

A WOMAN’S RIGHT TO CHANGE HER MIND: THE ABORTION PILL REVERSAL DEBATE

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INTRODUCTION

Across the United States, second chances are celebrated and provide opportunities for people to change their minds and choose a different path. Organizations such as prison reform initiatives and rehabilitation centers are founded on the idea of second chances, helping individuals get their lives back on track.¹ People often decide they are ready

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1. See, e.g., SECOND CHANCE, INC., <https://www.asecondchance-kinship.com/> [<https://perma.cc/4QB5-QX2s>] (last visited Nov. 2, 2024); SECOND CHANCE BUS. COAL., <https://>

to change their minds and start a different career. Is a change of mind or a second chance always something to be encouraged? What if a woman changed her mind about her abortion? Should state laws allow for such a change or discourage it?

The abortion pill protocol involves taking one pill to block progesterone in an ongoing pregnancy.² Twenty-four to seventy-two hours later, a second pill is taken to initiate contractions, leading to the expulsion of the uterine contents, specifically, the fetus.³ “Ryah” started the abortion pill protocol after finding out that she was seven weeks pregnant.⁴ At the clinic, the abortion provider urged Ryah to make sure she took the second pill, cautioning that not taking the second pill could lead to an incomplete abortion.⁵ The provider further explained that leaving products of conception in the uterus could lead to bleeding, infection, and even death.⁶ Two weeks later, Ryah took a pregnancy test and it still showed positive.⁷ She regretted her decision and prayed that her pregnancy had somehow continued.⁸ She requested a follow-up visit with her abortion provider, hoping they would do another ultrasound to see if somehow the fetus survived.⁹ The provider informed her that no follow-up care was necessary and advised her to go to the emergency room if she experienced bleeding, cramping, or fever.¹⁰ Unsatisfied, she searched on the internet for any other options and was connected to Nurse Diandra at a local pregnancy resource center.¹¹ Nurse Diandra listened to her story and helped her with resources to deal with the mental and emotional stress that she was experiencing.¹² Nurse Diandra also connected her with an obstetrician-gynecologist

secondchancebusinesscoalition.org/ [https://perma.cc/5WLL-HJ97] (last visited Nov. 2, 2024); SALVATION ARMY, <https://www.salvationarmyusa.org/usn/rehabilitation/> [https://perma.cc/G7GL-F44X] (last visited Nov. 2, 2024).

2. *The Abortion Pill*, PLANNED PARENTHOOD, <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill> [https://perma.cc/lastPH9V-EVAK] (last visited Aug. 15, 2024).

3. *Id.*

4. Interview with Diandra Bell, BSN, RN, Nurse Manager, Portico Pregnancy Resource Center, in Murfreesboro, Tenn. (November 17, 2023) (Patient names are fictitious to protect the privacy of the individuals).

5. *Id.*

6. *Id.*

7. *Id.*; Attia, *What Are the Signs of Pregnancy After You’ve Had an Abortion?*, PLANNED PARENTHOOD (April 24, 2024), <https://www.plannedparenthood.org/blog/what-are-the-signs-of-pregnancy-after-youve-had-an-abortion#:~:text=Regular%20pregnancy%20tests%20that%20you%20get%20at%20the,your%20body%20that%20the%20test%20can%20pick%20up> [https://perma.cc/Q73F-LCDQ] (explaining that it is not uncommon for a woman to show a positive pregnancy test for up to five weeks after an abortion or miscarriage).

8. Interview with Diandra Bell, *supra* note 4.

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

(OBGYN) to provide an examination.¹³ To her disappointment, the abortion was completed.¹⁴

Similarly, “Celeste” went to a pregnancy resource center for a limited ultrasound to confirm her pregnancy.¹⁵ She was about six weeks along and decided an abortion was her best option.¹⁶ Like Ryah, Celeste started the abortion pill protocol.¹⁷ After taking the first pill, she realized she made a mistake and changed her mind.¹⁸ She went back to the pregnancy resource center to see if there was anything that could be done to save the pregnancy.¹⁹ The center connected her with the Abortion Pill Rescue Network and an OBGYN who had experience prescribing a hormone supplement of progesterone to reverse the effects of the first abortion pill.²⁰ After a phone consultation, the OBGYN immediately prescribed progesterone.²¹ Two hours later, Nurse Diandra performed an ultrasound that confirmed the fetus still had a heartbeat.²² Follow-up ultrasounds continued through the first trimester to monitor the fetus’s continued development.²³ Celeste’s care was transferred to her regular OBGYN, and six months later, Celeste gave birth to a healthy baby.²⁴

Studies vary on the number of women who experience negative feelings or regret after their abortion.²⁵ One study shows as few as twenty-nine percent of women experience negative feelings after their abortion, with around five percent experiencing regret five years later.²⁶ Some critics suggest that this study may be misleading, as sixty-eight percent of women approached to be part of the study refused and many who participated dropped out, leaving only about seventeen percent of those approached to complete the study.²⁷ Critics suggest negative feelings and regret may be higher in those who did not want to participate in the study.²⁸ Another study found that abortion increased a woman’s risk of mental health problems by

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Infra* note 26, 29.

26. Corinne H. Rocca et al., *Emotions and decision rightness over five years following an abortion: An examination of decision difficulty and abortion stigma*, 248 SOC. SCI., & MED. 112704 (2019).

27. David C. Reardon, *The Embrace of the Proabortion Turnaway Study: Wishful Thinking? Or Willful Deceptions?*, 85 THE LINACRE Q. 204–12 (2018).

28. *Id.*

eighty-one percent.²⁹ Likewise, this study is not without its critics suggesting bias.³⁰ While these statistics vary greatly, even with the lowest estimate of women regretting their abortion at around five percent, should those five percent be afforded the opportunity of a second chance if it is possible and safe?

What if Ryah had been informed of a possible reversal? What if she could have had a second chance? If she wanted to make a different decision and the possibility was available to her, should she have had the right to try, and should her informed consent of the abortion have included information about a chance at reversal?

The abortion pill reversal protocol is a progesterone supplement prescribed to attempt to counteract the effects of the medication abortion regimen after a woman has taken the first pill.³¹ This reversal method is relatively new, having first emerged after medication abortion became a more common procedure.³² Having been first introduced in 2007, limited case studies have been conducted so far on the protocol's efficacy.³³ While the number of women desiring abortion pill reversal is low, controversy is stirring over the safety and ethics of allowing women to attempt to save their pregnancies once an abortion protocol has commenced.³⁴

States are just starting to address the issue of abortion pill reversal.³⁵ At least two states have passed legislation prohibiting doctors from discussing abortion pill reversal with their patients.³⁶ The legal landscape of the abortion pill reversal, much like the legal landscape of the state of abortion regulation itself, is just beginning to take shape.³⁷ By requiring information about abortion reversal, are states championing a

29. Priscilla K. Coleman, *Abortion and mental health: quantitative synthesis and analysis of research published 1995-2009*, 199 BRITISH J. OF PSYC. 180–86 (2011).

30. Rocca et al., *supra* note 26.

31. *Abortion Pill Reversal Overview*, ABORTION PILL RESCUE NETWORK, <https://abortionpillreversal.com/abortion-pill-reversal/overview> [<https://perma.cc/V7EP-J9FY>] (last visited Jan. 9, 2024).

32. *Infra* note 33.

33. George Delgado & Mary L. Davenport, Progesterone use to reverse the effects of mifepristone, 46 ANNALS OF PHARMACOTHERAPY 1723–23 (2012); George Delgado, et al., A case series detailing the successful reversal of the effects of mifepristone using progesterone, 33 ISSUES L. & MED. 21–31 (2018); Mitchell D. Creinin, et al., Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial, 135 OBSTETRICS & GYNECOLOGY 158–65 (2020).

34. Ruth Graham, *A New Front in the War Over Reproductive Rights: 'Abortion Pill Reversal'*, NEW YORK TIMES (July 18, 2017), <https://www.nytimes.com/2017/07/18/magazine/a-new-front-in-the-war-over-reproductive-rights-abortion-pill-reversal.html> [<https://perma.cc/CN75-8YEU>] (last visited Aug. 1, 2024).

35. *Infra* note 36.

36. See VT. STAT. ANN. tit. 3, § 129a (2023); COLO. REV. STAT. § 12-30-120 (2023).

37. Rahima Nasa, *As "Abortion Reversal" Laws Spread, Doctors and Scientists Are Pushing Back*, PBS (Aug. 27, 2019), <https://www.pbs.org/wgbh/frontline/article/as-abortion-reversal-laws-spread-doctors-and-scientists-are-pushing-back/> [<https://perma.cc/PCX6-8FKS>] (last visited Jan 15, 2024).

woman's right to be fully informed about her health choices, or are states prohibiting such information to protect women from an unproven medical treatment?

This note will argue that if a woman has the legal right to choose abortion, she also should have the legal right to try the abortion pill reversal method if she changes her mind and wishes to save her pregnancy. Part I will provide an overview of the background of medication abortion and abortion reversal, highlighting progesterone as the key hormone in both processes.³⁸ Mifepristone, a progesterone inhibitor, is the first of the two-pill regimen in a medication abortion, followed by misoprostol, which causes the uterus to contract and the fetus to be expelled.³⁹ The abortion pill reversal is the product of a physician's reasoning that if the abortion pill inhibits progesterone, a supplement of progesterone may serve to counter the effects.⁴⁰ Part II will examine the current legal landscape of abortion pill reversal laws across the nation. While some states require a woman getting an abortion to be informed of the possibility of a reversal, some courts have blocked these laws from taking effect.⁴¹ Further, some states are prohibiting abortion pill reversal altogether.⁴² Current laws regarding off-label treatment use and "Right to Try" protections offer insight surrounding possible regulations of abortion pill reversal. A survey of arguments for and against abortion pill reversal also helps to round out the issue.⁴³ Finally, Part III will assert that women should be allowed to attempt to save their pregnancies if they so desire. Progesterone has been safely used in pregnant women for decades and no other alternative currently exists for a patient who does change her mind.⁴⁴ Further, states should require medical

38. Leigh Ann Scott, *Progesterone Benefits*, FORUM HEALTH (2023), <https://www.forumhealthlascolinas.com/progesterone-benefits/> [<https://perma.cc/PPB7-TRKJ>] (last visited Jan 9, 2024); *infra* note 43.

39. *The Facts on Mifepristone*, PLANNED PARENTHOOD (hereinafter *Mifepristone*), https://www.plannedparenthood.org/uploads/filer_public/42/8a/428ab2ad-3798-4e3d-8a9f-213203f0af65/191011-the-facts-on-mifepristone-d01.pdf [<https://perma.cc/2N6H-PWXP>] (last accessed Jan. 15, 2024).

40. Delgado & Davenport, *supra* note 33.

41. Ruth Graham, *supra* note 34.

42. *Id.*

43. *Compare Facts Are Important: Medication Abortion "Reversal" Is Not Supported by Science*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, <https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science> [<https://perma.cc/8EEG-8Z7X>] (last visited Jan. 17, 2024), with *Responding to ACOG's Unscientific Statement on Progesterone Rescue Therapy after Mifepristone Ingestions*, AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS [hereinafter *Responding to ACOG*], <https://aaplog.org/responding-to-acogs-unscientific-statement-on-progesterone-rescue-therapy-after-mifepristone-ingestion/> [<https://perma.cc/R8SJ-78E9>] (last visited July 31, 2023), and *Mythbusters – Abortion Pill Reversal*, AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS [hereinafter *Mythbusters*], <https://aaplog.org/abortion-pill-reversal/> [<https://perma.cc/WN4F-78RK>] (last visited May 5, 2024).

44. See generally Simak Ali et al., *90 years of progesterone: Ninety Years of progesterone: The 'other' ovarian hormone*, 65 J. MOLECULAR ENDOCRINOLOGY E1–E4

professionals providing abortions to counsel women on all the options available to them, including abortion pill reversal as part of informed consent. Providing such information is both a matter of professional responsibility for medical professionals and a state's interest in ensuring patients are fully informed of all potential outcomes.

I. A BRIEF HISTORY OF THE ABORTION PILLS AND PROGESTERONE

Medication abortion, particularly the so-called “abortion pill,” revolves around a main player: progesterone. Progesterone and estrogen were discovered as the two main hormones necessary in the female reproductive system.⁴⁵ Progesterone was discovered in 1923 but was not isolated and formally named until around ten years later.⁴⁶ Progesterone benefits the female body in many ways, including regulating menstrual cycles, aiding thyroid function, supporting memory, and promoting bone growth.⁴⁷ For purposes of the abortion procedure and its reversal, however, progesterone’s most important function is sustaining pregnancy.⁴⁸ Without progesterone, a uterus is uninhabitable for an embryo or fetus.⁴⁹

Synthetic progestins were first developed in the 1950s through research into medication birth control.⁵⁰ In 1957, the United States Food and Drug Administration (FDA) approved the first hormonal pill utilizing synthetic progesterone and estrogen to regulate menstrual cycles.⁵¹ By 1960, the FDA approved the first oral contraceptive, Enovid.⁵² Further research into synthetic progestins found applications in hormone replacement therapy, the treatment of endometriosis, and treatment of ovarian cysts.⁵³ In 1998, the FDA approved Prometrium, a progestogen that

(2020); Dan Farine, et al., *The Use of Progesterone for Prevention of Preterm Birth*, 30 J. OBSTETRICS & GYNAECOLOGY CANADA 67–77 (2008); Sam A Mesiano, et al., *Progestin Therapy to Prevent Preterm Birth: History and Effectiveness of Current Strategies and Development of Novel Approaches*, 79 PLACENTA 46–52 (2019).

45. Ali et al., *supra* note 44.

46. Ali et al., *supra* note 44; Mesiano et al., *supra* note 44.

47. Scott, *supra* note 38.

48. *See id.*

49. *Id.*

50. *The Birth Control Pill: A History*, PLANNED PARENTHOOD (2015) (hereinafter *Birth Control History*), https://www.plannedparenthood.org/files/1514/3518/7100/Pill_History_FactSheet.pdf [<https://perma.cc/A9QU-FDAP>] (last visited Jan. 9, 2024)

(It is helpful to note that progesterone is the naturally occurring hormone made by the human body. Progestins are synthetic forms of progesterone and progestogens describe any substance natural or synthetic that creates the effects of progesterone.); *see* Ali et al., *supra* note 44.

51. *Birth Control History*, *supra* note 50.

52. *Id.*

53. Michael Edwards & Ahmet S. Can, *Progestin - StatPearls - NCBI BOOKSHELF NAT'L CTR. FOR BIOTECHNOLOGY INFO.* (2023), <https://www.ncbi.nlm.nih.gov/books/NBK563211/> [<https://perma.cc/7L6A-6V3D>] (last visited Jan. 9, 2024).

is bio-identical in molecular structure to the progesterone that is produced naturally in the female body.⁵⁴ Emerging research also indicates potential applications in breast cancer research.⁵⁵ While the original label contraindicated the drug during pregnancy, later studies revealed no evidence of any harm to a fetus or any long-term risks while using Prometrium or progesterone during pregnancy.⁵⁶ In fact, progestogens are utilized to support reproductive capacities for women who are pregnant or trying to become pregnant, for instance during in-vitro fertilization, miscarriage prevention, and the prevention of preterm labor by delaying the ripening of the cervix.⁵⁷

A. History of the Abortion Pill

Before the abortion pill reversal procedure can be understood, a knowledge of the history and process of medication abortion is helpful. A chemical abortion, also known as a medication abortion, is a two-step process involving two medications: the most common being mifepristone and misoprostol.⁵⁸ The first, mifepristone, blocks progesterone while the second, misoprostol induces uterine contractions.⁵⁹ The regimen has been FDA-approved to end a pregnancy within seventy days of the first day of a woman's last menstrual period.⁶⁰ The process begins with a physician confirming pregnancy and prescribing mifepristone.⁶¹ The pregnancy is often confirmed, or even required to be confirmed in some states, by both a pregnancy test of urine or blood and an ultrasound in order to show that the embryo has properly implanted in the uterus and no other contraindications

54. U.S. FOOD & DRUG ADMIN., PROMETRIUM LABEL, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019781> [<https://perma.cc/6YDE-VTDK>] (last visited Jan. 13, 2024).

55. Ali et al., *supra* note 44.

56. U.S. FOOD & DRUG ADMIN., PROMETRIUM LABEL, *supra* note 54; Jerome H. Check, et al., *The Risk of Fetal Anomalies as a Result of Progesterone Therapy During Pregnancy*, 45 FERTILITY & STERILITY 575–77 (1986); see also Org. of Teratology Info. Specialists, *Progesterone and Progestins - Mother to Baby*, NCBI BOOKSHELF (2022), <https://www.ncbi.nlm.nih.gov/books/NBK582914/> [<https://perma.cc/P6MH-BABN>] (last visited Jan. 15, 2024).

57. Edwards & Can, *supra* note 53.

58. *Drugs and Supplements: Mifepristone (Oral Route)*, MAYO CLINIC (last updated July 1, 2024), <https://t.ly/-NgXI>, [<https://perma.cc/JP6S-AF8T>].

59. Mifepristone, *supra* note 39.

60. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN (Mar. 23, 2023), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> [<https://perma.cc/GPL9-NG69>].

61. *How Does the Abortion Pill Work?* PLANNED PARENTHOOD, [hereinafter *How Abortion Pill Works*] <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-does-the-abortion-pill-work> [<https://perma.cc/42KE-EH8C>] (last visited Jan. 15, 2024).

are present.⁶² Mifepristone blocks a woman's progesterone receptors, inhibiting progesterone from attaching to the uterine wall.⁶³ Since progesterone is essential for the uterus to create an environment that would support an embryo, blocking the progesterone makes the uterus unable to support a pregnancy.⁶⁴ Around twenty-four to forty-eight hours later, a woman takes the second pill, misoprostol.⁶⁵ The misoprostol forces the woman's uterus to contract.⁶⁶ This causes the shedding of the uterine lining, expelling its contents, including the embryo.⁶⁷

This procedure has become the preferred method of abortion in the United States.⁶⁸ The Guttmacher Institute, a nonprofit organization dedicated to promoting reproductive health rights and a subsidiary of Planned Parenthood until 2007, estimates that sixty-three percent of all reported abortions in the United States in 2023 were chemical abortions.⁶⁹ Comparatively, medication abortions accounted for just under a quarter of reported abortions in 2011 (twenty-four percent) and six percent of abortions in 2001, one year after FDA approval of the medication regimen.⁷⁰ With an estimated 1,026,700 abortions in the United States in 2023, almost 650,000 abortions were performed through the medication abortion process.⁷¹

1. Mifepristone

Mifepristone, the first medication taken in the chemical abortion process, was developed by French pharmaceutical manufacturer Roussel-Uclaf when its team of researchers discovered receptors in uterine cells that received information from progesterone.⁷² The researchers hypothesized

62. See *Medication Abortion Up to 70 Days of Gestation*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (2020), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation> [https://perma.cc/F9BU-Q9NP] (last visited Jan. 16, 2024).

63. *Id.*

64. MAYO CLINIC, *supra* note 58.

65. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 62.

66. *Id.*

67. *How Abortion Pill Works*, *supra* note 61.

68. *Infra* note 69.

69. Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, GUTTMACHER INST. (Mar. 19, 2024), <https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020> [https://perma.cc/U53C-GKMV] (number does not include abortion pills mailed to states with abortion bans in place).

70. *Id.*

71. Rachel K. Jones, et al., *Abortion Incidence and Service Availability in the United States, 2020*, GUTTMACHER INST. (Nov. 20, 2022), <https://www.guttmacher.org/article/2022/11/abortion-incidence-and-service-availability-united-states-2020> [https://perma.cc/W4P7-ME39].

72. R. Alta Charo, *A Political History of RU-486*, INST. MED. (1991), <https://www.ncbi.nlm.nih.gov/books/NBK234199/> [https://perma.cc/5QBD-ELJZ].

that an inhibitor could prevent progesterone from reaching the receptors.⁷³ In the early 1980s, clinical trials were conducted in Switzerland.⁷⁴ The pill, known then as RU-486, was shown to be about eighty percent effective in inducing an abortion within forty-nine days after the first day of a woman's last menstrual period.⁷⁵ However, when taken with prostaglandins, which can induce uterine contractions, the efficacy increased to ninety-six percent.⁷⁶ The pill was inexpensive and was originally thought to be brought to market as a monthly contraceptive or so-called "morning-after pill."⁷⁷

When mifepristone, under the brand name Mifeprex, was approved by the FDA in 2000, it was not approved as a contraceptive as originally thought but as an abortifacient.⁷⁸ In its approval letter, the FDA cited two French trials of over 1,600 women and an American trial involving a little over 800 women.⁷⁹ The FDA required that the drug be administered by a physician who, among other requirements, was capable of diagnosing ectopic pregnancies, assessing the gestational age accurately, and providing surgical intervention if necessary.⁸⁰ It also required the administering physician to report any hospitalization or other serious adverse effects.⁸¹ Mifepristone was placed on the risk management program and later placed on the Risk Evaluation and Mitigation Strategy ("REMS") program.⁸² In 2016, the FDA increased the number of allowable days to take mifepristone from forty-nine days to seventy days after a woman's last menstrual period or ten weeks gestation.⁸³

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. U.S. FOOD & DRUG ADMIN., MIFEPRISTONE APPROVAL LETTER (2000), https://www.accessdata.fda.gov/drugsatfda_docs/appltr/2000/20687apltr.pdf [<https://perma.cc/NW29-5DQE>].

79. DEPT. HEALTH & HUMAN SERVS., U.S. FOOD & DRUG ADMIN., JOINT MEMORANDUM, POSTMARKET DRUG SAFETY INFO. FOR PATIENTS & PROVIDERS (2000) <http://wayback.archive-it.org/7993/20161024033545/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf> [<https://perma.cc/5HX2-94ND>].

80. *Id.*

81. *Id.*

82. The REMS program is a special FDA requirement that sets forth specific protocols for certain drugs believed to have serious safety concerns. *See* 21 U.S.C.S. § 355-1; U.S. FOOD & DRUG ADMIN., *supra* note 60; U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGIES, <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems> [<https://perma.cc/J29N-C5JH>] (last visited Jan. 16, 2024).

83. U.S. FOOD & DRUG ADMIN., QUESTIONS AND ANSWERS ON MIFEPREX <http://wayback.archive-it.org/7993/20161022205309/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm492705.htm> [<https://perma.cc/8YBF-JWCR>] (last visited Jan. 16, 2024).

A generic form of mifepristone was approved in 2019 and included in a shared system risk evaluation and mitigation strategy.⁸⁴ The mifepristone REMS program was modified to allow pharmacies to dispense and even mail mifepristone in 2021 after a temporary suspension of the requirements was permitted during the COVID-19 pandemic.⁸⁵ Abortion providers have also expanded mifepristone to off-label use in the second trimester of pregnancy.⁸⁶

2. Misoprostol

The second medication taken in the chemical abortion process, misoprostol, is taken twenty-four to forty-eight hours after mifepristone.⁸⁷ Marketed under the brand name Cytotec, misoprostol is a synthetic prostaglandin.⁸⁸ Developed in the U.S. in 1973 and FDA-approved by 1988, misoprostol was originally intended to treat stomach ulcers following the use of non-steroidal anti-inflammatory drugs (NSAIDs).⁸⁹ However, the drug had serious side effects on pregnant women.⁹⁰ Misoprostol was found to soften and dilate the cervix, causing labor.⁹¹ Despite contraindications for pregnant women, misoprostol became widely used for off-label purposes such as inducing pre-term and full-term labor.⁹² Unfortunately, many cases began to show that when used for labor induction, misoprostol caused uterine tears, uterine rupture requiring a hysterectomy, and fetal and maternal death, particularly where misoprostol was administered vaginally.⁹³

While conducting the clinical trials for mifepristone, discussions among researchers indicated that using misoprostol in conjunction with mifepristone would increase the number of successful abortions.⁹⁴ Cytotec's manufacturer, Searle, became concerned with the liability of the association with the abortion drug and urged the FDA to include a warning against

84. U.S. FOOD & DRUG ADMIN., *supra* note 60.

85. *See id.*

86. Dzuba et al., *Off-label Indications for Mifepristone in Gynecology and Obstetrics*, 92 *CONTRACEPTION* 203 (2015).

87. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 62.

88. U.S. FOOD & DRUG ADMIN., CYTOTEC LABEL (2002), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf [<https://perma.cc/53M7-HCNF>] (last visited Aug. 16, 2024).

89. *Id.*; Becky Little, *The Science Behind the Abortion Pill*, *SMITHSONIAN MAG.* (June 23, 2017), <https://www.smithsonianmag.com/health-medicine/science-behind-abortion-pill-180963762/> [<https://perma.cc/PU4H-28GK>].

90. Little, *supra* note 89.

91. U.S. FOOD & DRUG ADMIN., MEMORANDUM OF CYTOTEC ADVERSE EVENTS (2021), at 194, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2001/019268Orig1s000.pdf [<https://perma.cc/PT63-N3TA>].

92. *Id.*

93. *Id.*

94. *Id.* at 191.

the use of misoprostol for abortive purposes.⁹⁵ Shortly after mifepristone gained FDA approval, Searle released a statement cautioning the use of misoprostol in pregnant women either to induce labor or an abortion.⁹⁶ The American College of Obstetricians and Gynecologists (ACOG) followed up with a letter to the FDA stating its position in support of the use of misoprostol combined with the use of mifepristone in safe and effective abortions as well as its application in the ripening of the cervix and inducing labor.⁹⁷ This created a “battle of the experts” of sorts where Searle opposed labeling that recommended the use of misoprostol by pregnant women, whereas ACOG encouraged the FDA to require such labeling.⁹⁸ The label ultimately indicated only gastrointestinal uses for the treatment of ulcers but contained further information in the precautions section on how the drug has been used in labor and delivery.⁹⁹ In 2015, the FDA updated its patient safety information to reflect concerns about misoprostol use in labor and delivery, citing the risks of torn or ruptured uterus and fetal and maternal death as seen in reports of adverse effects.¹⁰⁰

Though the FDA has not specifically approved misoprostol for use in abortions, misoprostol is named in the FDA approval of mifepristone as part of the two-part regimen prescribed for abortions within the first ten weeks of gestation.¹⁰¹ More recently, with many states restricting or outright prohibiting abortions and mifepristone becoming less accessible, some physicians have started prescribing only misoprostol in multiple doses as a readily available option for women wanting abortions.¹⁰² ACOG asserts that using misoprostol-only medication abortions along with uterine aspiration has been shown to be safe and effective where mifepristone is not easily accessible or desirable for the patient.¹⁰³

Still, the most common and preferred abortion procedure utilizes mifepristone in conjunction with misoprostol to block progesterone and induce uterine cramping to terminate the fetus and empty the contents of the

95. *Id.* at 191–94.

96. *Id.* at 165–67.

97. *Id.*

98. *Id.*

99. U.S. FOOD & DRUG ADMIN., CYTOTEC PACKAGE INSERT (2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s0511bl.pdf [<https://perma.cc/ZC3C-RZ9R>].

100. U.S. FOOD & DRUG ADMIN., MISOPROSTOL WARNING (2015), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/misoprostol-marketed-cytotec-information> [<https://perma.cc/3C4M-PXSM>].

101. FOOD & DRUG ADMIN., *supra* note 60.

102. *Access to Mifepristone: Frequently Asked Questions*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, <https://www.acog.org/clinical-information/physician-faqs/access-to-mifepristone> [<https://perma.cc/2MV2-NBUQ>] (last visited Jan. 17, 2024).

103. *Id.*

uterus out of the body.¹⁰⁴ This procedure is used in some cases, off-label, up to twenty-four weeks gestation.¹⁰⁵

B. Entrance of Abortion Pill Reversal

In a case regarding partial-birth abortions, Justice Anthony Kennedy acknowledged, “[I]t seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained.”¹⁰⁶ Dr. George Delgado, a primary care physician in California with a special emphasis in Health Care Ethics and women’s reproductive health, encountered one such woman experiencing regret and set out to find a solution to reverse the effects of mifepristone before a woman has taken the second step in the chemical abortion process.¹⁰⁷ Dr. Delgado considered that progesterone was an agonist, meaning it caused a physiological response when combined with a receptor.¹⁰⁸ Mifepristone, therefore, acts as an antagonist or a substance that interferes with the physiological effect of another.¹⁰⁹ A well-known principle in biology states that the effects of an antagonist can be affected by concentrations of an agonist and vice versa.¹¹⁰ Therefore, Dr. Delgado reasoned that if more progesterone were introduced, the effects of the mifepristone could be counteracted by introducing more progesterone than the mifepristone could inhibit.¹¹¹

A Japanese study of rats by Dr. Yamabe supports this theory.¹¹² In 1989, RU-486 (mifepristone) was given to pregnant lab rats.¹¹³

104. Rose Thorne & Stacy A. Henigsman, D.O., *What Are the Different Types of Abortion?*, HEALTHLINE (2022) <https://www.healthline.com/health/types-of-abortion#medical> [<https://perma.cc/YL27-4GVW>].

105. *Abortion pill from 10-24 weeks*, BRITISH PREGNANCY ADVISORY SERV., <https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/abortion-pill-from-10-weeks-to-24-weeks/> [<https://perma.cc/AM8H-MZSM>] (last visited Jan. 16, 2024).

106. *Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

107. *Dr. George Delgado, M.D.*, U.S. NEWS & WORLD REP., <https://health.usnews.com/doctors/george-delgado-745006> [<https://perma.cc/P9MD-SULB>] (last visited Jan. 16, 2024). Dr. Delgado is board certified in family medicine as well as hospice and palliative care. Additionally, Dr. Delgado is certified in Health Care Ethics through the National Catholic Bioethics Center and is a Natural Family Planning Medical Consultant, having completed the NaProTechnology physician training program. *About*, STENO INST., <https://steno.institute.org/about/> [<https://perma.cc/D2MZ-QYLE>] (last visited Jan. 16, 2024); NAPROTECHNOLOGY, <https://naprotechnology.com/> [<https://perma.cc/9GZK-LVVN>] (last visited Jan. 16, 2024); Graham, *supra* note 34.

108. Delgado et al., *supra* note 33; *Agonist*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/agonist> [<https://perma.cc/JQ3U-FRA6>] (last visited Aug. 18, 2024).

109. *Antagonist*, Merriam-Webster.com Dictionary, <https://www.merriam-webster.com/dictionary/antagonist> [<https://perma.cc/GBY5-P4N8>] (last visited Aug. 18, 2024).

110. Delgado et al., *supra* note 33.

111. *Id.*

112. S. Yamabe et al., *[The effect of RU486 and progesterone on luteal function during pregnancy]*, JAPAN ENDOCRINE SOC. J., May 1989, at 497–511.

113. *Id.*

Subsequently, half of the rats were also given progesterone.¹¹⁴ In the rats that only received RU-486, thirty-three percent delivered live offspring.¹¹⁵ However, one hundred percent of the rats who received progesterone delivered live offspring.¹¹⁶ Furthermore, researchers analyzed samples of the uterine tissue of the rats.¹¹⁷ The progesterone receptors of the rats who received mifepristone alone were physiologically changed.¹¹⁸ Meanwhile, none of those changes were present in the rats who received the progesterone supplement after administering mifepristone.¹¹⁹

Since progestogens had been used safely for decades on pregnant women to support at-risk pregnancies,¹²⁰ Dr. Delgado attempted to supplement the progesterone levels of six women who expressed an interest in reversing their pregnancies to counteract the effects of mifepristone.¹²¹ In 2007, Dr. Delgado produced a report of six women who were treated by supplementing their progesterone levels.¹²² All of the women in the report received an intramuscular dose of 200 milligrams of progesterone after taking mifepristone.¹²³ Four out of six women delivered live, healthy babies.¹²⁴ The report concluded with the possibility that progesterone supplemented after mifepristone may reverse the effects of mifepristone.¹²⁵

Delgado then decided to conduct a study from 2012 to 2016.¹²⁶ A hotline was set up for women who changed their minds after taking the first pill of the chemical abortion regimen.¹²⁷ Out of the 1,668 calls received, 716 women qualified and elected to take part in the study and initiated progesterone therapy.¹²⁸ These women were all within seventy-two hours of taking mifepristone and had not yet taken the second dose of misoprostol.¹²⁹ Over the course of the study, 547 patients completed the study with analyzable outcomes.¹³⁰

114. *Id.*

115. Delgado et al., *supra* note 33.

116. *Id.*

117. Yamabe et al., *supra* note 112.

118. *See* Yamabe et al., *supra* note 112; Delgado et al., *supra* note 33.

119. Delgado et al., *supra* note 33.

120. *See, e.g.*, Org. of Teratology Info. Specialists, *supra* note 56; Check et al., *supra* note 56; Di Renzo et al., *Prevention of Preterm Birth with Progesterone*, J. CLIN. MED. (2021).

121. Delgado et al., *supra* note 33.

122. Delgado & Davenport, *supra* note 33.

123. *Id.*

124. *Id.*

125. *Id.*

126. Delgado et al., *supra* note 33.

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.* (Some women did not follow-up (112), some changed their minds again and elected for an abortion (57)).

This study utilized different forms of progesterone treatment including oral, injection, and vaginal suppository.¹³¹ No control group was used, however, as researchers found it to be unethical to use a placebo control group among women who wanted to save their pregnancy.¹³² To account for this, Dr. Delgado and his team assumed a high-end estimate of a twenty-five percent survival rate of fetuses exposed to mifepristone alone based on historical data.¹³³ The study found that introducing progesterone within seventy-two hours of taking mifepristone resulted in a sixty-four percent fetal survival rate in intramuscular administration of progesterone and a sixty-eight percent fetal survival rate in oral administration of progesterone.¹³⁴ This showed an increase of around 270% in surviving fetuses after exposure to mifepristone followed by progesterone as compared to fetuses exposed to mifepristone alone.¹³⁵ Additionally, the study saw no increase in birth defects and a lower pre-term birth rate than the general population.¹³⁶

Since then, the hotline has grown rapidly, and to accommodate for the infrastructure necessary, Dr. Delgado turned the hotline over to Heartbeat International, a pro-life network of pregnancy resource centers.¹³⁷ Now known as the Abortion Pill Rescue Network (“APRN”), the hotline does keep some separation from Heartbeat International, utilizing a separate medical director and staff.¹³⁸ APRN has been permanently established as a resource for women who regret their abortions and want to try to save their pregnancies.¹³⁹ Over 1,400 healthcare providers worldwide provide assistance on a twenty-four-hour per day, seven days per week basis for women around the world.¹⁴⁰ The Abortion Pill Rescue Network has documented over 5,000 pregnancies successfully continued after women

131. *Id.*

132. *Id.*

133. *Id.* This percentage was a little higher than a study done on fetuses exposed to a single 200 mg dose of mifepristone, the most common dose for a chemical abortion regimen. *Id.* Additionally, Dr. Grossman’s research suggests a 20% survival rate. Daniel Grossman, et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92 *CONTRACEPTION*, September 2015, at 206.

134. *Id.*

135. *Id.*

136. *Id.*

137. Telephone interview with Dr. Brent Boles, OBGYN, Medical Director, Abortion Pill Rescue Network (Dec. 13, 2023).

138. *Id.*

139. *About*, ABORTION PILL REVERSAL, <https://abortionpillreversal.com/about-us> [<https://perma.cc/2XTJ-ZEJU>] (last visited Jan. 17, 2024).

140. *Id.*; 2023 *Impact Report*, HEARTBEAT INT’L [hereinafter *Impact Report*], https://www.heartbeatinternational.org/images/ImpactReports/APRN_Impact_Report_2023.pdf [<https://perma.cc/2E49-H6AJ>] (last visited Jan. 17, 2024); see also Lisa Bourne, “We Celebrate Each of These Children”—APRN Marks 5K Lives Saved, *PREGNANCY HELP NEWS* (Jan. 30, 2024) <https://pregnancyhelpnews.com/we-celebrate-each-of-these-children-aprn-marks-5k-lives-saved> [<https://perma.cc/A9RC-SLMY>].

changed their decisions regarding their pregnancies.¹⁴¹ Their most recent data shows that on average, the hotline receives around 300 calls per month requesting reversal services around the world.¹⁴² Of those, between 150-200 women every month start the abortion pill reversal process.¹⁴³

II. CURRENT LANDSCAPE AND FERTILE GROUND FOR LEGAL BATTLES

Since *Dobbs v. Jackson Women's Health Organization* overturned *Roe v. Wade* in 2022, legislation regarding abortion has been turbulent.¹⁴⁴ Currently, fourteen states have abortion bans in place that only provide exceptions for the life of the mother, with seven more cutting abortions off before twenty weeks and thirteen bans currently tied up in the court system.¹⁴⁵ Some doctors recently even challenged the FDA approval of mifepristone itself in *Alliance for Hippocratic Medicine, et al., v. U.S. Food and Drug Administration, et al.*¹⁴⁶ Plaintiffs in this case claimed that the FDA unlawfully approved mifepristone in 2000 and made changes to the safety requirements regarding the regulation of the drug in 2016 and 2021.¹⁴⁷ Though the Fifth Circuit ruled that the statute of limitations had run on the original FDA approval, it found plaintiffs were likely to succeed on the merits of their claims regarding the 2016 and 2021 relaxation of restrictions.¹⁴⁸ The FDA appealed the ruling, however, and the Supreme Court found that the plaintiffs did not have standing to sue.¹⁴⁹ This slowed down the progress of the claim, but a new case from plaintiffs with standing can reasonably be expected in the near future.

A. Fifty Battlegrounds: Laws Regarding Reversal

One of the newest legal battlegrounds centers around state laws on abortion pill reversal.¹⁵⁰ At least eight states have current laws in place

141. *Impact Report*, *supra* note 140 (The Abortion Pill Rescue Network hosts a global hotline. Though most calls received come from the United States, this figure does include calls from around the globe.).

142. Telephone interview with Dr. Brent Boles, *supra* note 137.

143. *Id.*

144. *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022); *Roe v. Wade*, 410 U.S. 113, 162 (1973); see generally *Abortion Laws by State*, N.Y. TIMES, <https://www.nytimes.com/2023/09/12/magazine/abortion-laws-states.html> [<https://perma.cc/LQF3-K7GA>] (last visited Jan. 18, 2024).

145. ABORTION FINDER, <https://www.abortionfinder.org/abortion-guides-by-state> [<https://perma.cc/YT4Z-G7MY>] (last visited Jan. 18, 2024); *United States Abortion Law Map By State*, AM. CTR. FOR L. & JUST., <https://aclj.org/abortion> [<https://perma.cc/MU3E-5AP4>] (last visited Jan. 18, 2024).

146. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024).

147. *Id.* at 376–77.

148. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 244–45 (5th Cir. 2023).

149. *All. for Hippocratic Med.*, 602 U.S. at 396–97.

150. *Graham*, *supra* note 34.

requiring abortion providers to inform patients that a medication abortion may be reversible.¹⁵¹ Such laws range from requiring language that simply states, “mifepristone alone is not always effective,” to requiring language overtly stating that “it may be possible to counteract the effects of mifepristone.”¹⁵² Additionally, Oklahoma and Montana require materials to be provided to a patient with a phone number and website address for the Abortion Pill Rescue Network.¹⁵³

These laws requiring that patients be informed of the possibility of reversal have faced significant opposition.¹⁵⁴ At least five states passed legislation on the required disclosures but were enjoined by court rulings, three of which were blocked before the laws ever went into effect.¹⁵⁵ Most recently, Kansas became the latest state to have its required disclosures blocked.¹⁵⁶ The Kansas law, which went into effect in July of 2023, required any facility prescribing or dispensing mifepristone or any physician providing the abortion to inform women of the possibility of reversing the effects of mifepristone.¹⁵⁷ The statute further required women to be provided with a way to find out more information about reversing their abortion if they desired.¹⁵⁸ The Kansas Supreme Court ruled that the state failed to carry its burden of showing that the restrictions and requirements furthered the state’s interest in protection of maternal health.¹⁵⁹ Further, it refused to sever the unconstitutional restrictions, throwing out the statute entirely, including the requirements of disclosures about abortion pill reversal.¹⁶⁰

Other states are taking a different stance. Under SB23-190, Colorado became the first state to prohibit the abortion pill reversal protocol.¹⁶¹ Under the law, a physician is considered to engage in

151. OKLA. STAT. tit. 63, § 1-756.7 (2021); ARK. CODE ANN. § 20-16-1703(b)(9)(A) (2021); W. VA. CODE § 16-21-2 (2021); H.R. 578, 2021 Leg., Reg. Sess. (La. 2021); IDAHO CODE § 18-609 (2021); KY. REV. STAT. ANN. § 311.725 (LexisNexis 2019); MONT. CODE ANN. § 50-20-708 (2021); NEB. REV. STAT. § 28-327 (2022).

152. Graham, *supra* note 34; e.g., W. VA. CODE § 16-21-2 (2021); NEB. REV. STAT. § 28-327 (2022); Sarah K. Redd, PHD, MSPH, et al., *Medication Abortion “Reversal” Laws: How Unsound Science Paved the Way for Dangerous Abortion Policy*, 113 AM. J. PUB. HEALTH 202, 212 (2023).

153. OKLA. STAT. tit. 63, § 1-756.7 (2021); MONT. CODE ANN. § 50-20-708 (2021).

154. Redd et al., *supra* note 152.

155. *Id.*

156. KAN. STAT. ANN. § 65-6716; Paul Burch, *Injunction Blocks Kansas Law Requiring Doctors to Advise Patients on Medical Abortion, Cancer Link*, TENNESSEE BAR ASS’N (Oct. 31, 2023), https://www.tba.org/?pg=TBA Today&pubAction=viewIssue&pubIssueID=34904&pubIssueItemID=199096&utm_campaign=tba-today&utm_content=tuesday-october-31-2023&utm_medium=email&utm_source=membercentralpublications [https://perma.cc/VRM7-P3P2].

157. KAN. STAT. ANN. § 65-6716.

158. *Id.*

159. Hodes & Nauser, MDs, P.A. v. Stanek, 551 P.3d 62 (Kan. 2024).

160. *Id.*

161. S.B. 190, 74th Gen. Assemb., Reg. Sess. (Co. 2023).

unprofessional conduct and would be subject to disciplinary action for attempting an abortion pill reversal.¹⁶² However, in a recent decision, a federal judge granted a preliminary injunction prohibiting the implementation of the law's provisions regarding the abortion pill reversal treatment.¹⁶³

Vermont followed closely behind Colorado by adding abortion pill reversal services to its list of actions that constitute unprofessional conduct by a licensed healthcare provider.¹⁶⁴ The law subjects healthcare providers who offer or claim to offer services that attempt to reverse a medication abortion to disciplinary action, including but not limited to denial of his/her license.¹⁶⁵

Most recently, the Attorney General of New York sent notice of intent to sue a dozen pregnancy resource organizations in the state regarding the centers' information about abortion pill reversal.¹⁶⁶ In response, the New York-based pregnancy help organizations, along with Heartbeat International, filed a complaint against the Attorney General, alleging violations of the First Amendment, Fourteenth Amendment, the New York Constitution, and New York Civil Rights laws.¹⁶⁷ The complaint disputed any misleading statements or omissions regarding the Abortion Pill Reversal protocol and called for declaratory injunctive relief.¹⁶⁸ New York Attorney General returned fire by filing suit against Heartbeat International and eleven New York-based pregnancy centers for misleading advertising.¹⁶⁹ In a separate but related case, two pregnancy resource centers in the state brought suit in federal court for violations of the organizations' First and Fourteenth Amendment rights.¹⁷⁰ In that case, United States District Judge John. Sinatra, Jr. has ordered that New York Attorney General Letitia James is enjoined from taking action against the pregnancy centers in this case until the disposition of the case on the merits.¹⁷¹

162. COLO. REV. STAT. § 12-30-120.

163. *Bella Health & Wellness v. Weiser*, 699 F. Supp 1189, 1218 (D. Col. 2023).

164. VT. STAT. ANN. Tit. 3 § 129a(29) (2023).

165. *Id.*

166. Office of the Attorney General, Notice Of Proposed Litigation Pursuant To New York Executive Law Section 631(12) And Article 22-A of the New York General Business Law, April 22, 2024, <https://www.liveaction.org/news/wp-content/uploads/2024/04/New-York-AG-notice-of-lawsuit-against-prolife-pregnancy-centers.jpg> [<https://perma.cc/B7YF-TGYP>].

167. Complaint, *Heartbeat Int'l Inc. et. al, v. Letitia James*, No. E2024007242 (Sup. Ct. New York, Monroe County filed Apr. 30, 2024).

168. *Id.*

169. Complaint, *The People of the State of New York v. Heartbeat Int'l et. al*, No. 451314/2024 (Sup. Ct. New York, New York County filed May 6, 2024).

170. Complaint, *Summit Life Outreach Ctr., Inc. & The Evergreen Ass'n, Inc. v. Letitia James*, No. 1:24-cv-741 (W.D.N.Y. filed Aug. 7, 2024).

171. Order, *Summit Life Outreach Ctr., Inc. & The Evergreen Ass'n, Inc. v. Letitia James*, No. 24-cv-514(JLS) (W.D.N.Y. filed Sept. 24, 2024).

B. Using the “Off-label” Label

A common criticism of the use of mifepristone, misoprostol, and progestogens is that each is commonly used “off-label” in the context of abortion and its reversal.¹⁷² The FDA defines “off-label” use as an FDA-approved drug that is used for any unapproved purpose.¹⁷³ Unapproved uses encompass not only medical conditions for which the treatment has not been approved, but the FDA also uses the term to describe treatments given in different dosages than what was originally approved or in different forms such as a capsule instead of an oral solution.¹⁷⁴ Once the FDA approves a drug, healthcare providers are allowed to determine what uses of a particular drug are medically appropriate regardless of whether the drug is specifically approved for such purpose or the use is specified on the label.¹⁷⁵ Allowing uses for which the FDA has not approved a treatment allows room for innovation and the discovery of alternative applications for medications and procedures that have already been tested and found to be safe.¹⁷⁶ Examples of common off-label medications include: aspirin for prophylactic treatment of coronary disease in high-risk patients;¹⁷⁷ certain antidepressants for neuropathy, insomnia, and irritable bowel syndrome;¹⁷⁸ and recently Ozempic, approved for Type II diabetes and cardiovascular risks, has widely gained popularity as a weight loss treatment.¹⁷⁹

Physicians may use treatments off-label as long as they determine that it is medically appropriate for the patient.¹⁸⁰ What is medically appropriate depends on the physician’s responsibility to make this determination with thorough knowledge about the treatment, sound scientific rationale, and medical evidence, as well as the responsibility to maintain records of the product’s off-label use and its effects.¹⁸¹ Physicians

172. Sian Ferguson & Ami Patel, PharmD, BCPS, *There Isn’t a Way to ‘Reverse’ Emergency Contraception Pills or Medical Abortion*, HEALTHLINE (July 13, 2023), <https://www.healthline.com/health/reverse-abortion-pill> [<https://perma.cc/JB7T-CDNV>].

173. U.S. FOOD & DRUG ADMIN., UNDERSTANDING UNAPPROVED USE OF APPROVED DRUGS “OFF LABEL,” <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> [<https://perma.cc/A625-RK2X>] (last visited Jan. 18, 2024).

174. *Id.*

175. *Id.*; James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998).

176. Christopher M. Wittich et al., *Ten Common Questions (and Their Answers) About Off-label Drug Use*, 87 MAYO CLINIC PROC. 982, 989 (2012).

177. *Id.*

178. *Id.*

179. Daniel Gilbert, *Prescriptions for Ozempic and Similar Drugs Have Skyrocketed, Data Shows*, WASH. POST (Sept. 27, 2023), <https://www.washingtonpost.com/business/2023/09/27/ozempic-prescriptions-data-analysis/> [<https://perma.cc/8VMJ-HVXE>].

180. U.S. FOOD & DRUG ADMIN., *supra* note 173.

181. U.S. Food & Drug Admin., “Off-Label” and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices: Guidance for Institutional Review Boards and Clinical Investigators (1998) <https://www.fda.gov/regulatory-information/search-fda>

frequently use off-label treatments for a variety of reasons, including when there is no other drug suitable for treatment or the ones available have not worked in a patient's specific case.¹⁸² Off-label use is more common than most would realize: about one in five prescriptions are written for off-label use.¹⁸³

Both mifepristone and misoprostol are used frequently past the FDA-approved 10-week mark for chemical abortions.¹⁸⁴ Mifepristone has been promoted by the American College of Obstetricians and Gynecologists for use in the second trimester (around thirteen weeks), while its British counterpart, the Royal College of Obstetricians and Gynaecologists, promotes mifepristone use up to twenty-four weeks gestation.¹⁸⁵ Additionally, mifepristone is finding off-label uses in surgical abortions and even labor and delivery.¹⁸⁶ Misoprostol has proven useful off-label in ripening a woman's cervix before a procedure and treating postpartum hemorrhage.¹⁸⁷ Misoprostol itself is not specifically FDA-approved for abortions.¹⁸⁸ However, because of the limited access to mifepristone as well as the response to the abortion pill reversal procedure, a rising number of physicians are using misoprostol alone and off-label in medication abortions.¹⁸⁹ Likewise, progestogens are commonly used off-label for a variety of reasons including regulation of menstrual cycles, treatment of endometriosis, and even treatment of hormone-related tumors.¹⁹⁰

While prescribing a drug for off-label use does potentially place a physician at higher risk of a malpractice suit, the fact that a drug is used off-label does not by itself make a physician liable.¹⁹¹ The FDA itself says

guidance-documents/label-and-investigational-use-marketed-drugs-biologics-and-medical-devices [https://perma.cc/3GED-L9H7].

182. U.S. FOOD & DRUG ADMIN., *supra* note 173.

183. Wittich et al., *supra* note 176.

184. *See infra* note 185.

185. *Practice Bulletin No. 135: Second-Trimester Abortion*, AM. COLL. OF OBSTETRICS & GYNECOLOGY, https://journals.lww.com/greenjournal/Citation/2013/06000/Practice_Bulletin_No_135_Second_Trimester.42.aspx (2013) [https://perma.cc/PH6M-P7A8]; *Best Practice in Abortion Care*, ROYAL COLL. OF OBSTETRICIANS & GYNAECOLOGISTS, 1, 7 (2022) <https://www.rcog.org.uk/media/geify5bx/abortion-care-best-practice-paper-april-2022.pdf> [https://perma.cc/995Z-JMTE].

186. Dzuba et al., *supra* note 86.

187. Rebecca Allen, MD, MPH & Barbara M O'Brien, MD, *Uses of Misoprostol in Obstetrics and Gynecology*, 2 REVS. OBSTETRICS & GYNECOLOGY 159–68 (2009).

188. U.S. FOOD & DRUG ADMIN., *MISOPROSTOL (MARKETED AS CYTOTEC) INFORMATION* (2015), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/misoprostol-marketed-cytotec-information> [https://perma.cc/3VXC-VG4J] (last visited Jan. 18, 2024).

189. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 102.

190. T.A. Fedotcheva, MD, DSc, *Clinical Use of Progestins and Their Mechanisms of Action: Present and Future*, 13 MOD. TECHNOLOGIES MED. 93, 96 (2021).

191. Elizabeth Klumpp, *Liability and Off-Label Prescriptions*, 6 PSYCHIATRY (EDGMONT) 43 (2009).

physicians are free to prescribe medications for off-label use when it is appropriate as long as the physician is well-informed about the drug, has rational evidence on which the physician bases the drug's possible efficacy, and maintains records of the use and effectiveness of the prescribed drug.¹⁹²

Two common claims concerning off-label drug use are negligence and a lack of informed consent.¹⁹³ In medical malpractice, negligence follows the same elements as traditional negligence: the physician owes the patient a duty of care; the duty of care is breached by the physician; an injury arises requiring compensation; and said injury has a causal connection to the breach of the duty of care owed by the physician.¹⁹⁴ To ensure the duty of care is followed, the Mayo Clinic recommends physicians ensure the off-label use has been peer-reviewed, is medically necessary for treatment, and is nonexperimental.¹⁹⁵ However, physicians will likely be covered if they follow the tenets of FDA requirements by prescribing drugs in good faith, in the best interest of the patient, and without fraudulent intent.¹⁹⁶

The other common basis for a medical malpractice claim is lack of informed consent. Informed consent is defined as:

[A] person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternative. . . . A patient's knowing choice about a medical treatment or procedure, made after a physician or other healthcare provider discloses whatever information a reasonably prudent provider in the medical community would give to a patient regarding the risks involved in the proposed treatment or procedure.¹⁹⁷

The right to control one's own person and prohibit interference of others without permission is held as "sacred."¹⁹⁸ Ordinarily, physicians must provide patients with information regarding "the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences."¹⁹⁹

Case law regarding informed consent has largely centered around *Canterbury v. Spence*.²⁰⁰ In this commonly cited case out of the D.C. Circuit Court of Appeals, the court emphasized the importance of a medical

192. U.S. FOOD & DRUG ADMIN., *supra* note 173.

193. Wittich et al., *supra* note 176.

194. *Id.*

195. *Id.*

196. *Id.*

197. *Consent, informed*, BLACK'S LAW DICTIONARY (11th ed. 2019).

198. *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 266 (1990).

199. Beck & Azari, *supra* footnote 175, at 87.

200. *Id.*

professional's duty to inform patients of the risks of medications and/or procedures.²⁰¹ Whether or not information about a drug or procedure must be disclosed to the patient depends on its "materiality" or whether a reasonable person in the patient's position would attach significance to the disclosure when deciding whether to proceed with the prescribed treatment.²⁰² While the question of whether off-label use is "material" has yet to be answered definitively, no appellate court has ruled that off-label use must be disclosed.²⁰³ However, in such cases where an innovative treatment is used, a practitioner may be required to inform patients of the departure from "customary practice."²⁰⁴

C. Right to Try Laws

Many states and the federal government have passed right-to-try laws.²⁰⁵ Right-to-try laws generally allow patients who are terminally ill to try experimental treatments that do not yet have FDA approval.²⁰⁶ While these laws do not have an impact on progesterone, mifepristone, or misoprostol, as these laws do not impact off-label uses of treatments that do have FDA approval, they do give insight into potential obligations of informing patients of their options.

In May of 2018, Congress enacted the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right To Try Act of 2017.²⁰⁷ The act explicitly authorizes the use of unapproved investigational medical treatments and devices that have completed phase one of the FDA approval process.²⁰⁸ The use of such treatments requires that patients have a life-threatening disease or condition, exhaust all other treatment options, and provide written informed consent concerning the drug and its investigational status.²⁰⁹

Before the federal law, forty-one states passed their own versions of "Right to Try" legislation.²¹⁰ Colorado was the first state to pass such a

201. *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972).

202. *Id.* at 786–87.

203. Shariful A. Syed, et al., *The Law and Practice of Off-Label Prescribing and Physician Promotion*, 51, 53, 57 J.A.M. ACAD. PSYCHIATRY AND L. (Dec. 1, 2023).

204. Beck & Azari, *supra* footnote 175.

205. Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, P.L. 176, 115th Congress [hereinafter Right to Try Act].

206. U.S. FOOD & DRUG ADMIN., RIGHT TO TRY, <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try> [https://perma.cc/M7MK-6D56] (last visited Jan. 18, 2024).

207. Right to Try Act, P.L. 176, 115th Congress.

208. *Id.*

209. *Id.*

210. *What is Right to Try?*, GOLDWATER INST., <https://righttotry.org/about-right-to-try/> [https://perma.cc/3ULN-WL7U] (last visited Jan. 19, 2024).

law in 2014.²¹¹ The federal statute mirrored preceding state laws such as the Colorado statute in many ways.²¹² State laws provided access to potentially life-saving drugs that had completed phase one of the FDA approval process, ensured that all other FDA-approved treatment options had been exhausted, and written informed consent was provided by the patient.²¹³

While treatments that have already attained FDA approval do not require the special permission of “Right to Try” acts across state and federal law, it is significant to note that these laws empower individuals, with the advice of their healthcare provider, to elect to try treatments that are unproven.

D. Opponents of Reversal

Differing concerns have been raised about the abortion pill reversal. Naturally, the biggest concerns for any new treatment are safety and efficacy.²¹⁴ Though progesterone has been used safely in women for decades, research of a new application is limited.²¹⁵ Obstetrics and Gynecology are far behind the curve of other areas of medicine in terms of research.²¹⁶ Where many other areas of medicine may have patients lined up to try out a potentially life-changing or even life-saving experimental treatment, very few women are willing to put their unborn child at risk to test out a new treatment unless absolutely necessary.²¹⁷ It would logically follow that the challenge of finding willing participants could be greater in the context of abortion and its reversal where women who want an abortion do not want to risk the abortion being reversed and women who want a reversal do not want to risk having a placebo and having no chance of saving the pregnancy.²¹⁸ Due to these unique challenges in obstetrics, particularly regarding abortion, available data on the efficacy of the abortion pill reversal protocol is limited.

211. Patti Parson, *Colorado first state to pass ‘Right to Try,’ or the ‘Dallas Buyers’ Club’ law*, PBS NEWSHOUR (May 19, 2014), <https://www.pbs.org/newshour/health/colorado-first-state-pass-right-try-dallas-buyers-club-law> [<https://perma.cc/WR3U-3SAX>].

212. *Compare* Right to Try Act, P.L. 176 115th Congress, with COLO. REV. STAT. 25-45-101-08.

213. *See, e.g.*, COLO. REV. STAT. 25-45-101-108 (2023); CAL. HEALTH & SAFETY CODE § 111548 (Deering 2023); 2015 Ill. Laws 270; ARK. CODE ANN. § 20-15-2101 (2023).

214. U.S. FOOD & DRUG ADMIN., MISSION, <https://www.fda.gov/about-fda/what-we-do> [<https://perma.cc/8U3L-CR93>] (last visited Jan. 19, 2024) (describing the mission of the FDA is to ensure the safety and efficacy of treatments in the U.S.).

215. *See* Delgado & Davenport, *supra* note 33; Delgado et al., *supra* note 33.

216. *See* Mary C. Blehar, PhD, et al., *Enrolling Pregnant Women: Issues in Clinical Research*, 23 WOMEN’S HEALTH ISSUES E39-E45 (Jan. 2013); Errol R Norwitz, MD, PhD, *FDA Approval for Use of Medications in Pregnancy: An Uphill Battle*, 4 REVS. IN OBSTETRICS AND GYNECOLOGY 39 (2011).

217. Blehar, *supra* note 216; Norwitz, *supra* note 216.

218. Delgado et al., *supra* note 33.

Additionally, opponents assert that the data available regarding the abortion pill reversal protocol has flaws.²¹⁹ The 2012 case report of women undergoing abortion pill reversal care consisted of an extremely small group of only six subjects.²²⁰ Small sample sizes create doubt about the treatment's efficacy and repeatability.²²¹ The report also did not conduct long-term follow-up with the patients.²²² The 2018 study utilized a much larger group of women with 547 producing analyzable outcomes.²²³ Still, questions have been raised as the information in the study does not provide adequate data regarding the number of women who were excluded from the study because it was determined a miscarriage was already in progress or the embryo's heartbeat had already stopped.²²⁴ Additionally, there is some controversy as to whether the study was supervised by an institutional review board or an ethical review committee.²²⁵ These committees are put in place to ensure the safety of the human subjects and provide impartial validity to the ethics of the study and its results.²²⁶ Though the study was approved by the institutional review board at the University of San Diego,²²⁷ critics claim that no ethics committee approved the study.²²⁸

Questions of accuracy also arise due to the lack of a control group in the 2018 study.²²⁹ A more recent attempt to conduct a controlled study ended early because of safety concerns for the women involved in the study.²³⁰ This study by Dr. Creinin consisted of a randomized controlled trial of ten women who took mifepristone followed by either progesterone or a placebo twenty-four hours after administration of mifepristone and continuing for two weeks.²³¹ Continued embryonic cardiac activity was detected in four out of five women who had taken progesterone and two out of five women who had taken the placebo.²³² However, the study ended prematurely when three women experienced severe hemorrhages and were taken by ambulance to the hospital.²³³ One of the women was given progesterone and two were given the placebo.²³⁴ The woman who took the progesterone completed the abortion without requiring aspiration, but both

219. Khadijah Z. Bhatti, BA, et al., *Medical Abortion Reversal: Science and Politics Meet*, 218 AM. J. OBSTETRICS & GYNECOLOGY, 315, 317 (2018).

220. *Id.*

221. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

222. Bhatti, BA, et al., *supra* note 219.

223. Delgado et al., *supra* note 33.

224. *Id.*

225. *See id.*; AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

226. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

227. Delgado et al., *supra* note 33.

228. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

229. *Id.*

230. *Id.*

231. Creinin et al., *supra* note 33.

232. *Id.*

233. *Id.*

234. *Id.*

women who had taken the placebo required surgical aspiration to complete their abortion and one further required a blood transfusion.²³⁵ Due to the health concerns, the study ended early, and no judgments were made regarding the efficacy of progesterone use to reverse an abortion.²³⁶

Voices against abortion pill reversal argue that the progesterone regimen is unproven and unethical as an “off-label” use of progesterone, warranting state action to restrict such use.²³⁷ Both the Food and Drug Administration (“FDA”) and the Federal Trade Commission (“FTC”) have issued joint statements warning of the risks of unproven and misbranded products.²³⁸ One of their more recent widespread issues concerned the coronavirus.²³⁹ Multiple letters were issued to sellers requiring them to correct advertising that claimed their tea, silver, or essential oil products were effective in treating COVID-19.²⁴⁰ None of the companies presented evidence of the efficacy of their products and were required to take action to remove the false or misleading information.²⁴¹ Such treatments pose a danger to individuals who may depend on them for treatment, possibly even foregoing proven, effective treatments, potentially causing further harm.²⁴²

States also have a practically universally accepted duty to regulate health professions for public safety under their exercise of police power.²⁴³ Such regulations must be “reasonably related to the public health and welfare” and must not interfere arbitrarily with the “right to practice one’s profession.”²⁴⁴ In *In re Guess*, the Board of Medical Examiners of North Carolina (“the Board”) revoked the license of a doctor who practiced homeopathic medicine.²⁴⁵ Though the Board could not find any evidence that the physician’s treatment had ever harmed a patient, it nonetheless

235. *Id.*

236. *Id.*

237. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

238. FED. TRADE COMM’N, U.S. FOOD & DRUG ADMIN., JOINT MEMORANDUM, WARNINGS SENT TO SELLERS OF SCAM CORONAVIRUS TREATMENTS (March 9, 2020) [hereinafter *Scam Coronavirus Treatments*], <https://consumer.ftc.gov/consumer-alerts/2020/03/ftc-fda-warnings-sent-sellers-scam-coronavirus-treatments> [<https://perma.cc/CQN6-E8ZK>] (last visited Jan. 19, 2024). The FTC was established to protect consumers from misleading product advertising. 15 U.S.C. §§ 41-58.

239. SCAM CORONAVIRUS TREATMENTS, *supra* note 238.

240. *Id.*

241. *See id.*

242. Maggie Fox, *FDA to crack down on 'snake oil' homeopathy*, NBC NEWS (Dec. 18, 2017), <https://www.nbcnews.com/health/health-news/fda-crack-down-snake-oil-homeopathy-n830756> [<https://perma.cc/9CK3-53DQ>].

243. *See, e.g., Dent v. State of W. Va.*, 129 U.S. 114, 122–23 (1889); *In re Guess*, 327 N.C. 46, 51 (1990) (*certiorari denied*); *People v. Rogers*, 249 Mich. App. 77 (2001); *State ex rel. Iowa Dep’t of Health v. Van Wyk*, 320 N.W.2d 599 (1982) (“The regulation of health professions, for the preservation and protection of public health, is universally regarded as a duty of the state in the exercise of inherent police power.”).

244. *Clair v. Ctr. Cmty. Hosp.*, 317 Pa. Super. 25, 38–39 (1983).

245. *In re Guess*, 327 N.C. at 49.

revoked his license to practice in the state of North Carolina.²⁴⁶ The North Carolina Supreme Court upheld the revocation of the physician's license, holding that the State has the authority to regulate medical treatment and restrict medical professionals to conform to standards of acceptable and prevailing medical practice.²⁴⁷

Opposition to reversal claims that the abortion pill reversal protocol is unproven, and that states have a right to protect their citizens from unproven treatments.²⁴⁸ Regulation of health, welfare, and safety of the public falls under the authority of the states under the Tenth Amendment.²⁴⁹ Each state has at least one licensing medical board and those boards are vested with the authority to regulate the medical field, particularly where deception or fraud may risk the safety of the public.²⁵⁰ Additionally, the state, either through the legislature or the medical board, has the authority to regulate or ban treatments that have not been proven to be beneficial.²⁵¹ While practitioners do have a duty to keep up with innovations in the medical field pertaining to their practice, such innovations may be monitored and regulated by a state.²⁵²

Furthermore, ACOG argues that politicians should not require that physicians inform patients of unproven or inaccurate information.²⁵³ In *National Institute of Family & Life Advocates v. Becerra*, what most consider a win for the pro-life side,²⁵⁴ the majority recognized the danger of government interference in the doctor-patient relationship and manipulation of open discussions between physicians and patients.²⁵⁵ This case revolved around a California law that required certain facilities, both licensed and unlicensed, to give patients specific notice that California offered “free or low-cost access to comprehensive family planning services” including “prenatal care, and abortion for eligible women” or that the facility was not licensed as a medical facility, respectively.²⁵⁶ The Court found that this language violated the free speech rights of the facilities, finding that content-based restrictions on speech are presumptively unconstitutional and may only be justified if they pass strict scrutiny.²⁵⁷ Invoking *Becerra* as

246. *Id.*

247. *Id.* at 52–53.

248. See AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

249. Lottery Case, 188 U.S. 321, 364–65 (1903).

250. Jacqueline Landess, M.D., J.D., *State Medical Boards, Licensure, and Discipline in the United States*, 17 FOCUS: J. LIFELONG LEARNING PSYCHIATRY 337–42 (2019); Dent v. State of W. Va., 129 U.S. 114, 122 (1889).

251. Landess, *supra* note 250.

252. 61 AM. JUR. 2d *Physicians, Surgeons, and Other Healers* § 197.

253. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

254. Christen Hammock Jones, *A Second Chance at Choice?: Challenging Abortion "Reversal" as Law and Medical Practice*, 29 AM. U. J. GENDER SOC. POL'Y & L. 427, 469 (2021); see also Nat'l. Inst. of Family and Life Advocates v. Becerra, 585 U.S. 755 (2018).

255. *Becerra*, 585 U.S. at 771.

256. *Id.* at 760–64.

257. *Id.* at 766 (quoting *Reed v. Town of Gilbert*, 576 U.S. 155 (2015)).

supportive precedent, federal judges in both Tennessee and North Dakota struck down abortion reversal bills requiring patients to be informed about the possibility of abortion reversal.²⁵⁸

E. Proponents of Reversal

Voices in favor of abortion pill reversal argue that the concerns of those opposed are unbased.²⁵⁹ The safety of progesterone use has been demonstrated for decades.²⁶⁰ Progesterone is also specifically used in pregnant women to help prevent miscarriage or pre-term birth.²⁶¹ Studies show that short-term progesterone use poses no increased risk of harm to a pregnant woman or the unborn fetus.²⁶² Though the efficacy of progesterone use for abortion pill reversal is still being studied, proponents feel confident that the use of progesterone itself in an abortion reversal attempt poses no safety risk for the woman who wishes to try or the unborn child.²⁶³

Furthermore, proponents argue no study exists suggesting that the abortion pill reversal protocol increases any risks associated with mifepristone.²⁶⁴ For the fetus, one study found that incidence of birth defects were only slightly higher (about four percent) in children exposed to mifepristone than the incidence of birth defects in the general population (between two and three percent).²⁶⁵ The study found this “reassuring” for the “continuation of pregnancy after mifepristone exposure.”²⁶⁶ Biologically, it makes sense that mifepristone poses little threat to fetal development itself since mifepristone effects the uterus and placenta directly.²⁶⁷ In other words, mifepristone generally has an “all-or-nothing” effect on the fetus: either the environment becomes uninhabitable for the fetus and it does not survive, or the mifepristone does not have an effect on the development of the fetus at all, providing further support to the pro-

258. *Planned Parenthood Tenn. & N. Miss. v. Slatery*, 523 F. Supp. 3d 985, 1000 (M.D. Tenn. 2021); *AMA v. Stenehjem*, 412 F. Supp. 3d 1134, 1148 (D.N.D. 2019).

259. *Responding to ACOG*, *supra* note 43.

260. PLANNED PARENTHOOD, *supra* note 39; Org. of Teratology Info. Specialists, *supra* note 56; Check et al., *supra* note 56; Di Renzo et al., *supra* note 120.

261. Alsulmi ES, et al., *The use of progesterone during pregnancy to prevent preterm birth*, 41 SAUDI MED J. (2020); Org. of Teratology Info. Specialists, *supra* note 56.

262. Check et al., *supra* note 56 (finding in a survey of almost four hundred women who took progesterone in their first trimester to support their pregnancy that the incidence of birth defects were about the same as that of the general population, comporting with other studies mentioned in the article); Di Renzo, et al., *supra* note 120.

263. *Mythbusters*, *supra* note 43.

264. *Id.*

265. N. Bernard et al., *Continuation of Pregnancy after First-Trimester Exposure to Mifepristone: An Observational Prospective Study*, 120 BJOG: INT’L J. OF OBSTETRICS & GYNAECOLOGY 568–73 (2013).

266. *Id.* at 568.

267. MAYO CLINIC, *supra* note 58.

reversal theory that if the mifepristone can be overpowered, there is no significant risk of an adverse outcome to the fetus.

For the mother, if she wishes to discontinue her abortion, proponents of reversal argue that supplementing with progesterone is the best option, while opponents recommend simply not taking the second abortion pill, misoprostol, as the safest path.²⁶⁸ According to Dr. Creinin's research and the historical control group used by Dr. Delgado, the woman has between a ten to twenty-five percent chance of continuing the pregnancy after ingestion of mifepristone alone.²⁶⁹ Though opponents point to Dr. Creinin's short-lived study where three women were rushed to the emergency room as evidence of the safety concerns of abortion reversal, proponents of reversal protest that this does not accurately tell the full story.²⁷⁰ Two out of five women taking the placebo needed medical attention in comparison to one woman who took progesterone.²⁷¹ Additionally, the two women given the placebo required aspirations, with one even requiring a blood transfusion. In comparison, the woman who had taken progesterone stopped hemorrhaging before she even reached the hospital and before any medical intervention was administered.²⁷² Proponents of abortion pill reversal assert that Dr. Creinin's study actually suggests that progesterone may reduce the risk of adverse medical events after taking mifepristone alone.²⁷³ Additionally, Dr. Yamabe's study on lab rats supports this theory since the lab rats who were treated with mifepristone alone suffered cellular deformities in their reproductive organs, while those that were given progesterone after mifepristone were found to have healthy, regular cellular structures.²⁷⁴

Abortion pill reversal proponents further claim that using progesterone to counter-act a progesterone blocker is a "basic principle in biochemistry."²⁷⁵ Where a naturally occurring substance or "substrate" exists, an inhibitor can compete with the substance, decreasing the effectiveness of the substrate or substance.²⁷⁶ By increasing the amount of the substrate present, the inhibitor can be overpowered and outcompeted by the substrate, canceling the inhibiting effects of the competitive inhibitor.²⁷⁷

268. *Responding to ACOG*, *supra* note 43.

269. Creinin et al., *supra* note 33; Delgado et al., *supra* note 33; Katherine A Rafferty & Tessa Longbons, Medication Abortion and Abortion Pill Reversal: *An Exploratory Analysis on the Influence of Others in Women's Decision-Making*, 15 CUREUS (Dec. 2023).

270. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43; *Mythbusters*, *supra* note 43.

271. Creinin et al., *supra* note 33.

272. *Id.*

273. *Mythbusters*, *supra* note 43.

274. Yamabe et al., *supra* note 112.

275. *Responding to ACOG*, *supra* note 43; JOHN W. PELLEY, ELSEVIER'S INTEGRATED REV. BIOCHEMISTRY 33–34 (J. Hurley Myers et al. eds., 2d ed. 2012).

276. PELLEY, *supra* note 275.

277. *Id.*

Dr. Brent Boles, a Board-certified OBGYN and Medical Director of Abortion Pill Rescue Network, asserts that counteracting a hormone blocker with a hormone supplement is a concept that has been used in hormone replacement therapy for thirty years.²⁷⁸ Dr. Boles remembers being in residency and taking part in a research study with the same biological principle regarding estrogen blockers for the treatment of breast cancer.²⁷⁹ When estrogen receptors were blocked by the drug, supplementing a woman's estrogen supply overcame the blocker.²⁸⁰ For example, adding sugar to coffee "competes" with the bitterness of the coffee, but if you add more coffee to the cup, the coffee can overpower the effects of the sugar. Mifepristone acts as the inhibitor, competing with progesterone to prevent progesterone receptors from binding with progesterone.²⁸¹ As Delgado theorized, if progesterone floods the receptors, mifepristone could be rendered ineffective as the progesterone overpowers the effects of the mifepristone.²⁸²

It is also important to note that not all supporters of abortion pill reversal identify as pro-life. Harvey Kliman, Director of the Reproductive and Placental Research Unit at the Yale School of Medicine and proponent of abortion rights, acknowledges that the biological principles make sense and calls abortion pill reversal "totally feasible."²⁸³ He went so far as to say he would recommend progesterone supplements to one of his own daughters if she were exposed to mifepristone during pregnancy.²⁸⁴ Additionally, Dr. Daniel Grossman, a professor at the University of California at San Francisco in the Bixby Center for Global Reproductive Health and critic of pro-life laws around abortion pill reversal, agrees that the science behind abortion pill reversal makes "some biological sense."²⁸⁵

Regarding the alleged flaws in the studies on abortion pill reversal, proponents such as AAPLOG acknowledge the studies do not meet the "gold standard" of a double-blind clinical trial, but contend that the limitations do not make a study scientifically invalid because all studies

278. Telephone interview with Dr. Brent Boles, *supra* note 137.

279. *Id.*

280. *Id.*

281. *Practice Guideline 6: The Reversal of the Effects of Mifepristone by Progesterone*, AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS (2022), <https://aaplog.org/wp-content/uploads/2023/01/PG-6-Reversal-of-the-Effects-of-Mifepristone-by-Progesterone.pdf> [<https://perma.cc/9DTC-ZPGP>].

282. *Id.*

283. Graham, *supra* note 34.

284. *Id.*

285. Ariana Eunjung Cha, *As Controversial 'Abortion Reversal' Laws Increase, Researcher Says New Data Shows Protocol Can Work*, WASH. POST (Apr. 4, 2018), <https://www.washingtonpost.com/news/to-your-health/wp/2018/04/03/as-controversial-abortion-reversal-laws-multiply-researcher-says-new-data-shows-it-can-work-critics-are-still-skeptical/>.

have limitations.²⁸⁶ The key to any empirical study is to acknowledge the limitations present and understand the impact that those limitations may have on the results.²⁸⁷ Though opponents of reversal argue that no control group was used in the 2018 study yielding a sixty-four to sixty-eight percent survival rate of the embryo,²⁸⁸ proponents of reversal point out that no control group was used under the FDA approval of mifepristone either.²⁸⁹ Both mifepristone and the progesterone therapy utilized historical controls, as using a placebo in these studies would prove unethical.²⁹⁰ This is not uncommon.²⁹¹ Historical control groups are often used in studies and are acceptable where a randomized clinical control is not possible, most notably here, where ethical concerns are involved regarding patients.²⁹² The Delgado study reasoned that including a control group would require a group of women who regret their abortion and are trying to prevent the death of their child in utero to take a placebo and not receive the treatment for which they have signed up.²⁹³

Further, Dr. Boles clarified and the study itself confirms that the 2018 Delgado study was indeed approved by an institutional review board.²⁹⁴ Although pressure from opponents caused the institution to withdraw its approval before the trial was completed, Dr. Boles shared that Dr. Delgado successfully defended his study to the institutional review board and they subsequently re-approved the completion of the study and its publishing.²⁹⁵

Regarding the efficacy of treatment, the abortion pill reversal process is relatively new in the medical world, but advocates for reversal continue to study its use and effectiveness.²⁹⁶ Dr. Delgado's studies are only

286. *Responding to ACOG, supra* note 43; Paula T. Ross & Nikki L. Bibler Zaidi, *Limited by our limitations*, 8 PERSPS. MED. EDUC. 261–64 (Aug. 2019).

287. Ross & Zaidi, *supra* note 286.

288. Delgado et al., *supra* note 33; AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 43.

289. *Ru-486: Demonstrating A Low Standard For Women's Health?, Hearing before the S. Comm. on Crim. Just., Drug Pol'y, and Hum. Res. of the Comm. on Gov't Reform*, 109th Cong. (2006) [hereinafter *RU-486 Hearing*].

290. *Responding to the Campaign to Ban Reversal of Mifepristone in Colorado*, AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS (Sept. 27, 2023), <https://aaplog.org/responding-to-the-campaign-to-ban-reversal-of-mifepristone-in-colorado/> [https://perma.cc/CVE3-Q5RH].

291. *RU-486 Hearing, supra* note 289, at 114.

292. Mercedeh Ghadessi, et al., *A Roadmap to Using Historical Controls in Clinical Trials – by Drug Information Association Adaptive Design Scientific Working Group*, 15 ORPHANET J RARE DIS. 69 (2020).

293. Delgado et al., *supra* note 33, at 28.

294. Telephone interview with Dr. Brent Boles, *supra* note 137; Delgado et al., *supra* note 33 at 24.

295. Telephone Interview with Dr. Brent Boles, *supra* note 137.

296. See *Abortion Pill Rescue Network*, HEARTBEAT INT'L, <https://www.heartbeatinternational.org/our-work/apr> [https://perma.cc/3LJK-97JP] (last visited Jan. 19, 2024); Delgado et. al, *supra* note 33, at 29.

the beginning as he laid the groundwork for progesterone use in reversals and researching the proper dosage.²⁹⁷ To date, Heartbeat International, the parent organization of Abortion Pill Rescue Network has documented over 5,000 pregnancies that were successfully saved after administration of mifepristone, and they continue to study the efficacy of abortion pill reversal through progesterone.²⁹⁸ The ACOG's own Practice Bulletin 225 on medication abortion acknowledges the potential for progesterone to impact the effectiveness of mifepristone.²⁹⁹ The ACOG recommends that women taking mifepristone refrain from taking depot medroxyprogesterone acetate (DMPA), a progestin-only birth control, on the same day on the grounds that this combination increases the risk of an ongoing pregnancy.³⁰⁰ Additionally, the ACOG published a study of over 400 women and concluded that the women who received the DMPA shot around the same time of mifepristone administration increased their chances of continuing their pregnancies.³⁰¹ This study seems to further support the research showing that progesterone can indeed counteract the effects of the mifepristone.³⁰²

III. ARGUMENT

No matter what side of the abortion issue one chooses, all can agree that abortion is a sensitive topic and is not an easy decision.³⁰³ Many women wrestle with the decision before choosing to abort, parent, or place the child for adoption.³⁰⁴ Women who change their minds and seek to reverse their abortions may be in the minority of medical abortions in the United States,³⁰⁵ but as Dr. Grossman commented on the number of women changing their minds, “. . . it's not zero.”³⁰⁶ Just because they are in the

297. See 2019 AAPLOG Position Statement on Abortion Pill Reversal, AM. ASS'N OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, <https://aaplog.org/wp-content/uploads/2019/02/2019-AAPLOG-Statement-on-Abortion-Pill-Reversal.pdf> [<https://perma.cc/6HB5-DTH9>] (last visited July 2, 2024).

298. *Impact Report*, *supra* note 140.

299. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 62.

300. *Id.*

301. Elizabeth G. Raymond, MD, MPH, *Effects of Depot Medroxyprogesterone Acetate Injection Timing on Medical Abortion Efficacy and Repeat Pregnancy: A Randomized Controlled Trial*, 128 *OBSTETRICS & GYNECOLOGY* 739, 739–45 (2016).

302. Delgado et al., *supra* note 33, at 29; *Impact Report*, *supra* note 140.

303. E.g., M Törnbohm et al., *Decision-Making about Unwanted Pregnancy*, 78 *ACTA OBSTETRICIA ET GYNECOLOGICA SCANDINAVICA* 636–41 (1999); *What Facts About Abortion Do I Need to Know?*, PLANNED PARENTHOOD, <https://www.plannedparenthood.org/learn/abortion/considering-abortion/what-facts-about-abortion-do-i-need-know> [<https://perma.cc/JH23-5RFW>] (last visited Jan. 19, 2024); see Rocca et al., *supra* note 26, at 2–4; Coleman, *supra* note 29, at 180.

304. Törnbohm et al., *supra* note 303, at 636.

305. See Rocca et al., *supra* note 26; Coleman, *supra* note 29.

306. Eunjung Cha, *supra* note 285.

minority need not determine whether they should be informed of any chance of changing their choice.

The abortion pill reversal protocol may be relatively new to the medical world, but that should also not determine whether a woman may have access to information should she change her mind. For example, Ozempic was approved by the FDA in 2017 to treat type II diabetes.³⁰⁷ Within five years, it became highly sought after for weight loss.³⁰⁸ Progesterone, on the other hand, has been FDA-approved for more than five decades³⁰⁹ and has been safely used in pregnant women.³¹⁰ Still, the political temperature of the issue of abortion has made a decades-old supplement more controversial than a drug that has only been around for six years.³¹¹

Like many approved treatments that find applicability in alternate remedies, use of progesterone to reverse the effects of mifepristone is still being studied. Currently, the studies discussing the efficacy of progesterone use to reverse the effects of mifepristone are limited by the practical problems of finding women in the short seventy-two hour window of taking mifepristone who desire to reverse its effects. However, the Abortion Pill Rescue Network continues to track the use and efficacy of abortion pill reversal, detailing over 5,000 successful abortion reversals to date and continuing to monitor the success rate among women who undergo treatment.³¹² Reports show around 300 calls per month are made to Abortion Pill Rescue Network.³¹³ Of those calls, between 150-200 qualify and elect to begin the progesterone protocol.³¹⁴ Around sixty-six percent of those who begin the protocol report successfully reversing the effects of

307. U.S. FOOD & DRUG ADMIN., OZEMPIC APPROVAL (Dec. 5, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209637Orig1s000Approv.pdf (last visited Jan. 19, 2024); Dani Blum, *What Is Ozempic and Why Is It Getting So Much Attention?*, N.Y. TIMES (Nov. 22, 2022), <https://www.nytimes.com/2022/11/22/well/ozempic-diabetes-weight-loss.html> [<https://perma.cc/BFA5-MXZF>] (last visited Jan. 19, 2024).

308. See Blum, *supra* note 307 (#Ozempic has been viewed over 273 million times on TikTok where people shared their stories of the drug's effectiveness).

309. Ali et al., *supra* note 44.

310. Farine, et al., *supra* note 44, at 69.

311. See, e.g., Christine Fernando & Andrew DeMillo, *Abortion Debate Creates 'New Era' for State Supreme Court Races in 2024, with Big Spending Expected*, ASSOCIATED PRESS (Dec. 29, 2023), <https://news.yahoo.com/abortion-debate-creates-era-state-194708917.html> [<https://perma.cc/W86E-T2RQ>]; María Méndez, *Vouchers, Border Security, Abortion: The Issues You Heard about in 2023 Will Continue to be Hotly Debated in 2024*, TEXAS TRIBUNE (Jan. 1, 2024), <https://www.msn.com/en-us/news/us/vouchers-border-security-abortion-the-issues-you-heard-about-in-2023-will-continue-to-be-hotly-debated-in-2024/ar-AA1miH5U?ocid=socialshare> [<https://perma.cc/X5ZD-ABYT>].

312. Telephone interview with Dr. Brent Boles, *supra* note 137.

313. *Id.*

314. *Id.* (qualifications include being in the twenty-four to seventy-two-hour window and an ultrasound to confirm heartbeat still present for progesterone supplementation).

mifepristone.³¹⁵ Even the highest estimates of continued pregnancies after taking mifepristone alone are around twenty-five percent.³¹⁶

Further, arguments questioning the safety of taking mifepristone alone, as insinuated in Dr. Creinin's study, have problems. First, abortion proponents claim that mifepristone is "safer than Tylenol."³¹⁷ Such claims are founded on a FDA report numbering the deaths related to mifepristone reported between mifepristone's FDA approval date through December 31, 2022.³¹⁸ Second, many abortion providers and the ACOG recommend that if a woman changes her mind about her abortion, the best thing to do is simply not to take the second pill, misoprostol.³¹⁹ However, it seems contradictory to claim mifepristone is safer than Tylenol and a woman's best course of action if she regrets the first pill is to simply refrain from taking the second pill, while also claiming that Dr. Creinin's study raised a question of safety in not completing the abortion. The only common denominator of the women who hemorrhaged during the double-blind study was not progesterone but mifepristone.³²⁰ The outcomes of multiple women experiencing adverse events, while indeed concerning, show that more research needs to be done on the effects of mifepristone. Yet, mifepristone is prescribed in sixty-three percent of the more than one million abortions per year in the United States.³²¹

To the contrary, the limited evidence of progesterone's interaction with mifepristone suggests that progesterone may help to counteract some of the risky effects of mifepristone. Though conclusions cannot be drawn with certainty due to the size of the group of women in Dr. Creinin's study who did hemorrhage, the two who took mifepristone and the placebo required medical aspirations. However, the one who received the progesterone supplement did not ultimately need any medical treatment; she completed the abortion without medical intervention.³²² Dr. Yamabe's study of rats would also suggest progesterone counters negative effects of mifepristone. One hundred percent of the rats receiving progesterone delivered live offspring, and any cellular degeneration of the uterine tissue seen in the rats who received mifepristone alone was not present in those who received the progesterone supplement.³²³

315. *Id.*

316. Creinin et al., *supra* note 33; Delgado et al., *supra* note 33, at 23; Rafferty & Longbons, *supra* note 269, at 1.

317. *How Safe is the Abortion Pill?*, PLANNED PARENTHOOD, <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-safe-is-the-abortion-pill> [<https://perma.cc/QSS4-AVU7>] (last visited Jan. 20, 2024).

318. *Id.*; U.S. FOOD & DRUG ADMIN., MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2022 <https://www.fda.gov/media/164331/download> [<https://perma.cc/7VPT-FUXH>] (last visited Aug. 9, 2024).

319. See AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 62.

320. Creinin et al., *supra* note 33, at 158–61.

321. Jones & Friedrich-Karnik, *supra* note 69.

322. Creinin et al., *supra* note 33, at 158–61.

323. Yamabe et al., *supra* note 112, at 497–98; Delgado et al., *supra* note 33, at 23.

With progesterone being established over the last five decades as safe and some evidence pointing to its efficacy to reverse an abortion, states like Colorado start to lose their footing in terms of having a rational basis for preventing medical professionals from counseling patients on abortion pill reversal and prescribing progesterone accordingly. As discussed, states have a right to regulate the medical field to prevent misleading information. However, abortion pill reversal is not like *In re Guess*³²⁴ where the doctor was prescribing alternative medicine in lieu of FDA-approved treatments. Here, the treatment is FDA-approved and there is no alternative treatment available for a woman to try to continue her pregnancy after the medication abortion has started.³²⁵ So, by prescribing progesterone, physicians do not forego better or more effective treatments but rely on their medical rationale, existing research, and known safety to prescribe progesterone.

At the time of writing this paper, no news of a medical malpractice claim has been filed against a medical professional for off-label prescribing of the abortion pill reversal protocol. Based on the FDA's requirements, such a claim would likely be unsuccessful. A physician prescribing the abortion pill reversal protocol is prescribing progesterone in good faith, in the best interest of the patient, and without fraudulent intent.³²⁶ Furthermore, in keeping with the recommendations from the Mayo Clinic for off-label treatments, the physician has peer reviewed literature that gives plausibility to the treatment; treatment would be medically necessary to give the patient the best chance currently known at reversing the abortion; and the treatment is nonexperimental because progesterone does have FDA approval.³²⁷

As long as the physician has sound scientific rationale, medical evidence, procures informed consent, and maintains records of the effects of progesterone on a patient, he or she should, within one's judgment as a physician, be able to prescribe progesterone.³²⁸ If medical providers obtain informed consent, meaning women are properly informed about the nature of progesterone treatment after ingestion of mifepristone, the probability of success of the treatment, as well as any known risks of treatment, which at this time are unknown, women should not be denied the choice to attempt to reverse the effects of mifepristone.

The right to try laws also support a medical professional's ability to prescribe and a patient's right to attempt abortion pill reversal. If drugs that are not approved can be given to terminally ill patients as long as informed consent is obtained, how much more so should an FDA-approved treatment, which could potentially be life-saving for a fetus without causing risk to the mother, be accessible? Right to try laws bolster support for the informed

324. *In re Guess*, 327 N.C. 46, 51 (1990) (certiorari denied).

325. Ferguson & Patel, *supra* note 172.

326. Wittich et al., *supra* note 176, at 987.

327. *Id.*

328. *Id.*

consent of the medication abortion protocol to include abortion pill reversal. Where right to try laws allow patients to try experimental treatments lacking FDA approval,³²⁹ progesterone has been approved for over fifty years and has been used in pregnant women for decades.³³⁰ Use of such a treatment would not need a right to try law for it to be acceptable for a physician to counsel his or her patient or even prescribe. Yet, Colorado, the first state to champion right to try laws for unapproved, experimental treatments,³³¹ was also the first to label the progesterone abortion reversal treatment as medical malpractice and to demand that doctors keep a potentially life-saving treatment out of the reach of patients.³³² If patients have the right to try novel and experimental medications with unknown outcomes, pregnant women who want to save their pregnancies should get that choice with a treatment that has been shown to be safe in pregnant women long before its use to attempt abortion reversals.

For Colorado and Vermont, the question must be asked: why not? These states are tying the hands of their physicians in the name of safety, restricting them from using their sound medical judgment that the average legislator does not possess. These states claim bodily autonomy but refuse to allow women to change their minds and attempt a treatment that has been shown to be safe. Even if the efficacy is not universally agreed upon, the risk-reward scale tips heavily in favor of allowing a woman to try a treatment that will not harm her for the chance to save a pregnancy that she wants and potentially avoid the mental anguish that comes with regret.³³³

Of course, states should be concerned that their patients are fully informed about the treatments they receive, and medical professionals have an ethical duty to inform patients of the good, the bad, and the ugly.³³⁴ In so doing, the patient is placed as the priority, ensuring she can “call the shots” regarding her own health. With respect to abortion reversal, a patient should be allowed to make that decision if she feels the benefits outweigh the risks. In order to do so, she must be informed that the abortion pill reversal protocol does exist and has shown to be effective in over 5,000 other women.³³⁵ This way, if she feels she made the wrong choice, no matter how rare that feeling may be, her choice does not have to be final. Furthermore,

329. U.S. FOOD & DRUG ADMIN., *supra* note 206.

330. *See* Ali et al., *supra* note 44; Farine, et al., *supra* note 44; Mesiano et al., *supra* note 44.

331. Parson, *supra* note 211.

332. Jennifer Brown, *Colorado Medical Board finds that so-called abortion reversal is outside “generally accepted standard of practice”*, COLO. SUN (Aug. 17, 2023, 2:10 PM), <https://coloradosun.com/2023/08/17/abortion-reversal-pill-medical-board/> [<http://perma.cc/9WP6-VFAD>]; *see also* S.B. 190. 2023 Gen. Assemb., Reg. Sess. (Colo. 2023).

333. *See* Coleman, *supra* note 29, at 183.

334. *See, e.g.*, Ritter v. Delaney, 790 S.W.2d 29 (Tex. App. 1990); Masquat v. Maguire, 1981 OK 137, 638 P.2d 1105; Cobbs v. Grant, 502 P.2d 1, 9 (1972).

335. *Impact Report*, *supra* note 140.

if the treatment does not work, she can take some solace in knowing that she tried.

An easier case to make is that abortion providers should be required to inform patients of the possibility to reverse the abortion as part of the informed consent process. Although opponents of abortion pill reversal laws invoke *Becerra* as support for preventing states from requiring informed consent to include reversal, the majority opinion is careful to differentiate the ability to regulate speech in two specific contexts of professional medical conduct.³³⁶ First, the Court has allowed for required dissemination of information by medical professionals that is “factual” and “noncontroversial.”³³⁷ Abortion and its related issues are, in Justice Clarence Thomas’s words, “anything but [] uncontroversial.”³³⁸ Second, states may regulate “professional conduct that incidentally involves speech.”³³⁹ Both the federal and state governments regulate conduct incidental to speech through regulations regarding informed consent, an absence of which constitutes medical malpractice.³⁴⁰

States are granted broad discretion in regulating commerce and protecting citizens, specifically controlling the dispensing of medication.³⁴¹ Such regulation must be rationally related to a legitimate legislative interest, a historically low bar.³⁴² Although a state cannot violate first amendment rights in regulating professional conduct,³⁴³ the First Amendment is not offended by restrictions on conduct that incidentally affects speech.³⁴⁴ Healthcare professionals may be required to share specific information to comply with informed consent regarding all kinds of medical procedures.³⁴⁵ Though medical practitioners may not be forced to post signs disclosing the availability of services provided by the state as in *Becerra*, they are frequently required to comply with standards of informed consent.³⁴⁶

Using *Planned Parenthood of Southeastern Pennsylvania v. Casey* as its prime example, the *Becerra* Court outlined how a state may require

336. Nat’l Inst. of Fam. & Life Advocates v. *Becerra*, 585 U.S. 755, 761 (2018).

337. *Id.*

338. *Id.*

339. *Id.*

340. *Id.* at 2372–73; Edward L. Raab, *The Parameters of Informed Consent*, 102 TRANSACTIONS OF THE AM. OPHTHALMOLOGICAL SOC’Y 225, 225–26 (2004).

341. *Whalen v. Roe*, 429 U.S. 589, 597 (1977).

342. *Id.*; *see, e.g.*, *United States v. Carolene Products* 304 U.S. 144, 152 (1938); *Williamson v. Lee Optical*, 348 U.S. 483, 487–88 (1955); *see also* *Queenside Hills Realty Co. v. Saxl* 328 U.S. 80, 83 (1946); *Heller v. Doe*, 509 U.S. 312, 319 (1993).

343. *NAACP v. Button*, 371 U.S. 415, 438 (1963).

344. *Becerra*, 585 U.S. at 761.

345. *Id.*

346. *Canterbury v. Spence*, 464 F.2d 772, 786–87 (D.C. Cir. 1972) (explaining that the test for determining when a doctor should tell a patient a “particular peril” is when the peril would be material to the patient’s decision).

doctors to provide certain information.³⁴⁷ In *Casey*, the Court rejected a free-speech challenge of a Pennsylvania law requiring physicians to provide certain disclosures, including information on fetal development and options available to a woman should she change her mind.³⁴⁸ The Court saw no issue with a state requiring information be given to a woman regarding the consequences of her choice so that she would be fully informed in making her decision.³⁴⁹ Although *Casey* has since been overturned on other grounds, the same Roberts Court that overturned *Casey* reaffirmed the rejection of a first amendment application in *Becerra* where states require a physician to give a woman certain information regarding her abortion to properly obtain informed consent.³⁵⁰

By requiring patients to be informed of the abortion pill reversal as part of informed consent, states are acting within their police power to protect their citizens and regulate the commerce of the distribution of medication. In *Webster v. Reproductive Health Services*, the Court recognized a state's legitimate interest in conveying its support for childbirth.³⁵¹ Even *Roe v. Wade* recognized the important state interest of protecting maternal health and "potentiality of human life."³⁵² States can require that patients are fully informed of not only the physiological events occurring³⁵³ and the risks of the treatment selected³⁵⁴ but also the alternatives available.³⁵⁵ A state's interest in a woman being fully informed prior to her abortion is even more substantial considering the brief, seventy-two hour window in which the option of reversal is available.

Informing a woman of a possibility to reverse her choice to abort would appear to be reasonably related to a woman's "full knowledge of the risk involved and the alternative[s]." ³⁵⁶ Since progesterone is FDA-approved and there is no evidence that short-term use of progesterone in pregnant women causes harm to mother or fetus, the risk related to informing the woman is low.³⁵⁷ Although the treatment is used off-label,

347. *Becerra*, 585 U.S. at 761.

348. *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992) (overturned on other grounds by *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022)).

349. *Id.*

350. *Becerra*, 585 U.S. at 761–62 (overturning *Casey* by returning abortion regulation to the states alone).

351. *Webster v. Reprod. Health Servs.*, 492 U.S. 490, 511 (1989); *Poelker v. Doe*, 432 U.S. 519, 521 (1977).

352. *Roe v. Wade*, 410 U.S. 113, 162 (1973) (overturned by *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022)).

353. *See Gonzales v. Carhart*, 550 U.S. 124, 159 (2007).

354. *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

355. *Id.* at 881–82.

356. BLACK'S LAW DICTIONARY, *supra* note 197.

357. *Check et al.*, *supra* note 56; *Farine et al.*, *supra* note 44, at 69; *Delgado et al.*, *supra* note 33, at 26.

that does not make the treatment investigational.³⁵⁸ Including information about a potential reversal puts the control back into the hands of the patient, giving her the confidence that all of her options are in front of her. Doing so would prevent any woman from the potentially greater emotionally damaging risk of finding out about abortion pill reversal after it is too late and forever wondering if her outcome would have been different had she known about the alternative.

Furthermore, such informed consent is unlikely to lead to more women making a reckless decision, choosing the abortion pill with the imagination that it can just be reversed if she changes her mind, since reversal is not a guarantee. Rather, since the administration of progesterone is time-sensitive, requiring informed consent at the start of the abortion pill process ensures that the patient, if she does change her mind, is knowledgeable about the potential of reversal and has as much time as possible to change her mind. In Nurse Diandra's experience, most women she has spoken with through APRN reached out to the hotline within the first six hours of taking the abortion pill, many even from the parking lot of the abortion clinic or on their way home.³⁵⁹

It stands to reason then that a state could and should require a "reasonably prudent provider in the medical community" to inform a patient regarding both the risks involved in the abortion pill and the possibility to change her mind through abortion pill reversal.³⁶⁰ Dr. Grossman, who focuses his research on improving safe access to abortion, shared that he does think women who change their minds "should be given the best available information about what they should do."³⁶¹ If the best available information safely gives women a second chance, even if not guaranteed, is it not the responsibility of medical professionals to allow women to make an educated and informed decision?

CONCLUSION

Abortion reversal with progesterone is safe. Studies thus far point to it being effective in reversing the effects of mifepristone without increasing the risk of birth defects or harm to the mother. Though used off-label, progesterone has been used for decades in pregnant women to support continuation of pregnancy, and physicians regularly prescribe off-label medications for many uses for which they have a rational, scientific basis. Physicians are free to prescribe such medications so long as they obtain informed consent from their patients, by disclosing the risks, side effects, and probability of outcomes. Furthermore, federal and state laws asserting the right to try unapproved treatments support a woman's right to attempt

358. Beck & Azari, *supra* note 175, at 85.

359. Interview with Diandra Bell, *supra* note 4.

360. BLACK'S LAW DICTIONARY, *supra* note 197.

361. Eunjung Cha, *supra* note 285.

the FDA-approved treatment of progesterone, the side effects of which are minimal and well-known. States should not only allow a woman to choose to attempt to save her pregnancy if she changes her mind, but states should strongly consider adding information regarding the possibility of reversing an abortion to the informed consent requirement when a woman seeks a medication abortion. Since knowledge is power, states should empower women to be fully educated about the choice they are making and the potential alternative available to them.

The right to try should not be infringed – the Abortion Pill Reversal Network has seen the success of progesterone in counter-acting the effects of mifepristone more than 5,000 times with that number growing each month.³⁶² If states grant women the choice to terminate their pregnancies, women should also be afforded the choice to change their mind and try to save their pregnancies as well.

362. See Telephone interview with Dr. Brent Boles, *supra* note 137; *Impact Report*, *supra* note 140; *Mythbusters*, *supra* note 43.