changes is an increased risk for complications. From September 2000 to December 2022, the deaths of 32 women were reported as "adverse events" to the FDA. Until the FDA stopped requiring the reporting of non-fatal adverse events in 2016, documents show a total of 4,218 adverse events, including 1,049 hospitalizations (excluding deaths), 604 cases of blood loss requiring transfusions, 97 ectopic pregnancies, and 418 infections (75 of them "severe"). *See* "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022," FDA, https://www.fda.gov/media/164331/download (last visited Feb. 13, 2026). Furthermore, with the new protocols, women are not required to receive follow up care after taking the drugs, even though evidence shows a higher incident rate for chemical abortions than for other types of abortion. *See, e.g.,* Ushma Upadhyay *et al.*, *Incidence of emergency department visits and complications after abortion*, Obstetrics & Gynecology 125, 175-83 (2015) (finding in study of 55,000 women receiving abortions that rate of complications requiring treatment after chemical abortions was

5.2%, four times higher than for first-trimester aspiration abortions); Maarit Niinimaki *et al.*, *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, Obstetrics & Gynecology 114, 795-804 (2009) (Finnish study finding chemical abortions have a "fourfold higher" incidence of adverse events compared to surgical abortions (nearly 20%) and a risk of hemorrhage that was nearly *eight* times higher, at 15.6%).

The FDA accepts these risks on the grounds that a woman can receive any necessary follow up treatment at a hospital emergency department or other provider beside the one that originally prescribed the chemical abortion drugs. Research demonstrates the weakness of this answer. "[I]f complications from a medication abortion are miscoded by emergency room personnel as a natural miscarriage, the woman is twice as likely to be admitted for surgery for retained products of conception and at a significantly higher risk for recurring hospital admissions for treatment complications." Katherine Rafferty & Tessa Longbons, *Understanding Women's Communication with Their Providers During Medication Abortion and Abortion Pill Reversal: An Exploratory Study*, 90(2) Linacre Q. 172, 177 (May 2023) (citation omitted).

This lowers the standard of medical care, and the FDA's actions have left the states tragically hamstrung to address it, since a woman can easily receive mifepristone from an out-of-state non-physician, regardless of her home state's abortion laws.

2. Chemical abortion drugs are more freely available than ever, representing significant risk to women's health and safety.

In 2020, only 1% of APRN mission-critical contacts reported receiving chemical abortion drugs from the Internet, friends, or family. By 2023, that number rose to a staggering 22% of contacts. In 2025, it was 46%. Due to the FDA's actions, these abortion drugs are more accessible than ever, and women who did not receive a prescription from a provider are taking them, exposing themselves to the risks Plaintiffs have identified and the FDA has conceded, all without the benefit of medical support. Without an medical professional that women can turn to for support through their abortion process, they are left trying to determine on their own which symptoms are serious enough to warrant seeking urgent medical care. Some wait too long, resulting in serious physical harm. Others present in an emergency department when a visit with a trusted a medical professional might have been sufficient to address their concerns, causing an unnecessary burden on emergency department resources.

B. Increased Risk for Abortion Regret and Emotional or Psychological Complications

By jettisoning the need for a woman to have an in-person consultation with a medical professional prior to receiving mifepristone, the FDA now permits these drugs to be obtained remotely—drugs that need not even be prescribed by a licensed physician. This opens the door to more hastily made decisions and an increased chance for abortion regret and subsequent psychological and emotional complications. *Cf. Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 885 (1992)

("The idea that important decisions will be more informed and deliberate if they follow some period of reflection does not strike us as unreasonable.") (permitting state requirement of 24-hour waiting period for abortion); *A Woman's Choice-East Side Women's Clinic v. Newman*, 671 N.E.2d 104, 111 (Ind. 1996) ("It is also possible that a woman may suffer long term emotional or psychological injury from making an ill-informed decision to abort a pregnancy.").

Abortion regret is a real phenomenon, documented in medical literature. *See, e.g.,* David C. Reardon, *The Embrace of the Proabortion Turnaway Study Wishful Thinking? or Willful Deceptions?*, 85(3) Linacre Q. 204 (Aug. 2018) ("Widely publicized claims regarding the benefits of abortion for women have been discredited."). One study reports that "only women who describe their abortion choice as wanted and consistent with their own values and preferences attributed any mental health benefits or a net gain in positive emotions to their abortions. All other groups attributed more negative emotions and a decline in mental health to their abortions." David C. Reardon *et al.*, *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, Cureus: J. of Med. Sci., 15(5): e38882 (May 2023), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10257365/ (last visited Feb. 13, 2026). The same study further found that "[s]ixty percent [of post-abortive women surveyed] reported they would have preferred to give birth if they had received more support from others or had more financial security." *Id.*

In a recent study of post-abortive women who used abortion drugs, 34% "reported an adverse change in themselves, including depression, anxiety, substance abuse, and thoughts of suicide." Eileen Smith Dallabrida, *Study Shows Long-Term Negative Effects of Medication Abortion*, Oct. 2022, at 8, *available at* https://supportafterabortion.com/wp-content/uploads/2022/10/Study-Shows-Long-Term-Negative-Impact-of-Medication-Abortion.pdf (last visited Feb. 13, 2026).

Another recent article concerning women's experiences with abortion drugs confirms the importance of meaningful communication between a pregnant mother and her physician. Rafferty & Longbons, *supra*, at 172. Those researchers reported that "the majority of women in [the] study found that taking mifepristone was difficult," which was consistent with other studies finding such a decision was filled with "tension." *Id.* at 177. As to the issue of "tele-heath abortion," which was also studied, the authors observed that "limited communication with women's healthcare providers can be problematic because it undermines the exchange of important health information and the provision of optimal ongoing reproductive health care, while also increasing the probability of preventable adverse events." *Id.* (citation omitted).

The FDA's relaxed standards, however, rush a woman through her decision and remove important checks on her state of mind, ambivalence, and the presence of coercion or force, increasing the risk of post-abortion regret and mental or emotional health issues as a result. This danger is especially present when the woman decides to abort due to feeling that she has no other option (such as adoption) or that she is

not going to be supported in her decision to choose life by those around her, such as the child's father or even her own parents.[5]

C. Increased Risk of Coerced or Forced Abortions

The Abortion Pill Rescue Network has received an increasing number of women requesting help after someone has coerced or forced them to begin a chemical abortion, as well as callers who came to learn that another person surreptitiously slipped them abortion drugs.

Removing the in-person dispensing requirement increases the likelihood that the drugs will fall into the hands of someone who could use them to induce an abortion in an unwilling participant. Without the safeguards of seeing the patient face-to-face, obtaining a pregnancy test and ultrasound confirmation of pregnancy, and assessing the patient's emotional state and whether her consent is free and informed, all that is necessary to obtain the abortion pills is for a purported patient to self-attest that she is pregnant and claim an LMP that falls within the FDA 10-week limit.

In sum, the FDA concluded, with no explanation, that it is safe to prescribe abortion drugs to women who either may not be pregnant at all, or may have nonviable, suboptimally dated pregnancies, or even dangerous ectopic pregnancies for which the drugs are contraindicated. The FDA further ignored the devastating risks of the abortion drugs falling into the hands of bad actors, who could take the life

[5] Organizations like *amicus* Heartbeat International strive to help pregnant women who choose life through meeting their material and spiritual needs so that they feel empowered to embrace motherhood. Often women facing an unexpected pregnancy are unaware of these resources and thus feel compelled to get an abortion, especially when facing pressure from others to abort (*e.g.*, the child's father, a parent, or even an employer).

of a woman's unborn child, against her will, through coercion, force, or deception, leaving her with a lifetime of emotional trauma.

II. THE FDA'S ACTIONS TREAT PREGNANCY AS AN ILLNESS TO BE CURED AND THEREBY INTRUDE UPON VALID STATE EFFORTS TO PROTECT UNBORN LIFE.

A. Even under *Roe* and *Casey*, States Had an Interest in Protecting the Unborn, But the FDA's 2023 Changes Undermine State Protections for the Unborn.

Pregnancy is not an illness. *See, e.g., All. for Hippocratic Med. v. United States Food & Drug Admin.*, 78 F.4th 210, 263 (5th Cir. 2023) ("To be sure, pregnancy can sometimes result in illness . . . , [b]ut that does not make the pregnancy itself an illness.") (citing *Whitaker v. Bosch Braking Sys. Div.*, 180 F. Supp. 2d 922, 929 (W.D. Mich. 2001) (internal citation omitted)); *see Pacheco v. Gold Emblem Prod., Inc.*, No. 4:15-cv-288-BLW, 2016 WL 4250238, at *2, 2016 U.S. Dist. LEXIS 106619, at *5 (D. Idaho Aug. 10, 2016) ("[P]regnancy is not an illness."); *Sullivan v. Nat'l Cas. Co.*, 283 A.D. 516, 519, 128 N.Y.S.2d 717, 719 (1954) ("Pregnancy is . . . a normal biological function[,] and it is not an illness[.]"). Yet, by treating pregnancy as an illness, the FDA has undermined state-level protections for the lives of the unborn, and the FDA's actions prevent the state from enforcing its laws recognizing the dignity of unborn human life.

In *Dobbs v. Jackson Women's Health Organization,* the Supreme Court held that "the authority to regulate abortion must be returned to the people and their elected representatives." 597 U.S. 215, 292 (2022). Since then, states have taken various approaches to the regulation of abortion. *Compare, e.g.,* Tenn. Code Ann. § 39-

15-201, -213 (law protecting unborn triggered by *Dobbs* decision), *with* Mich. Const., art. I, § 28 (2022) (state constitutional amendment post-*Dobbs* to create access to abortion).

Even pre-*Dobbs*, the U.S. Supreme Court held that states have an interest in protecting the lives of unborn children. *See, e.g., Casey*, 505 U.S. at 857 (discussing "a State's interest in the protection of life"); *see also Gonzales v. Carhart*, 550 U.S. 124, 128 (2007) ("The government may use its voice and regulatory authority to show its profound respect for the life within the woman."). The FDA's arbitrary regulatory changes here interfere with a state's ability to restrict abortion within its jurisdiction during a significant period of a time—namely the first ten weeks of a pregnancy—by allowing mifepristone to be obtainable through mail order prescriptions. Moreover, the period within which states cannot stop abortions is even longer if the prescriber (who need not be a licensed physician and need not have an in-person consultation with the mother) misdiagnoses the gestational age—a possibility made all the more likely by eliminating the most accurate method of dating a pregnancy.

B. States Have Many Reasons to Recognize and Protect the Dignity of the Unborn.

Biology itself defines the beginning of human life with the fertilization of an egg by a sperm. *See generally* Emile M. Scarpelli, *Personhood: A Biological Phenomenon*, 29 J. Perinat. Med. 417 (2001). "[T]he fundamental approaches of biomedical and social (secular) practice must begin with the understanding that the subject before birth is a person . . . by successful fertilization of the egg." *Id.* at 425; *see* Asim Kurjak & Ana Tripalo, *The Facts and Doubts about Beginning of the Human*

Life and Embryo, 4(1) J. of the Assoc. of Basic Med. Sci. 5 (Feb. 2004) ("The biological line of existence of each individual, without exception begins precisely when fertilization of the egg is successful."); *see also* Maureen Condic, *A Scientific View of When Life Begins*, Charlotte Lozier Inst., June 11, 2014, *available at* https://lozierinstitute.org/a-scientific-view-of-when-life-begins/ ("The conclusion that human life begins at sperm-egg fusion is uncontested, objective, based on the universally accepted scientific method of distinguishing different cell types from each other and on ample scientific evidence (thousands of independent, peer-reviewed publications).") (last visited Feb. 13, 2026). "To hide from this in silence or ignorance should be unacceptable to all." Scarpelli, *supra*, at 425.

These scientific realities of when human life begins inform the consciences of religious and non-religious Americans alike, and they underscore for millions of religious Americans the dignity of each individual person. Reasoning from this proposition leads many to defend the rights of the unborn, as the unborn child is in fact a person with rights and not a disease to be treated. *See, e.g.,* Secular Pro-Life, *Mission*, *available at* https://secularprolife.org/ mission/ ("We envision a world in which . . . people of all faith traditions, political philosophies, socioeconomic statuses, sexualities, races, and age groups oppose abortion[.]") (last visited Feb. 13, 2026); *see also* Daniel Brudney, *"Pregnancy is not a Disease:" Conscientious Refusal and the Argument from Concepts*, 5 Hastings Ctr. Report 43, 44 (2014) (describing argument that "medicine is about curing or preventing disease; pregnancy is not a disease;

therefore, it is not a medical professional's job, *qua* medical professional, to 'cure' . . . pregnancy[.]").

C. The FDA's Actions Interfere with State Efforts to Protect the Lives of the Unborn.

Even when a state defines unborn life as legally protected, the FDA has arrogated to itself the power to define that unborn life as an illness to be remedied. This is an affront to the very return to federalism and popular determination of abortion regulation that *Dobbs* signaled. *See, e.g., Dobbs,* 597 U.S. at 286 ("Members of this Court have repeatedly lamented that no legal rule or doctrine is safe from *ad hoc* nullification by this Court when an occasion for its application arises in a case involving state regulation of abortion.") (internal quotation marks and citations omitted). The FDA's power grab would be troubling enough under any circumstances, but it is especially so given the various state efforts since *Dobbs* to increase protections for the unborn. *See, e.g.,* La. R. S. 14:87.1 *et seq.*; *see also* Tex. Health & Saf. Code § 170A.002.

What is more, the FDA acted in contravention of the federal Comstock Act, which prohibits the mailing of any "substance, drug, medicine, or thing [that] may, or can, be used or applied for producing abortion" and further prohibits a "common carrier or interactive computer service" to send in interstate commerce "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion[.]" 18 U.S.C. § 1461 & 1462(c). On the failure to abide by the Comstock Act alone, the FDA's actions have been "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A).

Besides simply ignoring the express terms of the Comstock Act, the FDA's action effectively vitiates the judgment of states to protect unborn life. The result of this action is that mail order chemical abortions are available in every state, regardless of the laws enacted by the people of a state and their elected representatives. *Amicus* Heartbeat International believes that all abortions harm at least two parties: the child aborted *as well as* the mother. Unfortunately, the FDA's expansion of the availability of mifepristone only makes this harm more likely and improperly undermines states' efforts to protect their most vulnerable populations.

CONCLUSION

For the foregoing reasons, this *amicus* respectfully urges the Court to stay the 2023 REMS under 5 U.S.C. § 705 and direct that "[t]he in-person dispensing requirement[ ], and FDA's obligation to enforce [it], will continue to apply," or alternatively enter a preliminary injunction under 5 U.S.C. § 705 against FDA's enforcement of the 2023 REMS.

[*Signatures appear on following page.*]

Dated: February 13, 2026

Respectfully submitted,

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