N0. 26-30203

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

Plaintiffs-Appellants/Cross-Appellee,

v.

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

Defendants-Appellees.

DANCO LABORATORIES, LLC; GENBIOPRO, INC.

Intervenors-Appellees/Cross-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
NO. 6:25-cv-01491, HON. DAVID C. JOSEPH

BRIEF FOR AMICI CURIAE OF WOMEN AND FAMILIES HARMED BY MIFEPRISTONE AND FORMER ABORTION PROVIDER AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following persons and entities listed below in accordance with 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.

Amici Curiae

Trinity Legal Center
Leslie Wolbert
Tammi Morris
Carol Everett
Monty Patterson, father of Holly Patterson

Respectfully submitted

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CORPORATE DISCLOSURE STATEMENT

Amicus Trinity Legal Center is a nongovernmental corporate entity and it has no parent corporations and no publicly held corporations hold 10% or more of their stock.

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INTEREST OF THE AMICI CURIAE

The Amici respectfully submit this amicus curiae brief in support of the State of Louisiana and Rosalie Markezich. All parties have given consent to file except Intervener Danco who does not oppose filing this amicus brief. This brief was prepared by counsel for Amici.[1]

Trinity Legal Center is a nonprofit, public interest foundation to help women hurt by abortion and to protect minors. Over the years, we have filed amicus briefs in the United States Supreme Court and provided testimony at state legislatures on Mifepristone and other abortion issues.

The women Amici who have taken Mifepristone,[2] their families, and former abortion provider have personal knowledge as to how Mifepristone negatively affects women both physically and psychologically. The women Amici attest that they were not given accurate and truthful information about the risks of Mifepristone. Their interest is that other women are not misled as they were and to

[1] The parties were notified ten days prior to the due date of this brief of the intention to file. 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. Trinity Legal Center is a nonprofit corporation and is supported through private contributions of donors who have made the preparation and submission of this brief possible. No person other than Amici, their counsel, or donors to Trinity Legal Center made a monetary contribution to its preparation or submission.

[2] Throughout this brief, three terms have been used depending on the sources. These are Mifepristone; RU-486; and, chemical or medical abortion and are used in contrast to surgical abortion. Although different terminology may be used, we are referring the same means of ending a pregnancy.

spare other women and families the grief and pain associated with this dangerous drug. The Amici are Carol Everett (Texas) who had an abortion and was also an abortion provider; Tammi Morris (Pennsylvania) who took Mifepristone; Monty Patterson, whose daughter Holly Patterson (California) died after taking Mifepristone; and, Leslie Wolbert (New York) who took Mifepristone.

Of particular concern of the Amici is the lack of appropriate safeguard and warnings by the FDA of the risks and dangers of Mifepristone. Because the FDA did not appropriately review and evaluate the data and scientific studies, it failed to provide adequate warnings. As a result of this willful blindness, women and families such as Amici have been hurt by the drug because they did not have accurate and truthful information to make an informed decision. Also of concern is that Mifepristone by mail can be even more dangerous without medical supervision.

Their affidavits demonstrate what these women and families experience and their testimony is heartbreaking. In a similar case, their affidavits were submitted to the United States Supreme Court. Each Amici asks that this court consider their affidavits and have consented to filing in this case. Their testimony remains the same and nothing has changed.

Amici urge this court to require the FDA to provide and enforce better safeguards and to uphold Louisiana's ban on Mifepristone by mail because it protects women.

SUMMARY OF THE ARGUMENT

I.

The FDA must prove that it did not act arbitrarily or capriciously. The FDA, however, had willful blindness in failing to appropriately review and evaluate the data and studies on Mifepristone, and therefore, acted in an arbitrary and capricious manner. A decade before the FDA reduced its standards and warnings of Mifepristone, the Congressional Staff Report on RU-486 warned of its dangers and risks. Contrary to the United States Supreme Court's requirements, women were not given accurate and truthful information to make an informed decision. Therefore, Amici urge this court to protect women by upholding Louisiana's ban on Mifepristone by mail.

II.

Chemical abortions expose women to an increased risk of both physical and psychological harm. This is supported by scientific and medical studies that demonstrate this increased risk. In addition, the women Amici attest to the physical and psychological trauma they experienced because of taking RU-486. Therefore, Amici urge this court to find for the Plaintiffs-Appellants.

ARGUMENT

I. THE FDA FAILED IN ITS RESPONSBILITY TO ENSURE MIFREPRISTONE WAS SAFE, AND THEREFORE, ITS INACTION WAS ARBITRARY AND CAPRICIOUS.

The stated responsibilities of the Food and Drug Administration (FDA) are to (1) "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;"[3] and, (2) "protect the public health by ensuring that…human and veterinary drugs are safe and effective."[4] These responsibilities are provided to the public through the FDA's website.[5]

The FDA failed its responsibilities by reducing the safety standards and not reviewing the studies that demonstrate Mifepristone is a dangerous drug that can cause serious physical and psychological harm including death. Had the FDA fulfilled its responsibilities, it would not have reduced the standards and would have provided better warnings.

A. The FDA Had Willful Blindness in Failing to Appropriately Review and Evaluate the Data and Studies on Mifepristone.

[3] 21 U.S.C. § 393 (b)(1).
[4] 21 U.S.C. § 393 (b)(2)(B) (emphasis in original) (stating a court could "hold unlawful and set aside agency action, findings, and conclusions" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").
[5] Food and Drug Administration, *available at* https://www.usa.gov/agencies/food-and-drug-administration (2024).

The FDA's actions are held to an arbitrary and capricious standard.[6] This court determined that the FDA failed to carry its burden that the FDA's actions were not arbitrary and capricious.[7] This court stated that it had two principal concerns.[8] First, the FDA failed to review the relevant data.[9] Specifically, "it relied on zero studies that evaluated the safety-and-effectiveness consequences of the 2016 Major REMS Changes as a *whole,*"[10] and thereby, it failed to consider "an important aspect of the problem" when it made its 2016 changes.[11]

Second, the 2016 changes eliminated the requirement that non-fatal adverse events (complications) must be reported to the FDA.[12] Then in 2021 the FDA declared that there were no non-fatal adverse reports, concluding Mifepristone was safe.[13] This court correctly concluded that FDA's "ostrich's-head-in-the-sand approach is deeply troubling" particularly considering FDA's own documents.[14] In 2023, the FDA removed the in-person requirement for Mifepristone thereby allowing it to be distributed by mail. These actions were arbitrary and capricious.

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[6] 5 U.S.C. § 706(2)(A).
[7] Alliance for Hippocratic Medicine v. FDA, ___ F.3d ___, 2023 U.S. App. LEXIS 8898 at *46 (5th Cir. 2023).
[8] *Id*.
[9] *Id*.
[10] *Id.* at *47.
[11] *Id*.
[12] *Id*.
[13] *Id*.
[14] *Id*.

Over the years, there have been many studies showing the dangers and psychological risks of chemical abortions.[15] But women did not believe they had been given adequate information.[16] Furthermore, there was a high rate of dissatisfaction with chemical abortions, and the surveyed women would not choose it again.[17]

It was egregious enough when the FDA failed to do its due diligence by not wanting the data, appropriately reviewing it, and considering the studies

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[15] *See, e.g.,* Rafferty, K. A., & Longbons, T., *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives* [published online ahead of print, Jun 1, 2020], Health Commun. 1-10 (2020) (reporting negative and difficult emotions following chemical abortions were common, with 38% explicitly stating problems with anxiety, depression, drug abuse, and suicidal thoughts); Lowenstein L, et al., *Psychological Distress Symptoms in Women Undergoing Medical vs. Surgical Termination of Pregnancy*, 28(1) GENERAL HOSPITAL PSYCHIATRY 43–47 (2006) (finding greater psychological consequences of medical abortion); Slade, P., *et al*., *A Comparison of Medical and Surgical Methods of Termination of Pregnancy: Choice, Psychological Consequences, and Satisfaction with Care*, 105 BRITISH J. OBSTETRICS AND GYNECOLOGY 1288-95 (1998) (finding difference between the two methods is the consciousness and participation of the patient in the medical procedure in a process that involves blood, pain, and death). *See generally* Coleman, *A Tidal Wave of Published Data* (2010), *available at* https://www.afterabortion.org/a-tidal-wave-of-published-data/ (citing hundreds of studies published in major medicine and psychology journals throughout the world).

[16] *See, e.g*., Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013) (stating "If a woman obtains subsequent information, contradicting that provided by the abortion facility and used as the basis of her earlier abortion decision, devastating psychological consequences become more probable"); Aamlid, I. B., Dahl, B., & Sommerseth, E., *Women's Experiences with Information Before Medication Abortion at Home, Support During the Process and Follow-up Procedures - A qualitative Study*, 27 J. SWEDISH ASSOC. OF MIDWIVES 100582 (2021) (concluding that women felt information provided for chemical abortion was inadequate, especially as related to bleeding and pain).

[17] Kelly, T., *et al.*, *Comparing Medical Versus Surgical Termination of Pregnancy at 13–20 Weeks of Gestation: A Randomized Controlled Trial*, 117 BJOG 1512–20 (2010) (finding 47% of women who underwent chemical abortions indicated they would not choose the method again and 53% felt the procedure was worse than expected); Slade, P., *et al*., *A Comparison of Medical and Surgical Methods of Termination of Pregnancy: Choice, Psychological Consequences, and Satisfaction with Care*, 105 BRIT. J. OBSTET. & GYNECOL. 1288-95 (1998) (stating 47% of women who had a chemical abortion would not choose the same procedure again).

demonstrating the dangers of Mifepristone. But, the information through both data and studies was known from the FDA's own information and from independent researchers. Women considering chemical abortion deserve better from government agencies in whom the public puts its trust to ensure drugs are safe.

It was equally egregious because of the subsequent effect that the FDA's failures had namely doctors did not provide women with important information concerning the risks of Mifepristone. Thus, women did not have the necessary information to make an informed decision as required by the United States Supreme Court. The women Amici stated in their sworn affidavits that they did not have this information and they wish it had been provided to them.[18]

B. Although the FDA Acted in Willful Blindness and Failed Its Responsibilities, Congress and the States Knew of the Dangers and Risks of Mifepristone and Attempted to Provide Warnings.

Congress Recognized the Dangers.

As early as 2006 the FDA knew there were serious complications with Mifepristone. The Congressional Staff Report[19] reviewed what the FDA knew about

[18] Affidavits of the women Amici.

[19] Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources (Oct. 2006), *available at* https://aaplog.wildapricot.org/resources/Souder%20Comm.%20Rprt_RU-486_October%202006_converted%5B1%5D%20%281%29.pdf.

the dangers and risks of Mifepristone and its "dismal" outcomes. The Report concluded that there were "startling adverse effects"[20] and a "dismal result."[21]

Both the FDA[22] and Danco, the drug manufacturer,[23] acknowledged that RU-486 poses health risks for women. The Mifeprex drug label acknowledges that "[n]early all of the women who receive Mifeprex and misoprostol [the RU-486 regimen] will report adverse reactions, and many can be expected to report more than one such reaction."[24] The MIFEPREX Label listed adverse reactions including abdominal pain, uterine cramping, nausea, vomiting, diarrhea, pelvic pain, fainting, headache, dizziness, and asthenia.[25]

The Congressional Staff Report cited FDA findings concerning the physical risks to women taking the RU-486 regimen.[26] This longer list included: "abdominal

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[20] *Id*. at 30.
[21] *Id*. at 31.
[22] *Id*. at 30 (*citing* FDA findings and reporting adverse reactions).
[23] *See* MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm..
[24] *See* MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm; Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), *available at* http://old.usccb.org/prolife/issues/ru486/SouderStaffReportonRU-486.pdf.
[25] MIFEPREX™ Label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.
[26] Congressional Staff Report, *The FDA and RU-486: Lowering the Standard for Women's Health*, prepared for the Chairman of the House Subcommittee on Criminal Justice, Drug Policy and Human Resources, at page 30 (Oct. 2006), *available at* https://aaplog.wildapricot.org/resources/Souder%20Comm.%20Rprt_RU-486_October%202006_converted%5B1%5D%20%281%29.pdf.

pain, uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis/salpingitis/pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting."[27]

The FDA's Medical Officer's review indicated that, "[m]ore than one adverse event was reported for most patients.…Approximately 23% of the adverse events in each gestational age group were judged to be severe."[28] The Congressional Staff Report calls these "startling adverse effects," which the FDA knew during the RU-486 NDA review process.[29]

The Report also was concerned about "the incredibly high failure rate of the drug."[30] The FDA knew the failure rate was averaging 14.6% in the U.S. trial testing the drug through 63 days gestation. The findings were that 27% had ongoing pregnancies, 43% had incomplete abortions, 10% requested and had surgical terminations, and the remaining 20% of patients had surgical terminations performed because of medical indications directly related to the chemical abortion procedure.[31]

[27] *Id*.
[28] *Id*.
[29] *Id*.
[30] *Id*.
[31] *Id*.

The Congressional Staff Report stated the "best" outcome was in the patient group where the pregnancies were less than or equal to 49 days of gestation.[32] In this group, the Report stated that 7.9% of patients required surgical intervention after taking RU-486.[33] The Report also stated that as "the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57- 63 days gestation group."[34] The Report concluded that "By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the 'best' outcome is a dismal result."[35]

In 2011, the FDA had more data concerning the adverse consequences of RU-486 and risk of death. The FDA issued a report on the post-marketing events of RU-486.[36] The FDA reported that there were 2,207 adverse events (complications) in the United States regarding the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.[37] Among the 2,207 adverse events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[38]

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[32] *Id*. at 31.
[33] *Id*.
[34] *Id*.
[35] *Id*.
[36] Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/2011* (July 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.
[37] *Id*.
[38] *Id*.

The serious complications from chemical abortions continues to grow. A 2025 study found that "one in ten women who took abortion pills ended up in the hospital with at least one serious adverse event, including hemorrhaging, sepsis, infections, and other life-threatening complications."[39]

Even without data and studies by independent researchers, the FDA knew of the serious complications of Mifepristone. Yet in 2016 and 2021, the FDA did not require the reporting of complications and lowered the standards. This was willful blindness and a failure of its responsibilities to protect the public from dangerous drugs.

The States Knew of the Dangers.

Although the FDA failed its responsibilities, the states attempted to explain the risks. The Woman's Right to Know laws were enacted to protect "a woman's right to know the medical risks associated with abortion, its alternatives, and nonjudgmental, scientifically accurate medical facts about the development of her unborn child before making this permanent and life-affecting decision."[40] Twenty-eight states have enacted such laws[41] including Louisiana. The booklets provided

[39] Bauwens, *The Physical and Mental Health Effects of Chemical Abortion* (2026) (citing studies), *available at* https://www.americafirstpolicy.com/issues/the-physical-and-mental-health-effects-of-chemical-abortion.
[40] National Right to Life, *A Woman's Right to Know: Casey-style Informed Consent Laws,* (2018), *available at* https://www.nrlc.org/uploads/stateleg/WRTKFactSheet.pdf (explaining the right to know laws).
[41] *Id*. (providing a chart of state laws).

pictures of the baby at two-week internals and discussed the physical and psychological risks of abortion as compared to childbirth.[42]

For example, the Louisiana Legislature held hearings, wrote findings, and stated the purpose for the Woman's Right to Know law.[43] In conjunction with the law, the Louisiana Department of Health (LDH) produced a booklet entitled "Abortion: Making a Decision" which discusses the risks associated with abortions.[44]

Following the *Dobbs*[45] decision and the United States Supreme Court returning the abortion issue to the states, states including Louisiana continued to enact legislation protecting women. Specifically, Louisiana prohibited any person from performing an abortion by means of an abortion-inducing drug such as Mifepristone.[46] The law included imprisonment and fines.[47] This is a decision that the people of a state, through their elected officials, can make.[48]

C. The FDA's Failures Had a Profound and Devastating Impact on Women as They Were Not Given Accurate and Truthful Information to Make an Informed Decision That Is Required By The United States Supreme Court.

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[42] La. Department of Health, "Abortion: Making a Decision" booklet *available at* https://dh.la.gov/assets/oph/AbortionMakingaDecision_2011.pdf.
[43] *See* LA. REV. STAT. § 40:1061.17 (stating in part that "It is essential to the psychological and physical well-being of a woman considering an abortion that she receives complete and accurate information regarding her alternatives). *Id*. at finding subsec. 4(a).
[44] *Id*.
[45] Dobbs v. Jackson Women's Health Organization, 597 U.S. 215 (2022).
[46] LA. REV. STAT. § 14.87.9.
[47] *Id*.
[48] *See* Dobbs v. Jackson Women's Health Organization, 597 U.S. 215 (2022).

In *Planned Parenthood v. Casey*,[49] the Supreme Court emphasized the need for full, accurate, and truthful information so that a woman can make an informed decision.[50] The Supreme Court correctly stated that it is important for a woman to have this information because of the "devastating psychological consequences" of later realizing that she did not have accurate information or know the truth.[51] The FDA's failures thus have a profound and devastating impact on women.

When the FDA argues that "Mifepristone is comparable to 'ibuprofen,'"[52] it is false and misleading. This court correctly determined that "Mifepristone bears no resemblance to ibuprofen."[53] In coming to this conclusion, this court reviewed the FDA's own documents and the "Black Box" warnings which is used when the drug "may lead to death or serious injury."[54]

Abortion statistics also emphasize the need for accurate and truthful information because of the increased use of Mifepristone. Eighteen percent of pregnancies in 2017 ended in abortion which was approximately 862,320

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[49] Planned Parenthood v. Casey, 505 U.S. 833 (1992), *overruled on other grounds*, Dobbs v. Jackson Women's Health Organization, 597 U.S. 215 (2022).
[50] *Id*. at 882.
[51] *Id*.
[52] Alliance for Hippocratic Medicine v. FDA, ___ F.3d ___, 2023 U.S. App. LEXIS 8898 at *27 (5th Cir. 2023).
[53] *Id*.
[54] *Id*.

abortions.[55] Chemical abortions accounted for 39% of all abortions in 2017 which was an increase from 29% in 2014.[56] Thus, even though the number of abortions decreased, chemical abortions increased from 5% of all abortions in 2001 to 39% in 2017.[57] With the steady increase in chemical abortions, it becomes even more important that women have the facts about the drugs that they are taking and what side effects and risks may occur. To do any less would not be informed consent.

From a medical perspective, abortion should mandate informed consent like any other medical procedure. The American Medical Association states that "Informed consent to medical treatment is fundamental in both ethics and law."[58] Furthermore, it states that "Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care."[59] Because informed consent is "fundamental," a woman needs accurate information at this critical time in her life.

Similarly from a legal perspective, a district court opined that women should be given factual information about the physical and psychological risks of the RU-486 regimen.[60] The court stated that the purpose of informed consent provisions is

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[55] Guttmacher Institute, *Fact Sheet: Facts on Induced Abortions in the United States* (Sept. 2019), *available at* http://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.
[56] *Id*.
[57] *Id*.
[58] American Medical Association Code of Ethics, *Informed Consent*, Opinion 2.1.1, *available at* https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent.
[59] *Id*.
[60] Planned Parenthood of Indiana, Inc. v. Commissioner, 794 F. Supp. 2d 892, 918 (S.D. Ind. 2011).

to "serve not only to communicate information that would not necessarily be known to the patient, but also help the woman to make a fully informed decision."[61] Therefore, women should know they are exposed to increased risks of physical and psychological complications by taking the RU-486 regimen.[62]

Although this is "fundamental," Amici contend and have experienced the fact that women are not given accurate information.[63] Amici Leslie Wolbert states in her affidavit that no one told her "how scary it would be to experience this alone at home," or that she would feel "a deep loss."[64] She attests that:

> These things just weren't discussed, yet they had great effects on me then and still do today. Women need to be counseled about all of their choices when it comes to an unplanned pregnancy, and not ushered into choosing one that is most convenient at the time. The truth needs to be told; it is far too great of a matter for it to continue to be handled the way it has been.[65]

Amici Tammi Morris also lacked information. She states the clinic said that "my chemical abortion would be simple, safe, and mostly painless. It would be a

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[61] *Id*.
[62] Planned Parenthood v. Rounds, 686 F.3d 889, 898 (8th Cir. 2012) (holding disclosure that an increased risk of suicide ideation and suicide is non-misleading and relevant to the patient's decision to have an abortion and other psychological distress was not challenged).
[63] *See* Affidavit of Leslie Wolbert, Appendix A; Affidavit of Tammi Morris, Appendix B; and Affidavit of Monty Patterson, Appendix D; *see also* Report of the South Dakota Task Force to Study Abortion 51 (Dec. 2005) (being the largest government study since *Roe* and discussing the lack of information provided), *available at* http://www.dakotavoice.com/Docs/South%20Dakota%20Abortion%20Task%20Force%20Report.pdf..
[64] Affidavit of Leslie Wolbert, Appendix A, ¶ 22.
[65] *Id*.

little more than a menstrual cycle. They did not prepare me for what was to come."[66] She states: "This was unexpected because the clinic only told me the benefits and not the risks."[67] She said that seeing her dead baby that she had expelled was devastating.[68]

Amici Carol Everett was both a consumer and a provider.[69] At one time, she was involved in the operation of four clinics with a fifth scheduled to open and oversaw 35,000 abortions.[70] She was Dallas' largest abortion chain owner.[71] She attests that abortion facilities lie to women about the physical and psychological risks and what will actually occur when they take the drug.[72] In addition, the abortion facilities do not speak accurately that it is a baby but say it is only a "product of conception," a "blood clot," or, a "piece of tissue."[73] This is what causes such psychological trauma because she sees it is a baby that she has expelled in the toilet or shower.[74]

In the case of Holly Patterson, her father describes the "pain experience" for their family after Holly took RU-486 and died.[75] He states that "Women need to

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[66] Affidavit of Tammi Morris, Appendix B, ¶ 3.
[67] *Id*. at ¶ 4.
[68] *Id*. at ¶¶ 17, 21.
[69] Affidavit of Carol Everett, Appendix C, ¶ 2.
[70] *Id*.
[71] *Id*.
[72] *Id*. at ¶ 22.
[73] *Id*. at ¶ 20.
[74] *Id*. at ¶ 21.
[75] Affidavit of Monty Patterson, Appendix D, ¶ 3.

have accurate and factual information regarding the potential risks of severe and life threatening side-effects."[76] Holly was not given that information.[77] He concludes: "No woman should risk her life or her health because she lacks factual and accurate medical abortion information to make a well-informed decision when terminating an early pregnancy with mifepristone (RU-486) and misoprostol."[78]

II. CHEMICAL ABORTIONS EXPOSE WOMEN TO INCREASED RISKS OF PHYSICAL AND PSYCHOLOGICAL HARM, AND THEREFORE, THE FDA SHOULD HAVE PROVIDED ADEQUATE WARNINGS AND SAFETY MEASURES TO PROTECT WOMEN.

A. Scientific and Medical Studies Demonstrate That Chemical Abortions Present Increased Risks of Physical and Psychological Problems Thereby Requiring Adequate Warnings.

Physical Risks of RU-486

In reviewing and assessing the scientific literature, researchers have concluded that there are increased risks of physical problems with the RU-486 regimen.[79] These include: more pain, more nausea or vomiting, higher failure rate, greater risks of acute bleeding requiring surgery, post-procedure bleeding continues for a longer period of time, more women require surgery for persistent bleeding, more total blood loss, and greater risk of massive, life-threatening hemorrhage.[80]

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[76] *Id*.
[77] *Id*.
[78] *Id*. ¶ 74.
[79] Shuping, Harrison, & Gacek, *Medical Abortion with Mifepristone (RU-486) Compared to Surgical Abortion*, *available at* http://rachelnetwork.org/images/Medical_Abortion_with_Mifepristone.pdf.
[80] *Id*.

They also report that "Mifepristone abortion has 10 times more risk of death from infection than surgical abortion and 50 times more risk of death from infection compared to childbirth."[81]

The risks of RU-486 are not only with the current pregnancy but may be transgenerational. Dr. Bernard Nathanson, co-founder of the National Association for the Repeal of Abortion Laws (NARAL) and who presided over 60,000 abortions, warned that if a woman starts taking the regimen but then changes her mind and wants to carry the baby to term, the newborn may have serious deformities.[82]

In addition, Dr. Nathanson warned there may be the possibility that disorders could be passed down to surviving offspring of women who have taken the drug.[83] "RU-486 is the drug which acts on the female reproductive system, and anything that does that we have to be keenly aware of what are called transgenerational effects."[84]

Psychological Risks of RU-486

The RU-486 regimen also has increased risks for psychological problems. In scientific studies, women rated chemical abortions more stressful and experienced

[81] *Id*. (citations omitted).
[82] The Silent Scream, *Former Abortionist Bernard Nathanson, M.D. Warns of RU-486 Dangers*, *available at* http://www.silentscream.org/ru486-drnat.htm.
[83] *Id*.
[84] *Id*.

more disruptions in their lives.[85] They also experienced a significant decline in self-esteem and higher PTSD intrusion scores.[86]

There are at least five major reasons why women are at greater risk of more severe psychological trauma with the RU-486 regimen than with a surgical abortion.[87] First, the woman has a participatory role with a chemical abortion which may cause greater psychological trauma.[88] This is because the woman is directly responsible for the abortion which may exacerbate guilt and other negative feelings.[89]

The RU-486 regimen is a very difficult process and simply adds to emotional consequences. Unlike surgical abortion, the woman acts as the abortionist.[90] The drug is self-administered by her own hand and there is no one else to blame or project anger on such as the abortionist or others.[91] Because the woman plays an active role in the procedure and is conscious of each step, it is more likely that there will be psychological consequences.[92] Here is one of the profound differences between

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[85] Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013) (*citing* scientific studies).
[86] *Id*.
[87] *Id*.
[88] *Id*.
[89] *Id*.
[90] Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).
[91] *Id*.
[92] *Id*.

surgical and chemical abortion. In a surgical abortion, the woman is usually given drugs to be relaxed or to wake up after the procedure is complete. With RU-486, however, "she will have a memory of each step and its effects on her body and the body of her child. She cannot close her eyes to the process and tell herself that someone else is doing this to her...Simply looking in the mirror can become a triggering event."[93]

Second, chemical abortion requires the woman to be more alert and involved during the process.[94] Therefore, it is impossible for her to distance herself psychologically from the abortion.[95]

Third, there is a greater potential for the woman to see her expelled unborn child.[96] There is no doubt in her mind that she has taken the life of her unborn child.

Fourth, although women usually say that they choose a chemical abortion because it is in the privacy of her home, it is that privacy that can also lead to greater trauma.[97] This is because the woman is more likely to be at home and alone. Thus, it is likely that she is without emotional support at the time of the abortion.[98]

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[93] *Id*.
[94] Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013).
[95] *Id*.
[96] *Id*.
[97] *Id*.
[98] *Id*.

Fifth, the woman's home becomes a trigger point for negative emotions instead of being a place of refuge.[99] This is because she is at home and more specifically in the bathroom. Therefore, her home and the bathroom are associated with the abortion that she participated in a major and very visual way.

The trauma continues because the woman's home becomes a daily trigger. Instead of being a sanctuary or refuge, the home is a trigger for the abortion experience[100] because she is in her home and specifically the bathroom or bedroom. Women who take the RU-486 regimen do "not have the luxury of using the normal coping mechanisms, like avoidance of their abortion clinic and doctors…."[101] These coping mechanisms allow her to distance herself from "the painful reality of what she has done."[102] Therefore, this "traumatic scene will be accessible each time a woman uses her bathroom, lays on her bed, or any other associations they make while waiting for the pill to do its job. Her very home becomes a daily trigger to traumatic feelings and sensations."[103]

The courts also have recognized the negative psychological impact that abortion has on women. For example, this court cited testimony that abortion as

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[99] *Id*.
[100] Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).
[101] *Id*.
[102] *Id*.
[103] *Id*.

practiced is "almost always a negative experience for the patient.…"[104] The Supreme Court has recognized that abortion:

> …is an act fraught with consequences for others; for the woman who must live with the implications of her decision; for the persons who perform and assist in the procedure; for the spouse, family, and society which must confront the knowledge that these procedures exist, procedures some deem nothing short of an act of violence against innocent human life; and depending on one's beliefs, for the life or potential life that is aborted.[105]

More recently, the Court recognized, "whether to have an abortion requires a difficult and painful moral decision" and is "fraught with emotional consequences."[106] In addition, women can suffer from depression, regret, guilt, and a loss of self-esteem following an abortion.[107] As Justice Ginsburg wrote, "The Court is surely correct that, for most women, abortion is a painfully difficult decision."[108]

B. Women Attest to the Trauma They Experienced as a Result of the RU-486 Regimen and Wish They Had Been Given Accurate Information to Make an Informed Decision.

The courts and the scientific research support the conclusion that there are negative physical and psychological consequences of abortion on women and

[104] Women's Medical Center v. Bell, 248 F.3d 411, 418 (5th Cir. 2001).
[105] Planned Parenthood v. Casey, 505 U.S. 833, 852 (1991), *overruled on other grounds*, Dobbs v. Jackson Women's Health Organization, 597 U.S. 215 (2022).
[106] Gonzales v. Carhart, 550 U.S. 124, 159 (2007).
[107] *Id*.
[108] *Id*. at 184 n.7 (Ginsburg, J., dissenting).

particularly the RU-486 regimen. But it is the real-life experiences of women that bring to light the true impact of this dangerous drug regimen.[109]

The RU-486 regimen exacerbates the impact because it takes longer than surgical abortion. The RU-486 regimen process is generally over a two week period, and therefore, much longer than a surgical abortion which is completed on the same day in approximately fifteen minutes.[110] On Day 1, the patient reads the *Medication Guide*, reads and signs the *patient agreement*, and then swallows three tablets of Mifeprex in the presence of a health professional.[111] On Day 3, she is supposed to return to the abortion facility and be examined to determine if she is still pregnant.[112] If she is pregnant, she is given two tablets of misoprostol.[113] However, this is not the experience of these post-abortive women as they are given a "brown bag of pills" to be taken at home.[114] On Day 14, she is supposed to return to the abortion facility

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[109] *See, e.g.,* Affidavit of Leslie Wolbert, attached as Appendix A; Affidavit of Tammi Morris, attached as Appendix B.

[110] Dr. Theresa Burke, Psychotherapist and founder of Rachel's Vineyard, Address at the American Association of Pro-Life OB-GYNS (AAPLOG) meeting entitled "Medical Abortion: New Emotional and Psychological Landscape" (Jan. 28, 2011).

[111] CRS Report for Congress, *Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)* at 14 (Feb. 23, 2001), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf (discussing the process and history of RU-486), s*ee also* National Abortion Federation, *Facts About Mifepristone (RU-486)*, *available at* http://www.prochoice.org/about_abortion/facts/facts_mifepristone.html (describing the process).

[112] CRS Report for Congress, *Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)* at 14 (Feb. 23, 2001) (discussing the process and history of RU-486), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf.

[113] *Id*.

[114] Affidavit of Tammi Morris, attached as Appendix B. The National Abortion Federation admits that there may not be a second visit to the clinic but that the drugs may be taken at home. National

for a follow-up visit to confirm the pregnancy has been terminated and assess the level of bleeding.[115] This also may not be the case if she has had to go to the emergency room due to hemorrhaging or infection. Just by the mere method of the RU-486 regimen, the woman's ordeal is prolonged over at least a two-week period in contrast to the surgical abortion procedure which is usually over in 15 minutes.

Although the abortion facility may generally tell a woman what the regimen will be, the women are not prepared for what is truly involved. For example, Amici Leslie Wolbert attests that "Nothing could have prepared me for what I would experience, or the emotional pain that I would carry for years."[116] She "trusted the clinic."[117] They referred to the baby as "just a blob of tissue."[118] When the clinic workers counseled her, they told her about the abortion pill and "how 'simple' it was and that you didn't have to go through surgery, but that you would have a heavy period instead."[119]

But Leslie quickly learned that what she had been told was not accurate or truthful information. "It was the second day that I experienced the worst pain I've

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Abortion Federation, *Facts About Mifepristone (RU-486), available at* http://www.prochoice.org/about_abortion/facts/facts_mifepristone.html.

[115] CRS Report for Congress, *Abortion: Termination of Early Pregnancy with RU-486 (Mifepristone)* at 14 (Feb. 23, 2001) (discussing the process and history of RU-486), *available at* http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30866.pdf.

[116] Affidavit of Leslie Wolbert, attached as Appendix A, ¶ 2.

[117] *Id*. at ¶ 4.

[118] *Id*. at 11.

[119] *Id*. at ¶ 4.

ever felt in my life. The experience wasn't just a heavy period. I was bleeding like I never knew possible."[120] She goes on to say that "…the cramps were not just severe --- I thought I was dying because they were so intense. I was crying hysterically and begging to die because the pain was more than I could handle. I was sweating like crazy and on the toilet while throwing up too."[121] She "was alone, and afraid" and too ashamed to share with anyone what was truly causing her physical and emotional pain.[122]

Leslie also experienced severe hemorrhaging. She states: "I bled so much that it clogged the drain...It was my baby that was clogging the drain of the shower. I had to turn off the water, get out, and clean it up myself and then I flushed it down the toilet. It was even more horrifying than it sounds."[123]

In addition, Leslie experienced trigger problems associated with the RU-486 regimen. She attests: "This was all done in my own home, in the family bathroom, the family shower, the home where I had to live after this experience. The emotional pain this caused made it almost unbearable to be at home after that. I hated showering and I hated sleeping in my bed, I hated being around my family, I didn't want to be there anymore and tried my best to avoid being home."[124]

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[120] *Id*. at ¶ 8.
[121] *Id*.
[122] *Id*. at ¶ 9.
[123] Id. at ¶¶ 11-12.
[124] *Id*. at ¶¶ 13-14.

Leslie's experience is not unusual.[125] Amici Tammi Morris had a similar experience.[126] She was not given truthful and accurate information about chemical abortion, and specifically, about what she would experience.[127] Although the clinic said that she would expel "tissue," she was devastated to see it was a baby, her baby.[128] Seeing her baby sent her "over the emotional edge. Everything got worse for me. Drinking heavily, hiding, anger, depression, and suicidal thoughts. I eventually filed for divorce from my husband. It also affected my relationship with my son and daughter."[129]

Amici Carol Everett says that since 2000 she has counselled women who have taken RU-486.[130] She attests that they have more physical and psychological problems than women who have surgical abortions.[131] They have more severe physical issues including "severe hemorrhaging and pain from RU-486."[132] "In addition, some of the most severe post-abortion syndrome occurs because the women actually see the baby is being expelled."[133]

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[125] For example, *see* Affidavit of Tammi Morris, attached as Appendix B; Affidavit of Carol Everett, attached as Appendix C.
[126] Affidavit of Tammi Morris, attached as Appendix B.
[127] *Id*. at ¶3.
[128] *Id*. at ¶¶ 3, 17.
[129] *Id*. at ¶ 20.
[130] Affidavit of Carol Everett, Appendix C, ¶ 19.
[131] *Id*.
[132] *Id*.
[133] *Id*. at ¶ 21.

One woman who was certainly hurt by RU-486 was Holly Patterson who was the first woman in the United States to die of the drug regimen. Planned Parenthood had given Holly the unapproved, off-label RU-486 chemical abortion regimen.[134] Holly tragically died from an infection known as Clostridium sordellii toxic shock syndrome that was associated with a chemical abortion.[135] Holly had not been given accurate and truthful information concerning the RU-486 regimen so that she could make an informed decision.[136] Mr. Patterson, Holly's father, attests that "This has been such a painful experience for our family. I do not want to see any other family go through what we have."[137] He states "This was the worst day of my life" as he watched his daughter die.[138] Chemical abortion not only hurts women, it hurts families.

The women Amici attest to the harm of chemical abortion. But the harm is magnified by the fact that chemical abortions are rising by large numbers. The Guttmacher Institute reports that the number of abortions is on the rise, and specifically, in 2020 "Medication abortion accounted for 53% of all abortions,

[134] Affidavit of Monty Patterson, attached as Appendix D, ¶ 2.
[135] *Id*.
[136] *Id*. at ¶ 35.
[137] *Id*. at ¶ 3,
[138] *Id*. at ¶ 13.

compared with 39% in 2017."[139] This number is even greater in 2023.[140] Therefore, the FDA's failing its responsibilities and having willful blindness to the scientific studies demonstrating the physical and psychological harm of Mifepristone is creating undue harm to women and their families.

CONCLUSION

The data, scientific studies, and personal testimony of women all attest that chemical abortion has serious negative physical and psychological consequences. This court correctly stated that the FDA "ostrich's-head-in-the-sand approach is deeply troubling." Therefore, Amici urge this court to find for the Plaintiffs-Appellants and uphold Louisiana's ban on Mifepristone by mail.

Respectfully submitted,

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[139] Guttmacher Institute, *Guttmacher Institute Releases 2020 Abortion Provider Census with Important Data on US Abortion Landscape Before the Fall of Roe* (Dec. 1, 2022), *available at* https://www.guttmacher.org/news-release/2022/guttmacher-institute-releases-2020-abortion-provider-census-important-data-us.

[140] Guttmacher Institute, *Number of Abortions in the United States Likely to Be Higher in 2023 than in 2020* (Jan. 17, 2024), *available at* https://www.guttmacher.org/news-release/2024/number-abortions-united-states-likely-be-higher-2023-2020.

CERTIFICATE OF SERVICE

I hereby certify that on the 18th day of June, 2026, I filed a true and accurate copy of the foregoing document with the Clerk of Court using the CM/ECF system, which automatically sends an electronic notification to all attorneys of record.

Respectfully submitted on the 18th day of June, 2026.

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CERIFICATE OFCOMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P 32(a)(7)(B) because it contains 6,487 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(1).

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Dated: June 18, 2026

APPENDICES