No. 23-235 & 23-236 VIDED

In The Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,

Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

DANCO LABORATORIES, L.L.C.,

Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

On Writs Of Certiorari To The Court Of Appeals For The Fifth Circuit

BRIEF OF WOMEN AND FAMILIES HARMED BY MIFEPRISTONE AND FORMER ABORTION PROVIDERS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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The Amici respectfully submit this amicus curiae brief in support of Respondents. This brief supporting Respondent was prepared by counsel for Amici.[1]

STATEMENT OF INTEREST OF THE AMICI CURIAE

The women Amici who have taken RU-486,[2] their families, and former abortion providers have personal knowledge as to how RU-486 negatively affects women both physically and psychologically. The women Amici attest that they were not given accurate and truthful information about the risks of RU-486. Their interest is that other women are not misled as they were and to spare other women and families the grief and pain associated with RU-486. The Amici are Carol Everett (Texas) who had an abortion and was also an abortion provider; Tammi Morris (Pennsylvania) who took RU-486; Monty Patterson, whose daughter Holly Patterson (California) died after taking RU-486; and, Leslie

[1] 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. Mifepristone is the one abortion drug; RU-486 is the two-drug abortion regimen; and, chemical abortion is used in contrast to surgical abortion.

Wolbert (New York) who took RU-486. They urge this Court to affirm the Court of Appeals for the Fifth Circuit decision.

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 this Court's requirements, women were not given accurate and truthful information to make an informed decision. Therefore, Amici urge this Court to protect women and affirm the Court of Appeals' decision.

II.

The RU-486 regimen used in 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 as a result of taking RU-486. Therefore, the lower court's decision should be upheld.

ARGUMENT

I. THE FDA FAILED IN ITS RESPONSIBILITY TO ENSURE MIFREPRISTONE WAS SAFE, AND THEREFORE, ITS ACTION 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 for Mifepristone and not reviewing the studies that demonstrate it is a dangerous drug that can cause serious physical and psychological harm including death. Had the FDA given "accurate, science-based health information to the public" as it was required to do, it would not have reduced the standards and would have provided better warnings.

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[3] 21 U.S.C. § 393(b)(1).

[4] *Id*. § 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).

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

The FDA's actions are held to an arbitrary and capricious standard.[6] The Court of Appeals for the Fifth Circuit determined that the FDA failed to carry its burden that the FDA's actions were not arbitrary and capricious.[7] The 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, and therefore, concluded that Mifepristone was safe.[13] The court of appeals correctly concluded that this "ostrich's-head-in-the-sand approach is deeply troubling"

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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*.

particularly considering FDA's own documents.[14] This makes the FDA's actions arbitrary and capricious.

Over the years, there have been many studies showing the dangers and psychological risks of Mifepristone and chemical abortions.[15] But women did not feel that they had been given adequate information.[16]

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[14] *Id*.

[15] *See, e.g.,* Rafferty, K. A., & Longbons, T., *#AbortionChanges You: 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 1288-1295 (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)

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

However, it was equally egregious because of the subsequent effect that its failures had. This had a trickle-down negative effect because doctors did not provide women with important information concerning the risks of Mifepristone. Thereby, women did not have the necessary information to make an informed decision. This Court has correctly required informed

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(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 1512–1520 (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 BRITISH J. OBSTETRICS AND GYNECOLOGY 1288-1295 (1998) (stating 47% of women who had a chemical abortion would not choose the same procedure again).

consent before an abortion. The Amici have indicated 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 of RU-486.

As early as 2006 the FDA knew there were serious complications with Mifepristone. The Congressional Staff Report for the House Subcommittee on Criminal Justice, Drug Policy and Human Resources[19] reviewed what the FDA knew about 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]

The FDA knew the RU-486 regimen posed a substantial risk to the physical health of women including

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[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.

[20] *Id*. at 30.

[21] *Id*. at 31.

the risk of death. 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 pain; uterine cramping; nausea; headache; vomiting;

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[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.

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]

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[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 related to the use of RU-486, including hemorrhaging, blood loss requiring transfusions, serious infections, and death.[37] Among the 2,207 adverse events were 14

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[32] *Id*. at 31.

[33] *Id*.

[34] *Id*.

[35] *Id*.

[36] Food and Drug Administration, *Mifepristone U.S. Post-marketing Adverse Events Summary Through 04/30/2011* (July 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf.

[37] *Id*.

deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").[38]

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 of RU-486

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."[39] Twenty-eight states have enacted such laws.[40]

The states' Departments of Health were responsible for "A Woman's Right to Know" booklet which was based on the medical board's scientific medical

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[38] *Id*.

[39] 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).

[40] *Id*. (providing a chart of state laws).

evidence concerning RU-486.[41] The booklets provided pictures of the baby at two-week internals and discussed the physical and psychological risks of surgical and chemical abortion as compared to child birth.[42]

For example, the Texas Department of State Health Services (DSHS) produced "A Woman's Right to Know" booklet which discusses the risks associated with chemical abortions.[43] Some of these risks include: nausea, weakness, fever/chills, vomiting, headache, diarrhea or dizziness.[44] There can be excessive bleeding and hemorrhaging requiring blood transfusions or surgery.[45] Severe infection is also a known risk following a chemical abortion and can cause death.[46] Three percent of chemical abortions fail and require surgery.[47] About five of every 100 procedures results in a woman going to the emergency room for care and treatment.[48]

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[41] For example, the Texas medical board held hearings and obtained evidence on the risks of abortion.

[42] Texas Department of State Health Services (DSHS), A Woman's Right to Know Booklet (2016), *available at* https://www.hhs.texas.gov/sites/default/files/documents/services/health/women-children/womans-right-to-know.pdf.

[43] *Id*.

[44] *Id*. at 16.

[45] *Id*.

[46] *Id*.

[47] *Id*.

[48] *Id*.

The risks associated with Mifepristone is greater than that of surgical abortions.[49]

In the largest government study since *Roe*, the South Dakota Task Force held extensive hearings and heard from medical and scientific experts and post-abortive women.[50] The Task Force articulated a long list of physical risks.[51] These risks were both short-term and long-term.[52]

The Task Force also heard extensive evidence from distinguished experts and post-abortive women of the psychological consequences of abortion.[53] The Task Force found that "there is a substantial discrepancy between current medical and psychological information and the medical and psychological information conveyed by abortion facilities (including Planned

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[49] *See* Shuping, Harrison, & Gacek, *Medical Abortion with Mifepristone (RU-486): Compared to Surgical Abortion* (2007), *available at* https://www.lifeissues.net/writers/shu/shu_06mifepristone_ru486.html.

[50] Report of the South Dakota Task Force to Study Abortion (Dec. 2005), *available at* http://www.dakotavoice.com/Docs/South%20Dakota%20Abortion%20Task%20Force%20Report.pdf.

[51] *Id*. at 48.

[52] *Id*. (finding long-term risks include placenta previa, higher rates of complications, and pre-term birth in subsequent pregnancies).

[53] Report of the South Dakota Task Force to Study Abortion 41-48 (Dec. 2005), *available at* http://www.dakotavoice.com/Docs/South%20Dakota%20Abortion%20Task%20Force%20Report.pdf.

Parenthood of South Dakota) to their abortion patients."[54]

Citing the results of the four largest record-based studies in the world, the Task Force stated that these studies "have consistently revealed that women with a known history of abortion experience higher rates of mental health problems of various forms when compared to women without a known abortion history." The mental health consequences of abortion have included guilt, post-abortion anger and resentment, anxiety, posttraumatic stress disorder (PTSD), psychological numbing, depression, suicidal ideation, substance abuse, relationship problems, and parenting problems.[55] Although the Task Force was focused on abortion in general, it is known that the psychological problems are magnified with chemical abortion.[56]

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 This Court.

In *Planned Parenthood v. Casey*,[57] this Court emphasized the need for full, accurate, and truthful

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[54] *Id*. at 41.

[55] *Id*. at 43-46 (*citing* studies).

[56] Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013).

[57] Planned Parenthood v. Casey, 505 U.S. 833 (1992), *overruled on other grounds*, Dobbs v. Jackson Women's Health Organization, ___ U.S. ___, 142 S. Ct. 2228 (2022).

information so that a woman can make an informed decision.[58] This 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.[59] The FDA's failures thus have a profound and devastating impact on women.

When the FDA argues that "Mifepristone is comparable to 'ibuprofen,' "[60] it is false and misleading. The Court of Appeals for the Fifth Circuit correctly determined that "Mifepristone bears no resemblance to ibuprofen."[61] In coming to this conclusion, the Court of Appeals reviewed FDA's own documents and the "Black Box" warnings which is used when the drug "may lead to death or serious injury."[62]

Abortion statistics also emphasize the need for accurate and truthful information because of the increased use of Mifepristone and more women are at risk. Eighteen percent of pregnancies in 2017 ended in abortion which was approximately 862,320 abortions.[63] Chemical abortions accounted for 39% of all abortions

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[58] *Id*. at 882.

[59] *Id*.

[60] Alliance for Hippocratic Medicine v. FDA, ___ F.3d ___, 2023 U.S. App. LEXIS 8898 at *27 (5th Cir. 2023).

[61] *Id*.

[62] *Id*.

[63] 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.

in 2017 which was an increase from 29% in 2014.[64] Thus, even though the number of abortions decreased, chemical abortions increased from 5% of all abortions in 2001 to 39% in 2017.[65] 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."[66] 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."[67] Because informed consent is "fundamental," a woman needs accurate information at this critical time in her life.

Similarly from a legal perspective, one court opined that women should be given factual information about the physical and psychological risks of the RU-486 regimen.[68] The court stated that the

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[64] *Id*.

[65] *Id*.

[66] 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.

[67] *Id*.

[68] Planned Parenthood of Indiana, Inc. v. Commissioner, 794 F. Supp. 2d 892, 918 (S.D. Ind. 2011).

purpose of informed consent provisions is 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."[69] Therefore, women should know they are exposed to increased risks of physical and psychological complications by taking the RU-486 regimen.[70]

Although this is "fundamental," Amici contend and have experienced the fact that women are not given accurate information.[71] 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."[72] 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.[73]

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[69] *Id*.

[70] 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).

[71] *See* Affidavit of Leslie Wolbert, Appendix A; Affidavit of Tammi Morris, Appendix B; and Affidavit of Monty Patterson, Appendix D.

[72] Affidavit of Leslie Wolbert, Appendix A, ¶ 22.

[73] *Id*.

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 little more than a menstrual cycle. They did not prepare me for what was to come."[74] She states: "This was unexpected because the clinic only told me the benefits and not the risks."[75] She said that seeing her dead baby that she had expelled was devastating.[76]

Amici Carol Everett was both a consumer and a provider.[77] At one time, she was involved in the operation of four clinics with a fifth scheduled to open and oversaw 35,000 abortions.[78] She was Dallas' largest abortion chain owner.[79] She attests that abortion facilities lie to women about the physical and psychological risks and what will actually occur when they take the drug.[80] 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."[81] This is what causes such psychological trauma because she sees it is a baby that she has expelled in the toilet or shower.[82]

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[74] Affidavit of Tammi Morris, Appendix B, ¶ 3.

[75] *Id.* at ¶ 4.

[76] *Id*. at ¶¶ 17, 21.

[77] Affidavit of Carol Everett, Appendix C, ¶ 2.

[78] *Id*.

[79] *Id*.

[80] *Id*. at ¶ 22.

[81] *Id*. at ¶ 20.

[82] *Id*. at ¶ 21.

In the case of Holly Patterson, her father describes the "pain experience" for their family after Holly took RU-486.[83] He states that "Women need to have accurate and factual information regarding the potential risks of severe and life threatening side-effects."[84] Holly was not given that information.[85] 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."[86]

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

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[83] Affidavit of Monty Patterson, Appendix D, ¶ 3.

[84] *Id*.

[85] *Id*.

[86] *Id*. ¶ 74.

increased risks of physical problems with the RU-486 regimen.[87] 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.[88] 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."[89]

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.[90]

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

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[87] Shuping, Harrison, & Gacek, *Medical Abortion with Mifepristone (RU-486) Compared to Surgical Abortion*, *available at* http://rachelnetwork.org/images/Medical_Abortion_with_Mifepristone.pdf.

[88] *Id*.

[89] *Id*. (citations omitted).

[90] The Silent Scream, *Former Abortionist Bernard Nathanson, M.D. Warns of RU-486 Dangers*, *available at* http://www.silentscream.org/ru486-drnat.htm.

drug.[91] "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."[92]

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 more disruptions in their lives.[93] They also experienced a significant decline in self-esteem and higher PTSD intrusion scores.[94]

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.[95] First, the woman has a participatory role with a chemical abortion which may cause greater psychological trauma.[96] This is because the woman is directly responsible for the abortion which may exacerbate guilt and other negative feelings.[97]

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[91] *Id*.

[92] *Id*.

[93] Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013) (*citing* scientific studies).

[94] *Id*.

[95] *Id*.

[96] *Id*.

[97] *Id*.

The RU-486 regimen is a very difficult process and simply adds to emotional consequences. Unlike surgical abortion, the woman acts as the abortionist.[98] 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.[99] 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.[100] Here is one of the profound differences between 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."[101]

Second, chemical abortion requires the woman to be more alert and involved during the process.[102]

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[98] 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).

[99] *Id*.

[100] *Id*.

[101] *Id*.

[102] Affidavit of Dr. Priscilla Coleman on file with Trinity Legal Center (2013).

Therefore, it is impossible for her to distance herself psychologically from the abortion.[103]

Third, there is a greater potential for the woman to see her expelled unborn child.[104] 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.[105] 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.[106]

Fifth, the woman's home becomes a trigger point for negative emotions instead of being a place of refuge.[107] 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, 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

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[103] *Id.*

[104] *Id.*

[105] *Id.*

[106] *Id.*

[107] *Id.*

experience[108] 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. . . ."[109] These coping mechanisms allow her to distance herself from "the painful reality of what she has done."[110] 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."[111]

The courts also have recognized the negative psychological impact that abortion has on women. For example, the Court of Appeals for the Fifth Circuit cited testimony that abortion as practiced is "almost always a negative experience for the patient. . . ."[112] This 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

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[108] 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).

[109] *Id*.

[110] *Id*.

[111] *Id*.

[112] Women's Medical Center v. Bell, 248 F.3d 411, 418 (5th Cir. 2001).

> 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.[113]

More recently, this Court recognized, "whether to have an abortion requires a difficult and painful moral decision" and is "fraught with emotional consequences."[114] In addition, women can suffer from depression, regret, guilt, and a loss of self-esteem following an abortion.[115] As Justice Ginsburg wrote, "The Court is surely correct that, for most women, abortion is a painfully difficult decision."[116]

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

The courts and the scientific research support the conclusion that there are negative physical and psychological consequences of abortion on women and particularly the RU-486 regimen. But it is the real life

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[113] Planned Parenthood v. Casey, 505 U.S. 833, 852 (1991), *overruled on other grounds*, Dobbs v. Jackson Women's Health Organization, ___ U.S. ___, 142 S. Ct. 2228 (2022).

[114] Gonzales v. Carhart, 550 U.S. 124, 159 (2007).

[115] *Id*.

[116] *Id*. at 184 n.7 (Ginsburg, J., dissenting).

experiences of women that bring to light the true impact of this dangerous drug regimen.[117]

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.[118] 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.[119] On Day 3, she is supposed to return to the abortion facility and be examined to determine if she is still pregnant.[120] If she is pregnant, she is given two tablets of

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

[118] 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).

[119] 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).

[120] 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.

misoprostol.[121] 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.[122] On Day 14, she is supposed to return to the abortion facility for a follow-up visit to confirm the pregnancy has been terminated and assess the level of bleeding.[123] 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."[124] She "trusted the

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[121] *Id*.

[122] Affidavit of Tammi Morris, attached as App. 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 Abortion Federation, *Facts About Mifepristone (RU-486), available at* http://www.prochoice.org/about_abortion/facts/facts_mifepristone.html.

[123] 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.

[124] Affidavit of Leslie Wolbert, attached as App. A, ¶ 2.

clinic."[125] They referred to the baby as "just a blob of tissue."[126] 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."[127]

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 ever felt in my life. The experience wasn't just a heavy period. I was bleeding like I never knew possible."[128] 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."[129] She "was alone, and afraid" and too ashamed to share with anyone what was truly causing her physical and emotional pain.[130]

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

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[125] *Id*. at ¶ 4.

[126] *Id*. at 11.

[127] *Id*. at ¶ 4.

[128] *Id*. at ¶ 8.

[129] *Id*.

[130] *Id*. at ¶ 9.

myself and then I flushed it down the toilet. It was even more horrifying than it sounds."[131]

In addition, Leslie experienced the 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."[132]

Leslie's experience is not unusual.[133] Amici Tammi Morris had a similar experience.[134] She was not given truthful and accurate information about chemical abortion, and specifically, about what she would experience.[135] Although the clinic said that she would expel "tissue," she was devastated to see it was a baby, her baby.[136] 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."[137]

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[131] *Id.* at ¶¶ 11-12.

[132] *Id*. at ¶¶ 13-14.

[133] For example, *see* Affidavit of Tammi Morris, attached as App. B; Affidavit of Carol Everett, attached as App. C.

[134] Affidavit of Tammi Morris, attached as App. B.

[135] *Id*. at ¶3.

[136] *Id*. at ¶¶ 3, 17.

[137] *Id*. at ¶ 20.

Amici Carol Everett says that since 2000 she has counselled women who have taken RU-486.[138] She attests that they have more physical and psychological problems than women who have surgical abortions.[139] They have more severe physical issues including "severe hemorrhaging and pain from RU-486."[140] "In addition, some of the most severe post-abortion syndrome occurs because the women actually see the baby is being expelled."[141]

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.[142] Holly tragically died from an infection known as Clostridium sordellii toxic shock syndrome that was associated with a chemical abortion.[143] Holly had not been given accurate and truthful information concerning the RU-486 regimen so that she could make an informed decision.[144] 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."[145] He states "This was the worst day of my life" as he

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[138] Affidavit of Carol Everett, Appendix C, ¶ 19.

[139] *Id*.

[140] *Id*.

[141] *Id*. at ¶ 21.

[142] Affidavit of Monty Patterson, attached as App. D, ¶ 2.

[143] *Id*.

[144] *Id*. at ¶ 35.

[145] *Id*. at ¶ 3.

watched his daughter die.[146] 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, compared with 39% in 2017."[147] This number is even greater in 2023.[148] 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

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[146] *Id*. at ¶ 13.

[147] 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.

[148] 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.

serious negative physical and psychological consequences. Therefore, the FDA's willful blindness in not reviewing and evaluating the data and studies which it knew from its own information caused it to fail its responsibilities and act in an arbitrary and capricious manner. Women deserve truthful and accurate information to make an informed decision.

Mifepristone and the RU-486 regimen creates greater risks of both physical and psychological harm to women than surgical abortion. Thus, the FDA should have protected women by fulfilling its responsibilities concerning this dangerous drug which has severe risks including death. The FDA's willful blindness has caused women sorrow, grief, and regret because they did not have the needed information. It has also caused families great pain and sorrow. Thus, Amici urge this Court to affirm the court of appeal's decision.

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