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A Second Chance at Choice?: Challenging Abortion “Reversal” as Law and Medical Practice

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A SECOND CHANCE AT CHOICE?: CHALLENGING ABORTION “REVERSAL” AS LAW AND MEDICAL PRACTICE

CHRISTEN HAMMOCK JONES*

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INTRODUCTION

I felt like my soul was crying and pleading with the Lord on behalf of my baby's life. I know God heard my prayer because Elizabeth called me back with the answer to my prayers: Patsy and Willie from the San Juan Diego center. I went to see Patsy the next morning at 7 am, less than 12 hours since I took the first pill. Of course, I was nervous, but I decided I had to trust the solution that God had provided me with. The morning I was scheduled to go and see Patsy, she called me and made sure I was coming, she even asked if I needed a ride. I took her call as a sign that I was doing the right thing . . . Everything fell into place after that and I remember hearing my son's heartbeat for the first time around Thanksgiving. Then in July, I gave birth to a perfectly healthy, beautiful 9 1/2 pound baby named Ezekiel which means 'God strengthens' because that's what God did. He protected and strengthened my baby against the abortion pill's effects through Dr. Delgado and Dr. Davenport's reversal process.

Emily's Story, Abortion Pill Rescue

"Emily's Story" comes from a testimonial on the website for Abortion Pill Rescue, a group that claims they can "reverse" medication abortion by injecting patients with progesterone, a hormone that supports pregnancy.¹ "Abortion Pill Reversal" was born in 2009 when Dr. George Delgado, an anti-choice Catholic physician who provides "Christ-centered medical care,"² encountered a patient who had taken the first half of the medication

1. *Abortion Pill Reversal Success Stories*, ABORTION PILL RESCUE, abortion-pill-reversal/success-stories (last visited Sept. 21, 2021); see generally *Our Passion*, HEARTBEAT INT'L, <https://www.heartbeatinternational.org/about/our-passion> (last visited Sept. 21, 2020) (Abortion Pill Rescue is part of the pro-life organization Heartbeat International, the mission of which is to "make abortion unwanted today and unthinkable for future generations" and to "reach and rescue as many lives as possible, around the world, through an effective network of life-affirming pregnancy help.").

2. Jessica Glenza, *Doctor Claiming to 'Reverse' Abortion Was Told to Stop Using Medical School's Name*, THE GUARDIAN (July 25, 2019, 1:00 PM), <https://www>

abortion regimen then changed her mind. Delgado decided to give the patient a high dose of progesterone without any evidence about its efficacy in halting medication abortion or clinical data about the safety of such a protocol. Fortunately, the patient was fine and gave birth to a baby boy later that year.³ Based on this incident, Delgado decided to expand his “protocol” to six other patients and published the results of this small case study in the journal *The Annals of Pharmacotherapy* along with co-author and fellow anti-choice physician, Mary Davenport.⁴ This “protocol” has never been approved by the Food & Drug Administration (“FDA”) and has been widely denounced by medical groups like the American College for Obstetricians and Gynecologists (“ACOG”) and the American Medical Association as unfounded and unsafe.⁵

Claims by individual doctors that they can reverse medication abortion pose a significant danger to patient safety and health. Even more troubling is that nine states—Arkansas, Idaho, Kentucky, Nebraska, South Dakota, Utah, Indiana, Montana, and Louisiana—currently require abortion providers to share information about reversal with their patients as part of the informed consent process that must take place before an abortion.⁶ This means that abortion providers are forced, under penalty of law, to lie to their patients and encourage them to seek out a potentially dangerous procedure.⁷

.theguardian.com/world/2019/jul/25/revealed-doctor-reverse-abortion-trump-administration.

3. See generally *Planned Parenthood Tenn. and N. Miss. v. Slatery*, No. 3:20-cv-00740, 2021 U.S. Dist. LEXIS 36422, at *1, *3 (M.D. Tenn. Feb. 26, 2021) (overviewing the pool of patients in the human studies).

4. See George Delgado & Mary L. Davenport, Case Studies: *Progesterone Use to Reverse the Effects of Mifepristone*, 46 THE ANNALS OF PHARMACOTHERAPY 1723, e36 (2012).

5. *Facts are Important: Medication Abortion “Reversal” Is Not Supported by Science*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, <https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science> (last visited Sept. 21, 2021); see generally *Compl. at 1*, Am. Med. Ass’n v. Stenehjem, Case No. 1:19-cv-125 (D.N.D., filed June 25, 2019) (filing lawsuit against North Dakota Attorney General to challenge North Dakota’s H.B. 1336, which required physicians to tell their patients about abortion reversal).

6. *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (Sept. 1, 2021), <https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion>. (noting that three other states—North Dakota, Oklahoma, and Tennessee—successfully passed reversal laws, but those laws are currently temporarily enjoined).

7. When states first began passing abortion reversal laws, the primary concern was that the abortion reversal protocol was ineffective. Recently, though, an OB/GYN who received a grant to test the use of progesterone in halting abortion had to cut his study short when several patients required emergency treatment. See generally Kayla Epstein,

These laws are part of a larger and well-documented effort by anti-choice advocates to weaponize informed consent laws and use doctors as mouthpieces for an anti-choice agenda.⁸ Typically, patients rely on the state to *prevent* medical professionals from disseminating misleading information and promoting dangerous, untested procedures. As reproductive health physicians Drs. Daniel Grossman and Kari White have argued, laws promoting abortion reversal represent a “disturbing intrusion” into the doctor-patient relationship and “encourage women to participate in an unmonitored research experiment.”⁹ Ironically, these laws also compromise providers’ ability to confirm that patients are confident in their abortion decisions and may actually encourage uncertain patients to proceed with an abortion because they think they can “undo” it.

This Article considers abortion reversal as both a troubling legislative trend and a dangerous medical practice. Part I explains how medication abortion works and examines the pseudo-science underlying these “abortion reversal” bills. Part II surveys reversal bills that have appeared (to varying degrees of success) in state legislatures across the country over the last six years. Part III situates reversal bills within the larger movement to wield informed consent as a tool to inject anti-choice ideology into the abortion decision making process. Part III also reviews successful challenges to reversal legislation on the grounds that the laws violate physician’s First Amendment rights against compelled speech and proposes that litigators make complementary “compelled listening” claims on behalf of patients.¹⁰

Finally, Part IV considers challenges to abortion reversal as medical practice. In addition to being expensive and time-consuming, litigation only

Some Lawmakers Push ‘Abortion Reversal’ Treatments. A Study Shows How Dangerous They Are, WASH. POST (last visited Dec. 24, 2019), <https://wapo.st/3gaXYKx> (stating that when states first began passing abortion reversal laws, the primary concern was that the abortion reversal protocol was ineffective. Recently though, an OB/GYN who received a grant to test the use of progesterone in halting abortion had to cut his study short when several patients required emergency treatment).

8. See, e.g., Ian Vandewalker, *Abortion & Informed Consent: How Biased Counseling Laws Mandate Violation of Medical Ethics*, 19 MICH. J. GENDER & L. 1, 3 (2012) (opining that abortion-specific regulations are driven by moral opposition to abortion).

9. Daniel Grossman & Kari White, *Abortion “Reversal”—Legislating without Evidence*, 379 NEW ENG. J. OF MED. 1491, 1491 (2018) (hereinafter Grossman & White, *Legislating without Evidence*).

10. See, e.g., *Am. Med. Ass’n v. Stenehjem*, 412 F. Supp. 3d 1134, 1134 (D.N.D. 2019). The as-yet-unrecognized right against being compelled to listen to a government-mandated message comes from Caroline Mala Corbin’s article *The First Amendment Right Against Compelled Listening*, *infra* note 195.

targets reversal as *law* and does nothing to prevent the proliferation of abortion reversal in the medical field. Because reversal threatens patient safety even in states where no reversal mandate exists, this Article proposes alternative methods for holding reversal proponents and practitioners accountable, including informed consent legislation and professional regulation of medical professionals and researchers who claim they can reverse abortions.

I. THE PSEUDO-SCIENCE OF “ABORTION REVERSAL”

This section provides the relevant medical background about how medication abortion works and analyzes the claim that injecting patients with progesterone can “reverse” a medication abortion. In short, there is no good evidence suggesting reversing a medication abortion is possible, much less sufficiently reliable to justify legislation requiring physicians to include information about abortion reversal as part of their standard informed consent process.

A. *How Medication Abortion Works*

Abortion can be accomplished by procedures like aspiration or by taking medication that ends the pregnancy.¹¹ Because medication abortion feels more “natural,” does not require the insertion of any instruments, and can be completed safely at home, many abortion patients prefer this method.¹² Indeed, nearly 40% of abortions in the United States are completed with medication.¹³ Medication abortion is also incredibly safe. In one comprehensive study of over 230,000 patients, only 0.16% experienced “significant adverse outcomes” like requiring a blood transfusion or transfer to an emergency room.¹⁴ As a point of comparison, abortion is about as risky

11. *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, 136 AM. COLL. OF OBSTETRICS & GYNECOLOGY e31, e32 (Oct. 2020).

12. Pak Chung Ho, *Women’s Perceptions on Medical Abortion*, 74 CONTRACEPTION 11, 11 (2006) (“[T]he most commonly given reasons for choosing medical abortion are as follows: (a) fear of surgery or general anesthesia, which women want to avoid with medical abortion; (b) perception that medical abortion is safer than surgical abortion; and (c) perception that medical abortion is more natural than surgical abortion.”)

13. *Fact Sheet: Induced Abortion in the United States*, GUTTMACHER INST. (Sept. 2019), <https://www.guttmacher.org/fact-sheet/induced-abortion-united-states> (“Medication abortions accounted for 39% of all abortions in 2017, up from 29% in 2014 Medication abortions increased from 5% of all abortions in 2001 to 39% in 2017, even while the overall number of abortions declined.”).

14. Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTETRICS & GYNECOLOGY 166, 168 (2013) (highlighting that in the two years that the study covered, only one patient—who was experiencing an undiagnosed

as a colonoscopy and is less risky than wisdom teeth removal or tonsillectomy.¹⁵

In 2000, the FDA approved a two-step protocol for medication abortion.¹⁶ First, the patient takes mifepristone (also known under the brand name “Mifeprex” or “RU-486”), a drug that blocks reception of the hormone progesterone in the uterus.¹⁷ Twenty-four to forty-eight hours after taking mifepristone, the patient takes misoprostol, a drug that dilates the cervix and eventually works to expel the pregnancy.¹⁸ Medication abortion is highly effective for patients who are in the first ten weeks of pregnancy, but efficacy decreases as gestational age increases.¹⁹ Mifeprex is currently approved for use through the first trimester, or seventy days from the last menstrual period (“70 days LMP”) the patient experienced.²⁰ The current FDA-approved regimen calls for patients to take 200 milligrams of mifepristone orally and 800 milligrams of misoprostol buccally, *i.e.*, in the pouch of the cheek.²¹ Typically, patients take mifepristone at their provider’s office and are sent home with misoprostol, which they take at a location of their choosing.²²

ectopic pregnancy—died); *see also* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 175, 177 (2015) (finding that the “major complication rate” among 11,319 patients was 0.23% for medication abortion. Major complications were defined as those requiring hospital admission, surgery, or blood transfusion).

15. *Groundbreaking Research Proves that Abortion is an Extremely Safe Procedure*, BIXBY CTR. FOR REPROD. HEALTH (Dec. 11, 2014), <https://bixbycenter.ucsf.edu/news/groundbreaking-research-proves-abortion-extremely-safe-procedure> (referencing study by Upadhyay et al., *supra* note 14).

16. *Mifeprex (mifepristone) Information*, FDA, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information> (last visited Sept. 21, 2021).

17. *Questions and Answers on Mifeprex*, FDA, <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex> (last visited Sept. 21, 2021).

18. *See e.g.*, *Mifeprex (mifepristone) Information*, *supra* note 16; *see also* Planned Parenthood, *How Does the Abortion Pill Work?*, PLANNED PARENTHOOD, <https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-does-the-abortion-pill-workworkworkwork> (last visited Sept. 21, 2021).

19. *See generally* Cleland et al., *supra* note 14, at 1694 (reporting a 0.5% ongoing pregnancy rate for patients who had a medication abortion through sixty-three days (or nine weeks) of pregnancy as dated from their last menstrual period (“LMP”)); *Practice Bulletin No. 225*, *supra* note 11, at e39 (“Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.”).

20. *Mifeprex (mifepristone) Information*, *supra* note 18.

21. *Id.*

22. *See, e.g.*, Heidi E. Jones, et al., *First Trimester Medication Abortion Practice in*

Both mifepristone and misoprostol work by manipulating the reception of certain pregnancy-related hormones. Mifepristone is a progesterone antagonist, meaning that it binds to the same receptors as progesterone.²³ In fact, mifepristone binds to progesterone receptors with a greater affinity than progesterone itself.²⁴ This means that when a patient takes mifepristone, that drug blocks receptors from absorbing any additional progesterone.²⁵ Indeed, mifepristone can actually change the shape of progesterone receptors to make them “less hospitable” to progesterone.²⁶

Progesterone “plays a dominant role throughout pregnancy from implantation to parturition.”²⁷ On implantation, progesterone “is known to induce secretory changes in the lining of the uterus essential for the successful implantation of a fertilized egg.”²⁸ During pregnancy, progesterone has “uterine-relaxant properties”²⁹ that “maintain[] uterine tranquility” and prevent contractions.³⁰ Because progesterone is so important for maintaining a pregnancy, mifepristone accomplishes the opposite effect. Physiologically, mifepristone primes the uterus during a medication abortion by softening the cervix and “increas[ing] uterine contractility.”³¹ Mifepristone also makes the uterus more sensitive to misoprostol, which causes uterine contractions.³²

Although mifepristone affects significant change in the uterus on its own,

the United States and Canada, PLOS ONE 1, 5 (2017) (“Most [U.S.] providers reported administration of mifepristone at the facility (92.9%), and buccal (84.7%) administration of misoprostol at home (96.7%).”); Nathalie Kapp, et al., *Medical Abortion in the Late First Trimester: A Systematic Review*, 99 CONTRACEPTION 77, 77 (2019) (“Home administration of misoprostol has similar effectiveness as clinic administration . . . and is endorsed as a safe and acceptable practice . . .”).

23. See *Mifeprex (mifepristone) Information*, *supra* note 18.

24. *Practice Bulletin No. 225*, *supra* note 11.

25. Regine Sitruk-Ware & Irving M. Spitz, *Pharmacological Properties of Mifepristone: Toxicology and Safety in Animal and Human Studies*, 68 CONTRACEPTION 409, 410 (2003).

26. Schreiber Decl., at 25-26, *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, No. 3:20-cv-00740 (M.D. Tenn. Sept. 1, 2020).

27. Tamas Zakar & Frank Hertelendy, *Progesterone Withdrawal: Key to Parturition*, 196 AM. J. OBSTETRICS & GYNECOLOGY 289, 289 (2007).

28. D.M. Haas et al., *Progesterone for Preventing Miscarriage in Women with Recurrent Miscarriage of Unclear Etiology*, 10 COCHRANE DATABASE OF SYSTEMATIC REVIEW 1, 5 (2018).

29. *Id.*

30. Zakar & Hertelendy, *supra* note 27, at 289.

31. *Practice Bulletin No. 225*, *supra* note 11, at e31.

32. *Id.*

there is a reason why medication abortion is accomplished as a two-drug regimen: mifepristone alone does not consistently and predictably end pregnancy development.³³ Early studies of mifepristone's efficacy show that as many as 46% of pregnancies continue after a single dose of mifepristone is administered.³⁴ As a point of comparison, a patient who takes the mifepristone-misoprostol combination within the first seventy days of pregnancy will see their pregnancy end nearly 97% of the time.³⁵

B. *The Abortion Reversal "Protocol"*

So-called "abortion reversal" proponents claim that an in-progress medication abortion can be halted by giving a patient who has changed her mind after taking mifepristone a large dose of progesterone. Most discussions of abortion reversal in the United States lead inevitably back to Dr. George Delgado, a family practice physician who serves as the medical director of "Abortion Pill Reversal," "a program that connects women who have changed their minds after taking mifepristone (RU 486) and want to reverse the effects of the abortion pill."³⁶ Delgado, who received his Doctor of Medicine (M.D.) from the University of California, Davis, is often credited as having "published the first peer-reviewed article in the medical literature describing the reversal of mifepristone (RU 486) using progesterone."³⁷ Dr. Delgado is not an obstetrician or gynecologist, and has no training in pharmacology.³⁸ In the past, Dr. Delgado claimed affiliation

33. Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion*, 135 OBSTETRICS & GYNECOLOGY 158, 159 (2020) ("[M]ifepristone has some activity to induce abortion when used alone. However, overall efficacy is generally [80%] or less, and these studies typically included patients at less than forty-nine days of gestation.").

34. See, e.g., Zheng Shu-rang, *RU 486 (Mifepristone): Clinical Trials in China*, 149 ACTA OBSTETRICIA GYNECOLOGICA SCAND. SUPPL. 19, 21 (1989); see also *Facts Are Important*, *supra* note 5; Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92 CONTRACEPTION 206, 208 (2015) (finding continuing rates of pregnancy as low as 8% and as high as 46% after one dose of mifepristone).

35. Creinin et al., *supra* note 33, at 159 (noting that, more precisely, only approximately 0.3% of pregnancies continue with patients at forty nine days gestation or less, and up to 3.1% continue with patients between sixty four and seventy days).

36. *About Us*, George Delgado, M.D., F.A.A.F.P., Guest Contributor, CHARLOTTE LOZIER INST., <https://lozierinstitute.org/team-member/george-delgado/> (last visited Aug. 31, 2021).

37. *Id.*

38. *Planned Parenthood of Tenn. and N. Miss. v. Slatery*, No. 3:20-dv-00740, 2021 U.S. Dist. LEXIS 36422, at *12 (M.D. Tenn. Feb. 26, 2021).

with the University of San Diego's Department of Family Medicine, but the school has since asked him to stop.³⁹

A federal judge in Tennessee (who enjoined Tennessee's reversal law on First Amendment grounds) recounts Dr. Delgado's testimony about how abortion reversal came to be:

Dr. Delgado described how he came up with the idea for the use of progesterone therapy. He testified that he received a call, in 2009, about a woman who had changed her mind about having an abortion after taking mifepristone. Based on his knowledge of mifepristone and progesterone, Dr. Delgado drew up a protocol for the administration of progesterone and provided it to another physician who agreed to prescribe the progesterone to the patient. Dr. Delgado testified that the woman later gave birth to a healthy baby. Based on subsequent interest expressed by others around the country in his progesterone therapy, in 2012, Dr. Delgado started the "Abortion Pill Reversal" website, hotline, and network of physicians who are willing to prescribe the progesterone therapy. The organization is now run by Heartbeat International and is called "Abortion Pill Rescue."⁴⁰

The story prefacing this Article's introduction is from a testimonial by "Emily," an abortion reversal participant who supposedly called the Abortion Pill Rescue hotline and underwent "progesterone therapy" after taking mifepristone.⁴¹ Emily's reference to "Elizabeth," who called her back, is likely Liz Delgado, George Delgado's wife, one of the "main staffers" of the hotline.⁴² It is impossible to know for sure, though, who answered the phone when Emily called. This is one of abortion providers' many qualms with referring their patients to the hotline. Abortion Pill Rescue claims their hotline is staffed by "professional healthcare providers who are available to assist women that call our helpline . . . twenty-four

39. Glenza, *supra* note 2.

40. *Id.*; Slatery, at *12-*13. Although other physicians in the United States practice or espouse reversal, "[t]hat [the Tennessee's abortion reversal bill] is based on Dr. Delgado's papers appears to be undisputed. Defendants rely on Dr. Delgado's papers in responding to plaintiffs' challenge to the legislation, and defendants have filed testimony given at a legislative committee meeting regarding Section 218 during which Dr. Delgado's papers are discussed."

41. ABORTION PILL RESCUE, <https://abortionpillreversal.com> (last visited Sept. 21, 2021).

42. *Why We Support CANFP by Liz and George Delgado*, Cal. Ass'n of Nat. Family Planning, (June 14, 2015), <https://www.canfp.org/newsletter/why-we-support-canfp-by-liz-and-george-delgado-md/> ("Liz Delgado, R.N. is one of the main staffers of the 24/7 Abortion Pill Reversal hotline. Her other anti-abortion work has included being a client advocate with Culture of Life Family Services. Dr. Delgado and Liz have four children and one grandchild.").

hours a day, seven days a week.”⁴³ However, no information is provided on the website about who these “professional healthcare providers” are or what credentials they hold. Even an expert witness defending Tennessee’s abortion reversal bill, who serves on the Medical Advisory Board of the Abortion Reversal Network, could not identify the “healthcare providers” who operate the hotline and provide medical services to patients.⁴⁴

Even for a proven, effective treatment, the lack of transparency about the Abortion Reversal Network alone would give abortion providers warranted pause in recommending the organization to their patients. For a treatment that has *not* been proven to be effective or safe, recommending the hotline is akin to “encourag[ing] women to participate in an unmonitored research experiment.”⁴⁵ The following two sub-sections outline the pitfalls of Delgado’s theory and the flawed research design that has provided the pseudo-scientific basis for abortion reversal bills.

1. *Biologic Logic & Bad Analogies*

Delgado claims that three “pillars of evidence” contribute to his theory that progesterone can halt or “reverse” an abortion after the patient takes mifepristone: (1) what Delgado calls “biologic logic”; (2) animal studies; and (3) Delgado’s own experimentation with giving large doses of progesterone to patients who allegedly changed their minds after taking mifepristone.⁴⁶ The first “pillar of evidence” supporting Dr. Delgado’s “progesterone therapy” for abortion patients is what he calls “biologic logic.”⁴⁷ As the Tennessee district court judge summarized:

As for biologic logic, Dr. Delgado explained the interaction of mifepristone and progesterone with a “lock and key” analogy. According to Dr. Delgado, mifepristone acts as a “false key” fitting into the receptor “lock,” and by blocking hormones from the receptor, causes separation of the placenta from the lining of the uterus. Dr. Delgado described progesterone as the “good key,” which, when it attaches to the receptor, decreases the effects of mifepristone. Biology suggests, according to Dr. Delgado, that raising the concentration of progesterone allows the progesterone molecules to “outcompete” the mifepristone molecules in

43. *About Us*, ABORTION PILL REVERSAL, <https://abortionpillreversal.com/about/our-team> (last visited Sept. 21, 2021).

44. *Planned Parenthood of Tenn. and N. Miss. v. Slatery*, No. 3:20-cv-00740, 2021 U.S. Dist. LEXIS 36422, at *45 n.20 (M.D. Tenn. Feb. 26, 2021).

45. Grossman & White, *supra* note 9, at 1491.

46. *See Slatery*, at *13-*16.

47. *See id.* at *13.

attaching to the receptor.⁴⁸

From a medical perspective, this analogy and the logic behind it make little sense. As explained in Section I.A, mifepristone binds *preferentially* to the same receptors that progesterone does.⁴⁹ In other words, if the “false key” has already been placed inside of the relevant “locks,” flooding a patient’s system with 200 “good keys” will not change much. As Dr. Courtney Schreiber (an obstetrician and gynecologist at the University of Pennsylvania Health Center and frequent expert witness for plaintiffs challenging reversal) points out, high levels of naturally occurring progesterone already circulate within the uterus of a pregnant patient, so there is no reason to think that additional progesterone might do what endogenous progesterone cannot.⁵⁰ To further complicate Delgado’s strained analogy, because mifepristone actually alters the shape of mifepristone receptors, these new, external progesterone “keys” cannot possibly fit within locks that have been “changed” by locksmith mifepristone.⁵¹

2. *Research Design & Assessing Abortion Reversal*

Beyond Delgado’s flawed biologic logic, there is no evidence that this process actually works to “reverse” an abortion. Inherent in the reversal protocol is a patient who has changed her mind and decided not to take misoprostol, the second drug in the FDA-approved medication abortion regimen. For those “successful” abortion reversal patients, an obvious question arises: was the abortion “reversed,” or did the pregnancy continue because the medication abortion was never completed?

Like every other untested scientific hypothesis, Dr. Delgado’s theory is dependent on how many pregnancies would continue *after* a patient has taken a dose of mifepristone but *before* that patient ingests misoprostol. If, for example, in a sufficiently large group of similar pregnancies, 25%

48. *Id.* Other pro-ABR advocates have used the “good lock, bad lock” analogy to support their bills. See, e.g., Testimony of Dr. Matthew Harrison, Kan. H. Health & Hum. Servs. Comm. in Support of HB 2274 (Feb. 20, 2019) [hereinafter Harrison Test] (“Mifepristone is like a key that fits into a lock but cannot open it. By adding more functional keys, we are able to outcompete the mifepristone and turn the lock, activate the progesterone receptor, and sustain the life of the embryo.”).

49. *Practice Bulletin No. 225*, *supra* note 11, at e31.

50. See Schreiber Decl., at 23, *Planned Parenthood of Tenn. & N. Miss. v. Slatery*, No. 3:20-cv-00740 (M.D. Tenn. Sept. 1, 2020) ¶ 54 (hereinafter “Schreiber Tenn. Decl.”).

51. See Sitruk-Ware & Spitz, *supra* note 25, at 410.

typically continued after a standard dose of mifepristone, but 75% of pregnancies continued after a dose of progesterone, then we could potentially conclude the “progesterone therapy” worked. On the other hand, if 25% of pregnancies typically continued after taking mifepristone, and that percentage remained steady after taking progesterone, it would be impossible to conclude if the progesterone *worked* or if the pregnancies were simply part of the one-quarter that would continue regardless of intervention.

In other words, assessing the efficacy of progesterone “therapy” would require an experiment that compares the outcomes associated with progesterone to the outcomes associated with a placebo or control group. No such experiment has ever been completed on abortion reversal therapy.⁵² Instead, Delgado and other supporters of progesterone therapy for abortion reversal rely on animal studies,⁵³ the results of which cannot be accurately extrapolated to humans without further research;⁵⁴ and two articles published by Delgado and Davenport, neither of which prove that abortion reversal is effective.

a. The 2012 Case Study

The first paper that Drs. Delgado and Davenport published was a case study of seven women who underwent “progesterone therapy” after taking mifepristone.⁵⁵ The paper, called “Progesterone Use to Reverse the Effects of Mifepristone,” appeared in the “Case Reports” section of *Annals of*

52. See *infra* Section I.C p. 17 (describing a proposed experiment that compared a placebo to progesterone, but the study was halted after three patients sought emergency care after hemorrhaging).

53. *Slatery*, No. 3:20-cv-00740 at *66 (stating that much of the research cited by abortion reversal proponents measures the effect of progesterone on pregnant rats or rabbits, not humans); see *Planned Parenthood of Ariz. v. Brnovich*, Case No. 2:15-CV-01022-SPL (D. Ariz. July 30, 2015), ECF 60-2 (citing rat studies and stating that “animal experiments give further credibility to the validity of the concept of progesterone reversal of mifepristone abortion in humans”); Harrison Testimony Test., *supra* note 48 (“Animal models have shown that the effects of mifepristone on rats are reversed and nullified by progesterone supplementation.”).

54. See, e.g., Michael B. Bracken, *Why Animal Studies are Often Poor Predictors of Human Reactions to Exposure*, 101 J. ROYAL SOC’Y MED., 120 (2008) (“The concept that animal research, particularly that relating to pharmaceuticals and environmental agents, may be a poor predictor of human experience is not new Pharmacologists, in particular, have long recognized the difficulties inherent in extrapolating drug data from animals to man.”); Gail A. Van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials: Is it Time to Rethink Our Current Approach?*, 4 J. AM. COLL. CARDIOLOGY: BASIC TO TRANSLATIONAL SCI. 845, 845 (2019) (discussing the issues of using animals to predict human toxicity in preclinical pharmaceutical testing).

55. Delgado & Davenport, *supra* note 4, at e36.

Pharmacotherapy. Although *Annals of Pharmacotherapy* is a reputable, peer-reviewed journal, Dr. Courtney Schreiber (a frequent expert witness for plaintiffs challenging abortion reversal bills) pointed out that *Annals* “is geared toward authors and readers who are pharmacologists and pharmaceutical scientists” and “is not known as being a journal that obstetrician/gynecologists or women’s health clinics regularly consult.”⁵⁶

This paper, which provided the “scientific” foundation for the pre-2018 abortion reversal bills in Arizona and Arkansas, suffers from several fundamental problems. First, the size and structure of the study make it impossible to draw any conclusions from the research. The case study only reflected the results of six women, as one patient was lost to follow-up after taking progesterone. Case reports “usually contain detailed information about the individual patients,” like age, gender, or ethnic origin,⁵⁷ but the report reveals no information about patient demographics, such as age or potentially complicating health conditions. Even the gestational age of the pregnancy—a key variable in whether a pregnancy continues after ingesting mifepristone—is missing in one of the cases.⁵⁸ The regimen itself varied from case to case: some patients received the progesterone orally, some via injection, and some vaginally—all at different doses and intervals, with different amounts of time passed post-mifepristone.⁵⁹ Although Delgado and Davenport repeatedly point out that none of the babies born post-“reversal” experienced birth defects, there was no long-term follow-up to determine any negative outcomes for the baby *or* the mother.⁶⁰

Moreover, the case series suffers from research design flaws that range from problematic to unethical. A case report typically reflects “a *retrospective* analysis of three or fewer cases” and may not require Institutional Review Board (“IRB”) approval.⁶¹ Without a control group, case studies are considered to be among the weakest forms of medical

56. Schreiber Decl. ¶ 21, *Am. Med. Ass’n v. Stenehjem*, No: 1:19-cv-00125-DLH-CRH, 2019 WL 9122965 (D.N.D. June 19, 2019).

57. *Evidence Based Practice: Levels of Evidence and Study Designs*, Ascension Library Servs. (Aug. 10, 2021, 3:07 PM), https://ascension-wi.libguides.com/ebp/Levels_of_Evidence.

58. Delgado & Davenport, *supra* note 4, at e36 (“Case 5: A 21-year-old woman elected to have the mifepristone effects reversed; gestational age was unknown.”).

59. *Id.* at e36; *see also* Grossman, *supra* note 34, at 207-08.

60. Delgado & Davenport, *supra* note 4, at e36 (noting that for some of the cases “no neonatal complications or birth defects [were] noted”); Khadijah Z. Bhatti, et al., *Medical Abortion Reversal: Science and Politics Meet*, *AM. J. OBSTETRICS & GYNECOLOGY* 315, 333 (2018) (“However, there are many limitations to their case series: [including] lack of long-term follow-up . . .”).

61. Grossman, *supra* note 34, at 2105.

evidence.⁶² By definition, case studies do not set out to prove or disprove a hypothesis and are not structured to provide recommendations or a “protocol” for practitioners.⁶³

Although the case study’s results are too small to generalize, the actual primary outcome—how many pregnancies continued after progesterone therapy—is also not particularly compelling. Of the seven patients, four continued their pregnancies to term and delivered healthy babies. One was lost to follow-up, and the abortions were completed in two other cases.⁶⁴ Out of the seven women who received the treatment, four were confirmed to have carried to term. Because one patient was lost to follow-up, the final percentage of women who carried to term was either 57% (if the lost patient aborted) or 71% (if the lost patient carried to term). In an experiment, that percentage would be compared to the percentage who carried to term in the control group. Without a similarly situated control group (*i.e.*, one that matches patients according to age, gestational age, prior health conditions, or other qualities that might impact continuing pregnancy), the percentages are interesting, but ultimately meaningless for any kind of generalization or treatment recommendation. These research design flaws combined with a disturbing lack of ethical oversight prove to be an experimental and unproven treatment.⁶⁵ Despite this defect, three states passed abortion reversal bills based on this study alone.⁶⁶

b. The 2018 Case Series

In 2018, Drs. Delgado and Davenport published a second paper—*A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*—along with five additional authors.⁶⁷ This second case series

62. *Facts Are Important*, *supra* note 5; see also *Evidence Based Practice: Study Designs & Evidence Levels*, MED. COLL. OF WIS. LIBRARIES (June 23, 2021, 4:23 PM) <https://mcw.libguides.com/c.php?g=644314&p=4643389> (listing “theory-based evidence from expert opinion or multiple case reports” as the second-to-last type of evidence in pyramid, second only to “manufacturer recommendation” or research sponsored by the maker of the drug).

63. Trygve Nissen, *The Clinical Case Report: A Review of its Merits and Limitations*, 7 BRITISH MED. J. RES. NOTES 264 (2014) (“The major limitations [of a case study are]: Lack of ability to generalize, no possibility to establish cause-effect relationship, danger of over-interpretation, publication bias, retrospective design, and distraction of reader when focusing on the unusual.”).

64. Delgado & Davenport, *supra* note 4.

65. Bhatti, *supra* note 60, at 317.

66. See generally, *infra* Appendix A (referencing that Utah, Arizona, and Arkansas all passed laws before the 2018 study was published).

67. George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 ISSUES IN L. & MED. 21 (2018). The other

was published in the journal *Issues in Law and Medicine*, a “peer reviewed professional journal” that “provid[es] technical and informational assistance to attorneys, health care professionals, educators and administrators on legal, medical, and ethical issues arising from health care decisions.”⁶⁸ The plaintiff abortion providers in litigation challenging Tennessee’s abortion bills pointed out that the journal is sponsored in part by the Watson Bowes Research Institute, which is affiliated with the American Association of Pro-Life Obstetricians and Gynecologists (“AAPLOG”).⁶⁹ Even the defendants’ experts—including Dr. Delgado—“conceded that [the journal] is not particularly well-known in the medical field” and that every other journal to which Dr. Delgado submitted the article rejected it.⁷⁰ Donna Harrison, the Executive Director of AAPLOG and a frequent expert witness for abortion restrictions, is an Associate Editor for *Issues in Law and Medicine*.⁷¹

The 2018 study is more sophisticated than the 2012 case series in multiple respects. First, the study tracked the results of 754 patients who underwent progesterone “therapy,” with 547 total subjects after exclusions (e.g.,

authors listed on the paper are Steven J. Condly, PhD; Thidarat Tinnakornsriruphap Ph.D.; Jonathan Mack, Ph.D.; NP, RN; Veronica Khauv, B.S.; and Paul S. Zhou. At least three of the co-authors either have ties to the anti-choice scholarly community or have credentials that do not match the content of the paper. Steven Condly, for example, has published articles about abortion as an “independent risk factor” for breast cancer. *Steven Condly*, RESEARCHGATE, <https://www.researchgate.net/profile/Steven-Condly> (last visited Aug. 23, 2021); *Thidarat Tinnakornsriruphap, PhD*, U. SAN DIEGO INDUS. AND SYS ENGINEERING. ENG’G, https://www.sandiego.edu/engineering/programs/industrial-and-systems-engineering/biography.php?profile_id=3460 (last visited Aug. 23, 2021)²³, 2021) (saying that Thidarat Tinnakornsriruphap has a Ph.D. in Industrial Engineering and appears to have no experience in pharmacology, research design, or reproductive health); *Biography, Dr. Jonathan Mack*, U. SAN DIEGO, https://www.sandiego.edu/directory/biography.php?profile_id=1304&utm_source=directoryonebox&utm_medium=search&utm_campaign=DirectoryOneBox (last visited Aug. 23, 2021) (noting that Jonathan Mack is the Director of Health Care and Nursing Informatics Programs at University of San Diego. His only experience in reproductive health seems to be development of “a smart phone-based device to conduct wireless fetal monitoring and non-stress testing of high-risk pregnancies.”) The article does not provide credentials or any other searchable information for Veronica Khauv or Paul S. Zhou. Veronica Khauv’s only citations are related to abortion reversal.

68. *What is Issues in Law & Medicine?*, ISSUES L. & MED., <https://issuesinlawandmedicine.com/about/> (last visited Aug. 23, 2021).

69. Schreiber Tenn. Decl., *supra* note 50, at 15-16 (citing Form 990, Am. Ass’n of Pro-Life Obstetricians and Gynecologists (2015), available at <https://rewirenewsgroup.com/wp-content/uploads/2017/02/AAPLOG-990-2015.pdf>).

70. *Planned Parenthood of Tenn. And N. Miss. V. Slatery*, No. 3:20-cv-00740, 2021 U.S. Dist. LEXIS 36422, at *19 (M.D. Tenn. Feb. 26, 2021).

71. *About Us, Donna Harrison, M.D., Associate Scholar*, CHARLOTTE LOZIER INST., <https://lozierinstitute.org/team-member/donna-harrison/> (last visited Aug. 23, 2021).

patients who were lost to follow-up or decided to continue their pregnancies)—a much larger subject pool, obviously, than the seven-patient case study from 2012.⁷² The study also excluded thirty-eight patients who took mifepristone more than seventy-two hours before calling the hotline.⁷³ The progesterone regimens were tracked by dosage and route of administration, although the paper never breaks those regimen sub-groups down by gestational age.⁷⁴ Of the 547 patients “with analyzable outcomes who underwent progesterone therapy,” there were 257 births—48% of the total non-excluded subject pool.⁷⁵ From these results, the 2018 authors conclude that “[t]he reversal of the effects of mifepristone using progesterone is safe and effective”⁷⁶—a “claim[] that vastly overstate[s] what their studies can possibly show.”⁷⁷ The “success” of the 2018 study is derived from the fact the fetal or embryo survival rate after certain progesterone therapy regimens was higher than the 25% control group rate the authors chose.⁷⁸

i. Research Design and Institutional Review

Just like the 2012 paper, the 2018 study is structured as a “case series”; the study is not a double-blind experiment that administers and compares both non-treatment and treatment. Case studies are the start of good research, not an endpoint that allows for recommendations. Delgado et al. address this issue in the “Study Limitations” section: “[t]his study is limited in that it is not a randomized placebo-controlled trial. However, a placebo-controlled trial in the population of women who regret their abortion and want to save the pregnancy would be unethical.”⁷⁹ As Dr. Courtney Schreiber points out, though, the design of the study is really prospective (rather than simply observational) “because . . . the researchers actively

72. Delgado et al., *supra* note 67, at 25-26.

73. *Id.* at 25.

74. *Id.* at 27 (stating that the paper includes a chart of ten regimen sub-groups and their respective “reversal” rates. The sub-groups included high-dose oral, intramuscular (all groups); intramuscular broken down by number of injections (ranging from one to eleven or more); all oral; oral capsules administered vaginally (all doses); and vaginal suppositories).

75. *Id.* at 26.

76. *Id.* at 21.

77. Ivan Oransky, *Study Claiming “Abortion Reversal” is Safe and Effective Temporarily Withdrawn for Ethical Issues*, RETRACTION WATCH (July 17, 2018), <https://retractionwatch.com/2018/07/17/study-claiming-abortion-reversal-is-safe-and-effective-temporarily-withdrawn-for-ethical-issues/> (quoting Dr. Kelly Cleland of the Office of Population Research at Princeton University).

78. Delgado et al., *supra* note 67, at 26.

79. *Id.* at 28–29.

enlisted participants to undergo an experimental intervention.”⁸⁰ The strange design implies the authors want the benefits of a research study (credibility and generalizability) without any of the responsibilities (IRB approval or ethical oversight).

ii. *The Historical Control Group*

Instead of creating a pool of subjects and treating half of them with progesterone therapy, which would require IRB approval and oversight, the authors rely on a “historic” control group based on studies conducted in the 1980s when mifepristone was first being used as an abortifacient.⁸¹ The purpose of a control group in this particular study would be to assess how often pregnant patients who take mifepristone but not misoprostol experience continuing pregnancies. For this study, Delgado et al. decided on a 25% embryo or fetal survival rate; in other words, they chose the outcome of their own control group.⁸² Delgado et al.’s 25% “historical control” figure comes from a single study from the 1980s: Maria et al., which gave thirty patients a 200-milligram total dose of mifepristone and found that 23.3% of the embryos survived.⁸³

80. Schreiber Tenn. Decl., *supra* note 50, at 17.

81. See generally James Bell Associates, *Evaluation Brief: Understanding the Institutional Review Board*, CHILDREN’S BUREAU (2008) https://www.acf.hhs.gov/sites/default/files/documents/cb/understanding_the_irb.pdf; Delgado et al., *supra* note 67, at 23–24.

82. See *id.* at 24 (A 25% survival rate is not quite arbitrary, but Dr. Delgado has cited other numbers in different contexts. For example, Dr. Delgado testified before the Colorado legislature in support of a proposed abortion reversal bill that the “survival rate” is as low as 15%). See also Testimony Before Colorado Legislature, George Delgado, M.D., F.A.A.F.P., Medical Director, Abortion Pill Reversal (February 9, 2017) (“Our success rates with our best protocols are 65-70% while our overall success rate is 50-55%. These rates are much better than the 15% survival rate if a mother takes mifepristone and does nothing.”).

83. See Delgado et al., *supra* note 67, at 24 (“We selected a 25% embryo or fetus survival rate . . . as a control because it is at the upper range of mifepristone survival rates and close to the 23% survival rate of the one early study that used a single 200 mg dose, the dose currently favored for medical abortions.”); see also Grossman & White, *supra* note 9, at 1491 (“The authors conclude that reversal treatment is effective, citing the higher proportion of continuing pregnancies in their study as compared with a historical control rate of 25% of women who had continuing pregnancies after taking mifepristone alone. This estimate comes from Maria et al., the only published report that examined rates of pregnancy continuation after a single 200-mg dose of mifepristone, which is the dose most commonly used in current medication-abortion regimens.”); Grossman & White, *supra* note 3, at 1492-93 (citing to Bernard Maria et al., *Early Pregnancy Interruption Using an Antiprogesterone Steroid: Mifepristone (RU 486)*, 17 J. GYNECOL. OBSTET. BIOL. REPROD. (PARIS) 1089-94 (1988)).

Although historical controls are sometimes used in research when creating a contemporaneous placebo group is impossible or unethical, “it is important that details about the population included in the historical control group be well documented and understood so that researchers can ensure the control patients are as similar as possible to the patients who receive the treatment.”⁸⁴ Just like a regular control group, “researchers should ensure that whether the participant received the treatment is the only variance between the participants selected for the historical control group and those selected for the treatment group.”⁸⁵ Delgado et al. never explain the similarities or differences between their subject pool and Maria et al.’s thirty subjects.

It is difficult to determine the precise continuing pregnancy rate after mifepristone use alone.⁸⁶ The primary reason for this is that contemporary practitioners and researchers have had no reason to test it. In the 1980s, mifepristone was first suggested as a progesterone antagonist and abortifacient by a French doctor named Etienne-Emile Baulieu.⁸⁷ After the first clinical trial in 1982, researchers realized that adding a prostaglandin (a type of hormone that causes uterine cramping) could improve mifepristone’s efficacy in terminating pregnancies.⁸⁸ Thereafter, clinical trials primarily used mifepristone in conjunction with misoprostol. As Dr. Schreiber describes, there are very few studies demonstrating how often mifepristone alone causes embryonic or fetal demise, and those studies are not representative of contemporary medical practice. First, nearly all the studies focus on early pregnancies, forty-nine days from the patient’s last menstrual period or earlier.⁸⁹ Because mifepristone is more effective earlier in pregnancy and loses efficacy as gestational age increases, those studies do

84. Schreiber Tenn. Decl., *supra* note 50, at 19.

85. *Id.* at 19.

86. *Id.* at 9-10.

87. See R. Alta Charo, *A Political History of RU-486*, in *BIOMEDICAL POLITICS* 49 (1991), available at https://www.ncbi.nlm.nih.gov/books/NBK234206/pdf/Bookshelf_NBK234206.pdf; see also Etienne-Emile Baulieu, *Contraception and Other Clinical Applications of RU 486, an Antiprogesterone at the Receptor*, 245 *SCIENCE* 1351, 1351 (1989) (stating that, interestingly, Delgado seems to have borrowed Baulieu’s original “key” analogy for how mifepristone functions); *id.* at 50 (quoting Baulieu as saying, “The receptors are like a keyhole . . . and we were trying to produce a false key.”) (internal citation omitted)).

88. Etienne-Emile Baulieu, *THE ‘ABORTION PILL’: RU 486: A WOMAN’S CHOICE* 34 (Mort Rosenblum trans., New York: Simon & Schuster, 1991).

89. Schreiber Tenn. Decl., *supra* note 50, at 7-8 (noting that the study included only patients whose gestational age was 42 days LMP or earlier) (citing L. Kovacks et al., *Termination of Very Early Pregnancy by RU 486 – An Antiprogestational Compound*, 29 *CONTRACEPTION* 399 (1984)).

not accurately reflect the effect of mifepristone as it is currently administered in clinical settings. Second, the early studies prescribed mifepristone at far higher dosages than the contemporary FDA protocol.

In 2017, Drs. Delgado and Davenport conducted a literature review entitled “Embryo Survival after Mifepristone: A Systematic Review of the Literature” that included twenty-one studies total, the most recent of which was published in 1989.⁹⁰ Their review encountered the same problems. Only one of those studies used “the current prevailing 200 mg single dose regimen.”⁹¹ The other doses ranged from 400 milligrams to up to 1000 milligrams; the most common regimen was a single dose of 600 milligrams.⁹² Moreover, the gestational ages at which medication abortion was administered were lower than the current clinical cut-off. Only six of the studies went beyond forty-nine days, and of the 678 total subjects in all the studies, only nine were above forty-nine days.⁹³

iii. Data Presentation Problems

In addition to the “historical control group” issue, the second fundamental problem with the 2018 study is how the authors chose to structure and generalize their data. The total study population was 547 patients, excluding those lost to follow-up and those who chose to continue with their abortions. From the outset, this patient population reflects a bias towards reversal:

[S]ome providers performed ultrasonography in patients presenting for reversal and excluded those found to have embryonic death. These patients were removed from the denominator of the proportion of women with continuing pregnancies, which could have contributed to the higher success rate for reversal treatment—especially at gestational ages of more than six weeks, when cardiac activity is more apparent.⁹⁴

During litigation to challenge Tennessee’s abortion reversal bill, Dr. Delgado admitted he excluded patients who aborted after taking mifepristone and did not adjust his reversal success rate accordingly.⁹⁵

90. Davenport et al., *Embryo Survival after Mifepristone: A Systematic Review of the Literature*, 32 ISSUES IN L. & MED. 3, 12, 14-15 (2017).

91. *Id.* at 3-4.

92. *Id.* at 14-15.

93. *Id.* (noting that, for several of the studies, the chart provided in the article lists the population as, e.g., “≤55 days,” so it is impossible to definitively state how many subjects were below 42 days LMP).

94. Grossman & White, *supra* note 9, at 1491.

95. Tenn. Prelim. Inj. Order., 2021 U.S. Dist. LEXIS 36422 at *18.

Moreover, the way Delgado et al. present their data—by regimen and by gestational age, separately—also compromises the strength of the authors’ recommendations. The total abortion “reversal” rate among 547 patients was 48%; the authors claim the difference between their rate and the historic control is statistically significant.⁹⁶ As expected, the success rate varies dramatically by gestational age. At earlier gestational ages, mifepristone effects fetal or embryo demise on its own with much higher frequency.⁹⁷ Delgado et al.’s data reflects this. At five weeks gestational age, the patients’ abortions were supposedly reversed 25% of the time. By nine weeks gestational age, 77% were reversed.⁹⁸ The biggest jump in supposed efficacy of reversal was between five and six weeks, where reversal rates rose from 25% to 46%.⁹⁹ As Grossman points out, six weeks is also the time that fetal cardiac activity becomes discernible, meaning that providers would be less able to selectively exclude patients who had already experienced embryo demise.¹⁰⁰

The authors also present different rates of successful reversal by regimen, but they do not provide additional information (like gestational age) about the patients who underwent each regimen. In their results summary, the authors do not mention their overall reversal rate among the 547 patients. Instead, they highlight two specific regimens that supposedly show the most promise: the intramuscular route (with a success rate of 64%) and the “high dose oral” route (with a success rate of 68%).¹⁰¹ The number of subjects in those subgroups is much smaller. Indeed, the sub-groups with the smallest number of patients yield the largest percentages of reversal. For example, the nine patients who received between six and eight intramuscular injections had a survival rate of 100%. The high dose oral group, which is recommended by the authors as one of the “most effective” doses and routes of administration, only included thirty-one women. Because the group of patients is so small, the confidence interval¹⁰² of their success rate ranges

96. See, e.g., Amy Gallo, *A Refresher on Statistical Significance*, HARV. B. REV. (Feb. 16, 2016), <https://hbr.org/2016/02/a-refresher-on-statistical-significance> (noting that statistical significance is a measure of the likelihood that a given difference in treatment groups is caused by random chance, rather than the treatment itself).

97. See Grossman & White, *supra* note 9, at 1492.

98. Delgado et al., *supra* note 67, at 28.

99. *Id.*

100. Grossman & White, *supra* note 9, at 1491 (“[Exclusions] could have contributed to the higher success rate for reversal treatment—especially at gestational ages of more than [six] weeks, when cardiac activity is more apparent” [emphasis added]).

101. Delgado et al., *supra* note 67, at 22.

102. 1.3.5.2. *Confidence Limits for the Mean Engineering Statistics Handbook*, NAT’L

from 51% to 84%.

Because the success rate is so closely correlated with gestational age, it is impossible to assess the effectiveness of the high dose oral or intramuscular routes without additional information. Imagine, for example, that a majority of the patients who received the high dose oral route were among the thirty patients in the study who were nine weeks pregnant. The 68% success rate (the highest in the study) is actually lower than the 77% success rate for patients at nine weeks pregnant, so conclusions about the high dose oral route's efficacy would be impossible to draw.¹⁰³ Similarly, consider the impact on the authors' recommendations if most of the patients who received progesterone through oral capsules administered vaginally (both the route with the lowest success rate at 39% and the largest subgroup group) were five or six weeks pregnant. The reversal failures associated with early pregnancy would thus be concentrated in one subgroup—a kind of evidentiary gerrymandering that shifts the focus from assessing the overall efficacy of progesterone to drawing conclusions about individual regimens.¹⁰⁴

C. Testing Delgado's "Unmonitored Research Experiment"

As the previous two sections demonstrated, there is no sound biological basis to support the theory of abortion reversal and no sound evidence to support the practice of abortion reversal. In 2018, Dr. Mitchell Creinin, an OB/GYN at the University of California, Davis Health, received a grant from the Society for Family Planning to test the abortion reversal protocol with a "double-blind, placebo-controlled, randomized trial"—the "gold standard" of research.¹⁰⁵ Dr. Creinin is not an abortion reversal advocate; indeed, he

INST. FOR STANDARDS & TECH., <https://www.itl.nist.gov/div898/handbook/eda/section3/eda352.htm> (last visited Aug. 23, 2021) (stating that, statistical analysis of this kind involves determining how likely it is that an outcome (here, a "reversed" abortion) is the result of the treatment being studied and not random chance. Confidence intervals reflect with a determined level of certainty (here, 95%) that the "real" result is somewhere in a given range. So, when Delgado et al. present a success rate of 68% with a 95% confidence interval of .51 to .84, they are 95% sure that the "real" success rate is somewhere between 51% and 84%).

103. See Press Release, *Bill Introduced to Allow Abortion Pill Reversal Information*, RIGHT TO LIFE MICH. (Jan. 23, 2020), <https://rtl.org/abortion-pill-reversal-bill/>.

104. *Id.* ("Research shows the progesterone treatment is effective 64 to 68% of the time"); see also *Reversal FAQ*, ABORTION PILL RESCUE, <https://abortionpillreversal.com/abortion-pill-reversal/faq> (last visited Aug. 23, 2021) ("What is the success rate of abortion pill reversal? Initial studies of APR have shown it has a 64-68% success rate.").

105. Epstein, *supra* note 7; see also *A Randomized Trial of Mifepristone*

“never expected to be in the position of investigating a treatment he doesn’t think works.”¹⁰⁶ But because so many states have proposed or passed abortion reversal bills, Dr. Creinin hoped to complete a “formal study” that could be “definitive” on the issue.¹⁰⁷ In Dr. Creinin’s grant proposal, he described the study’s methods as follows:

We propose such a study which will enroll 40 women seeking surgical abortion to receive mifepristone 200 mg then randomized to 2 weeks of oral progesterone therapy or placebo starting the following day. Participants will attend follow-up visits 3 and 7 days after initiating progesterone/placebo and have a surgical abortion, if still pregnant, after approximately [two] weeks.¹⁰⁸

The study started enrolling patients between February and July 2019.¹⁰⁹ In that time, twelve patients who were between forty-four and sixty-three-days gestation were enrolled. The research team confirmed “gestational cardiac activity” via ultrasound before administering mifepristone. Each of the twelve enrolled patients took 200 milligrams in front of an investigator.¹¹⁰ Within twenty-four hours of taking mifepristone, study participants were instructed to take two additional capsules, twice daily for three days, and then two capsules daily until the end of the study period.¹¹¹ Half of the participants were given placebos to assess the results of mifepristone alone. The other half were given 200 milligram capsules of progesterone.¹¹² The researchers “chose this dosing regimen because it was the most effective option previously described in” Delgado’s 2018 study.¹¹³

Unfortunately, the study had to be halted after three of the twelve patients (one who received progesterone, and two who received the placebo) received emergency treatment after experiencing severe bleeding.¹¹⁴ This rate of

Antagonization with High-Dose Progesterone to Prevent Medical Abortion, SOC’Y FOR FAM. PLAN. & SFP RSCH. FUND, https://www.societyfp.org/awarded_grants/SFPRF12-MA2/ (last visited Aug. 23, 2020).

106. Mara Gordon, *Controversial ‘Abortion Reversal’ Regimen Is Put to The Test*, NPR (March 22, 2019), <https://n.pr/3em0IKL>.

107. *Id.*

108. SOC’Y FOR FAM. PLAN., *supra* note 105.

109. Creinin, *supra* note 33.

110. *Id.* at 159.

111. *Id.* at 159–60.

112. *Id.*

113. *Id.* at 160.

114. *Id.* at 160–61; *see also* Epstein, *supra* note 7.

severe bleeding is significantly higher than the typical hemorrhage rate for medication abortion completed with both mifepristone and misoprostol, which is about .17%.¹¹⁵

The study's discussion section highlights the importance of appropriately designed research for drawing conclusions and, more importantly, for applying those conclusions to law and public policy:

This study, although small, provides important insight into the safety of mifepristone antagonization with progesterone during early pregnancy. We should not dismiss mifepristone antagonization as impossible; fully understanding outcomes will serve as the best means to accurately inform our patients, the medical community, and legislators. Existing literature before this study is comprised of case reports and series, which are not evidence of efficacy and do not address safety. This level of evidence is inadequate to support or refute the benefits and risks of any treatment. Unfortunately, legislators often fail to understand differences in levels of evidence, and some states now require physicians who provide medical abortion to counsel patients that the actions of mifepristone can be reversed if they change their mind.¹¹⁶

Without additional evidence, any requirement that providers share information about abortion reversal with their patients is, at best, misleading. At worst, as the unfortunate end to Dr. Creinin's study demonstrates, abortion reversal may endanger patients and create easily avoidable medical emergencies.

II. LEGISLATING REVERSAL

Arizona passed the first abortion reversal bill in 2015.¹¹⁷ Since then, twenty-six additional states have proposed or passed abortion reversal bills. Nine states currently (or imminently will) require that abortion providers "inform" patients that their medication abortion can be reversed: Arkansas, Idaho, Kentucky, Nebraska, South Dakota, Utah, Indiana, Louisiana,

115. Upadhyay, *supra* note 14 at 176 (noting that this figure is likely overstated, since it represents both "major" (*i.e.*, requiring hospital admission, blood transfusion, or surgery) and "minor" hemorrhage).

116. Creinin, *supra* note 33, at 164.

117. Rick Rojas, *Arizona Orders Doctors to Say Abortions With Drugs May Be Reversible*, N.Y. TIMES (Mar. 31, 2015), <https://www.nytimes.com/2015/04/01/us/politics/arizona-doctors-must-say-that-abortions-with-drugs-may-be-reversed.html>.

Montana, and West Virginia.¹¹⁸ Four states—Arizona,¹¹⁹ Tennessee, Oklahoma, and North Dakota—passed abortion reversal bills that were later enjoined.¹²⁰ At least a dozen other states have proposed reversal bills that either failed to pass, were vetoed, or repealed.¹²¹ Some, like Idaho, Kansas, and Indiana, have tried more than once.¹²² During the drafting of this Article, five more states passed bills.¹²³ The chart in Appendix A reflects all of the abortion reversal bills proposed, passed, and/or enjoined as of this Article's publication. This Section tracks the evolution and substance of reversal bills, starting with Americans United for Life's model reversal bill and then

118. *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (Aug. 1, 2021) <https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortionabortion>; *State Legislation Tracker*, GUTTMACHER INST., <https://www.guttmacher.org/state-policy> (last visited Aug. 23, 2021) (stating that Montana and Indiana both passed abortion reversal bills during the 2021 legislative session).

119. *Order, Planned Parenthood of Ariz. v. Brnovich*, No. CV-15-01022-PHX-SPL (D. Ariz. Oct. 16, 2015), ECF No. 107 (saying that Arizona's bill was litigated in federal court and enjoined on October 16, 2015 after the parties stipulated to a Preliminary Injunction); Mary Jo Pitzl, *Court: Arizona Abortion-Reversal Law is No More*, AZCentral (Aug. 23, 2016) <https://www.azcentral.com/story/news/politics/arizona/2016/08/23/court-arizona-abortion-reversal-law-no-more/89229028/> (noting that the bill was later repealed by the Arizona legislature).

120. *Am. Med. Ass'n v. Stenehjem*, 412 F. Supp. 3d 1134 (D.N.D. 2019) (hereinafter "N.D. Prelim. Inj. Ord."); Journal Entry of Judgment, *Tulsa Women's Reproductive Clinic v. Hunter*, Case No. CV-2019-2176 (Okla. Cty. Dist. Ct. Oct. 29, 2019) (hereinafter "Okla. Judgment").

121. *See, e.g.*, S.B. 1318, 52d Leg., 1st Reg. Sess. (Ariz. 2015) (passed, litigated, enjoined, and then was repealed by the governor); H.B. 1086, 71st Gen. Assemb., 1st Reg. Sess. (Colo. 2017) (failed to progress past committee); H.B. 5374, 100th Leg., Reg. Sess. 2020 (Mich. 2020) (failed to progress past committee); S.B. 67, Sess. 2019, (Kan. 2019) (vetoed by the governor in 2019); Assemb. B. 180, Sess. 2019 (Wis. 2019) (vetoed by the governor in 2019).

122. Indiana first tried to pass a bill in 2017, which failed in the Senate. The second attempt, in 2021, was successful. Similarly, a 2017 law failed in committee in Idaho, but passed in 2018. Both laws are currently in effect. H.B. 1577, 112d Gen. Assemb., 1st Reg. Sess., (Ind. 2021). S.B. 1243, 2nd Reg. Sess. (Idaho 2018).

123. Indiana H.B. 1577 was passed by the Indiana Senate and sent to the Governor on April 14, 2021. It took immediate effect. South Dakota's bill was signed by the Governor on March 25, 2021. H.B. 1130, 2nd Reg. Sess. (S.D. 2021). West Virginia's bill was passed April 10, 2021, and will go into effect July 9, 2021. H.B. 2982, Reg. Sess. (W. Va. 2021). Montana's Governor signed their abortion reversal bill in April 2021, and it will go into effect October 1, 2021. Mont. Code Ann. § 1-2-201(1)(a) (Amended 2003). On June 29, 2021, Louisiana's governor signed an abortion reversal law which went into effect on July 1. *Louisiana Abortion Pill 'Reversal' Bill Signed Into Law by Edwards*, AP News (July 2, 2021), <https://apnews.com/article/la-state-wire-louisiana-abortion-health-government-and-politics-ff828fe76c36a332ae36df4656ed6f6d>.

analyzing how reversal bills have changed in response to litigation since 2015, using bills passed in Arizona and Louisiana as examples.

A. *Americans United for Life's Model Reversal Bill*

Like many abortion restrictions, most of the bills include similar language and requirements. This is no coincidence. As part of its Women's Protection Project, Americans United for Life¹²⁴ has drafted a sample "Abortion-Inducing Drugs Information and Reporting Act," which "mandates that women be told that drug-induced abortions can be reversed."¹²⁵ The provisions relating to reversal appear within a larger bill that requires abortion providers to report certain information after medication abortion and provide the patient with informed consent materials, including, among other things, the final printed label for Mifeprex and the probable gestational age of the "unborn child."¹²⁶ The thrust of the bill is that medication abortion is generally unsafe and that physicians who provide medication abortion prefer it because it is cheaper and faster than an abortion procedure.¹²⁷

124. *About*, AMS. UNITED FOR LIFE, <https://aul.org/about/> (last visited Aug. 23, 2021) (stating that Americans United for Life is an anti-choice group whose "Mission [is to] advance the human right to life in culture, law, and policy" by "equip[ping] advocates and lawmakers with the facts and strategies that change hearts and minds and protect human life).

125. AMS. UNITED FOR LIFE, *DEFENDING LIFE 2021* (Tom Shakely et al. eds. 2021), <https://aul.org/wp-content/uploads/2021/02/Defending-Life-2021.pdf>.

126. *See* AMS. UNITED FOR LIFE, *Abortion-Inducing Drugs Information & Reporting Act: Model Legislation & Policy Guide for the 2018 Legislative Year* § (5)(e)(5) (2018), <https://aul.org/wp-content/uploads/2019/07/Abortion-Inducing-Drugs-Information-Act.docx> (noting that, although this section examines the most recent iteration of AUL's model bill, the group promoted reversal bills and was partly responsible for Arizona's S.B. 1318); *see, e.g.*, Olga Khazan, *Planning the End of Abortion*, THE ATLANTIC (July 16, 2015), <https://www.theatlantic.com/politics/archive/2015/07/what-pro-life-activists-really-want/398297/> ("Thanks to AUL, Arizona doctors are now required to tell women who undergo chemical abortions that the procedure can be reversed midway through if the woman changes her mind. Some pro-life doctors claim to have executed this procedure successfully, but the American College of Obstetricians and Gynecologists says it is not safe or even routinely possible. AUL included the measure in *Defending Life*, and even though the gynecologists' group lobbied against the measure this spring, it passed into law.").

127. AM. UNITED FOR LIFE, *supra* note 126, at 2 ("Such an increase [in medication abortion rates] does not come as a surprise. AUL has long warned of a 'chemical abortion revolution'—a marked increase in and emphasis on drug-induced abortions—because such abortions are easier for abortion providers and more profitable. By handing out abortion drugs to a woman and sending her on her way (often without an opportunity to see a physician), abortion providers are able to 'serve' (and charge) more women in a day.")

The model bill, which has inspired anti-choice legislators across the country, directs physicians to tell patients that “[i]t may be possible to reverse the effects of a medication abortion if the woman changes her mind but that time is of the essence.”¹²⁸ Per the model bill, providers are required to share information about abortion reversal at three separate points: (1) by posting the information in the facility; (2) by sharing the information orally as part of the informed consent process; and (3) by sending the patient home with written information about abortion reversal.¹²⁹

As enforcement mechanisms, the model bill recommends “appropriate” criminal penalties for those who “intentionally, knowingly, or recklessly violate[] any provision of” the Act.¹³⁰ In addition to potential criminal penalties, the bill provides for “whatever remedies are available under the common or statutory law of this State,” as well as creating a cause of action for “actual and punitive damages.”¹³¹ The model bill also states that failure to comply with the act “shall . . . provide a basis for a professional disciplinary action” under the state’s medical malpractice act.¹³²

The model bill does not explicitly reference George Delgado or Abortion Pill Rescue, but it does hint at the connection. In its explanation of the “science behind the mechanism of action of mifepristone,” the model bill’s “Legislative Findings” section states that understanding mifepristone helped “physicians to design a specific ‘rescue’ for a woman who has used mifepristone to induce an abortion”—a clear nod towards Abortion Pill Rescue.¹³³ The model bill also invokes familiar rescue language about the safety of progesterone¹³⁴ and the inaccurate characterization of progesterone “kick[ing] off” and “revers[ing]” mifepristone.¹³⁵ As the next sub-section demonstrates, the model bill has been hugely influential to legislators but suffers from a number of problems that have left it vulnerable to litigation. Most of these issues stem from the foundational problem that reversal has not been proven to be a safe or effective medical practice. Nevertheless, as

128. See, e.g., Ariz. S.B. 1318; Okla. S.B. 614 § 1(C)(1); AM. UNITED FOR LIFE, *supra* note 126 § 5(e)(5).

129. AM. UNITED FOR LIFE, *supra* note 126, §§ 4, 5, 6.

130. *Id.* § 9(a).

131. *Id.* § 10(a)(1).

132. *Id.* § 10(a)(2).

133. *Id.* at (2)(a)(20).

134. *Id.* at (2)(a)(22) (“Progesterone itself has been used safely in pregnancies for decades. It is used in in vitro fertilization, infertility treatments, and high-risk pregnancies (such as those experiencing pre-term labor. Using progesterone to reverse the effects of mifepristone is a targeted response that is safe for the woman”).

135. *Id.* at 2(a)(19).

reversal advocates and legislators get savvier about obvious linguistic problems with reversal bills, challenging the bills in court may become more difficult.

B. The Substance & Evolution of Abortion Reversal Bills

1. Arizona: The First Reversal Bill

In 2015, the Arizona legislature passed the first abortion reversal bill: Senate Bill 1318.¹³⁶ The bill was signed by Arizona's Republican Governor Doug Ducey on March 30, 2015, and was slated to go into effect on July 3, 2015.¹³⁷ S.B. 1318 revised Arizona Statute 36-2153, which relates to informed consent requirements, to include the following language:

[C]onsent to an abortion is voluntary and informed only if all of the following are true: At least twenty-four hours before the abortion, the physician who is to perform the abortion, the referring physician or a qualified physician, physician assistant, nurse, psychologist or licensed behavioral health professional to whom the responsibility has been delegated by either physician has informed the woman, orally and in person, that: *It may be possible to reverse the effects of a medication abortion if the woman changes her mind but that time is of the essence* [and] information and assistance with reversing the effects of a medication abortion is available on the Department of Health Services website.¹³⁸

The language is nearly identical to AUL's model bill. The bill also required the Arizona Department of Health Services to post "information on the potential ability of qualified medical professionals to reverse a medication abortion, including information directing women where to obtain further information and assistance in locating a medical professional who can aid in the reversal of a medication abortion" on their existing "A Woman's Right to Know" website.¹³⁹ Penalties for violating the act included

136. S.B. 1318, 52nd Leg., 1st Reg. Sess. (2015).

137. Complaint for Injunctive and Declaratory Relief at 1, Planned Parenthood of Ariz. v. Brnovich, 2:15-cv-01022-SPL (D. Ariz. June 4, 2015), <https://www.aclu.org/legal-document/planned-parenthood-arizona-inc-v-brnovich-complaint-injunctive-and-declaratory-relief>.

138. Ariz. Rev. Stats. § 36-2153(A)(2)(f) (emphasis added) (noting that Senate Bill 1318 also prohibited state insurance exchanges established by the Affordable Care Act from providing coverage for abortion; *see also* § 36-2153(A)(1) (stating the Arizona statute being revised already required providers to give patients certain information about abortion in person twenty-four hours before their abortion)).

139. *See also* Pls.' Mot. & Mem. of L. for Prelim. Inj. and/or TRO at 6, Planned

license suspension or revocation for physicians, as well as civil liability in lawsuits brought by “a woman on whom an abortion has been performed without her informed consent,” the “father of the unborn child” (if he was married to the mother at the time of the abortion), and the maternal grandparents of a minor abortion patient.¹⁴⁰

On June 4, 2015, the ACLU, the ACLU of Arizona, and Planned Parenthood Federation of America filed suit in federal court against various state officials charged with enforcing the law.¹⁴¹ The plaintiffs in the case were all abortion providers in Arizona: Planned Parenthood Arizona, Inc., Desert Star Family Planning, and independent providers Eric Reuss, Paul Isaacson, and DeShawn Taylor. The challenge was brought under 42 U.S.C. 1983, the federal statute that allows citizens to sue state governments for constitutional violations.¹⁴² The plaintiffs claimed that the abortion reversal statute violated the First Amendment rights of physicians by compelling them to share a “state-mandated message about an experimental medical treatment that is not supported by credible evidence, that violates accepted ethical standards and best practices for informed medical consent, and that they would not otherwise tell their patients.”¹⁴³ The plaintiffs also brought Fourteenth Amendment claims on behalf of their patients, alleging that the Act forces patients “receive information from their physician that is untruthful, misleading, and/or irrelevant to the decision to have an abortion.”¹⁴⁴

Plaintiffs challenged the bill by pointing out several misleading features of the statutory language. First, the act applied to *all* patients seeking abortions—even those planning to undergo surgical or procedural abortions, to whom “abortion reversal” obviously would not apply.¹⁴⁵ Second, the bill did not specify that the “reversal” technique only applies to patients who have taken mifepristone but not misoprostol; as written, the language would include patients who have completed both steps of the medication abortion

Parenthood of Ariz. V. Brnovich, 2:15-cv-01022 (D. Ariz. June 4, 2015) (hereinafter “Ariz. Pls.’ Prelim. Inj. Motion”) (noting that, as of the filing of the lawsuit, no information had been posted on the website). Am. United for Life, What We Do: State Legislation, Woman’s Right to Know Act, *available at* <https://aul.org/what-we-do/state-legislation/> (stating that the “Woman’s Right to Know” framework also comes from an AUL model bill).

140. *Id.* § 36-2153(K)(1)-(3).

141. *Brnovich*, 2:15-cv-01022 at 1.

142. *Id.* at 1.

143. *Id.* at 12-13.

144. *Id.* at 13.

145. *See* Ariz. Pls.’ Prelim. Inj. Mot., *supra* note 139, at 15.

regimen.¹⁴⁶ Finally, based on Arizona’s definition of medication abortion (which includes any use of medication “that is intended to cause or induce an abortion”)¹⁴⁷, the bill would also cover patients who were given digoxin—a drug that causes fetal demise—as part of a surgical abortion, or who were given misoprostol alone in a hospital setting.¹⁴⁸

The Arizona lawsuit survived a wave of motions to dismiss by various defendants and proceeded to discovery. Before depositions, though, both Drs. Davenport and Delgado were removed as expert witnesses by the state—presumably because the state recognized that it needed more credible experts. A public records request revealed that the state scrambled to find additional expert witnesses to help defend the bill.¹⁴⁹ Despite contacting perennial pro-life expert witnesses like Theresa Collett,¹⁵⁰ John Thorpe,¹⁵¹ and Michael New,¹⁵² the state was unable to find a single expert witness to help.¹⁵³ Without any expert witnesses to defend the bill, Arizona eventually agreed to a stipulation that allowed a preliminary injunction to be put in place until the Arizona legislature could repeal the bill.¹⁵⁴ In 2016, the legislature passed Senate Bill 1112, which repealed the reversal bill.¹⁵⁵ The litigation was subsequently dismissed in July 2016.¹⁵⁶

146. *Id.* at 8.

147. SB. 1457, 55th Leg., 1st Reg. Sess. (Ariz. 2021).

148. Ariz. Pls.’ Prelim. Inj. Mot., *supra* note 139, at 4.

149. Sofia Resnick, *Not Even Leading Anti-Choice Group Could Help Arizona Defend Its ‘Abortion-Reversal’ Law*, REWIRE NEWS (Mar. 22, 2017), <https://rewirenewsgroup.com/article/2017/03/22/not-even-leading-anti-choice-group-help-arizona-defend-abortion-reversal-law/>.

150. False Witnesses: Teresa Collett, REWIRE NEWS, <https://rewirenewsgroup.com/false-witnesses/#teresa-collett> (last visited July 29, 2021) (noting that Collett is a lawyer, not a medical doctor or statistician, but has been allowed to testify in multiple abortion-related lawsuits).

151. False Witnesses: John Thorpe, REWIRE NEWS, <https://rewirenewsgroup.com/false-witnesses/#john-thorp> (last visited July 29, 2021).

152. False Witnesses: Michael New, REWIRE NEWS, <https://rewirenewsgroup.com/false-witnesses/#michael-new> (last visited July 29, 2021).

153. Resnick, *supra* note 149 (citing to https://rewirenewsgroup.com/wp-content/uploads/2017/01/Resnick-PRR-1_Redacted.pdf#page=22).

154. Mary Jo Pitzl, *Court: Arizona Abortion-Reversal Law is No More*, AZCENTRAL (Aug. 26, 2016), <https://www.azcentral.com/story/news/politics/arizona/2016/08/23/court-arizona-abortion-reversal-law-no-more/89229028/>.

155. *Id.*

156. ACLU of Arizona, Press Release: End of the Line for For Anti-Abortion Law Forcing Doctors to Mislead Women (July 23, 2016), <https://www.acluaz.org/en/press-releases/end-line-anti-abortion-law-forcing-doctors-mislead-women>.

2. *Louisiana's Concurrent Resolution*

In 2016, Louisiana passed a concurrent resolution directing the Department of Health to study and publish a report “concerning the possibility of reversing the effects of an abortion induced with drugs or chemicals.”¹⁵⁷ Although not a reversal bill per se, the bill was likely intended to eventually support a reversal bill since all six of the bill’s sponsors have been rated 100% by Louisiana Right to Life Federation.¹⁵⁸ In April 2017, the Louisiana Office of Public Health released their response to the resolution: a “Study Related to Whether the Effects of an Abortion Induced With Drugs or Chemicals Can Be Reversed.”¹⁵⁹ The legislation required the Department of Health to “convene a panel of experts in obstetrics and gynecology and pharmacology to provide guidance on this matter and to aid the department in the study.”¹⁶⁰ The Department held a conference call with the convened experts and asked them to provide written responses to two questions:

The resolution cites reports of a method to reverse medication-induced abortions. In your professional opinion, are such procedures scientifically sound and meet established standards of safety and efficacy?

Is there a position or formal position statement from your professional association(s) regarding procedures intended to reverse medication-induced abortions?¹⁶¹

157. La. H. Conc. Res. 87 (2016).

158. VoteSmart, Frank Hoffman’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/93662/frank-hoffmann> (last visited July 29, 2021); VoteSmart, Katrina Jackson’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/134647/katrina-jackson> (last visited July 29, 2021); VoteSmart, Dodie Horton’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/165610/dodie-horton> (last visited July 29, 2021); VoteSmart, J. Rogers Pope’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/93682/j-rogers-pope> (last visited July 29, 2021); VoteSmart, Lawrence Bagley’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/165607/lawrence-bagley> (last visited July 29, 2021); VoteSmart, Kenny Cox’s Ratings and Endorsements, <https://justfacts.votesmart.org/candidate/evaluations/93641/kenny-cox> (last visited July 29, 2021).

159. *Legislative Report on 2016 House Concurrent Resolution 87: Study Related to Whether the Effects of an Abortion Induced with Drugs or Chemicals Can Be Reversed*, LA. DEP’T OF HEALTH (Apr. 12, 2017), <https://ldh.la.gov/assets/docs/LegisReports/HCR87RS20161.pdf>.

160. La. Dep’t of Health at 2.

161. *Id.*

The convened experts included professors of pharmacy, obstetrics and gynecology, and nursing from the University of Louisiana, Xavier University, Tulane University, and Louisiana State University.¹⁶² The report cited Dr. Grossman's literature review of mifepristone reversal and noted that Dr. Delgado's 2012 paper was the only published article purporting to reverse abortion.¹⁶³ The report also reviewed the positions of relevant professional associations, including the amicus brief that ACOG and the AMA filed in the Arizona litigation.¹⁶⁴ The experts that LDH convened to review reversal "unanimously concluded, based on their professional experience in the areas of obstetrics/gynecology, pharmacology, and nursing and the above-referenced research, that there was insufficient evidence to conclude that the administration of progesterone in an attempt to reverse a medication abortion is scientifically sound."¹⁶⁵ The report also noted that "the panel expressed great concerns about the experimental nature of using progesterone treatment after taking mifepristone, as highlighted in the Delgado study, and the failure of the study to meet the established standards of safety, efficacy, and ethics."¹⁶⁶ Ultimately, the report concluded that "there is neither sufficient evidence nor a scientific basis to conclude that the effects of an abortion induced with drugs or chemicals can be reversed."¹⁶⁷

3. *The Evolution of Reversal Bills*

Despite this strong conclusion, Louisiana introduced a reversal bill in April 2021.¹⁶⁸ The proposed bill requires abortion providers to staple or otherwise attach the following language to the patient's prescription for misoprostol or the patient's discharge instructions:

Research has indicated that the first pill provided, identified as mifepristone, is not always effective in ending a pregnancy. If after taking the first pill you regret your decision, please consult a physician or healthcare provider immediately to determine if there are options available

162. *Id.* at 3.

163. *Id.* at 4.

164. *Id.* at 5.

165. *Id.*

166. *Id.*

167. *Id.* at 6.

168. Rosemary Westwood, *New Bill Pits Anti-Abortion Groups Against The Health Department Over Controversial 'Abortion Reversal'*, WWNO (May 27, 2021), <https://www.wwno.org/public-health/2021-05-27/new-bill-pits-anti-abortion-groups-against-the-health-department-over-controversial-abortion-reversal>.

to assist you in continuing your pregnancy.¹⁶⁹

The requirements of this bill are far more careful than that of Arizona's S.B. 1318 or the original model bill—a trend that reversal bills, in general, have followed. Newer reversal statutes have gotten more precise in their language, and some, like Louisiana, have even abandoned the term “reversal” altogether. The phrasing “assist you in continuing your pregnancy”—which does not promise any sort of affirmative reversal—might be seen as technically more accurate by a judge. Similarly, in 2020, a Michigan legislator proposed an abortion reversal bill that did not use the word “reversal” at all; instead, the bill stated that a patient could “increase the possibility of maintaining the pregnancy if the patient changes her mind.”¹⁷⁰ During the 2020–21 legislative session, the South Dakota legislature passed language stating that “even after a pregnant mother takes Mifepristone or another drug approved by the FDA for the same use, it is still possible to *discontinue* a drug-induced abortion by not taking the prescribed Misoprostol” and that “information on discontinuing a drug-induced abortion is available on the Department of Health website.”¹⁷¹ The language in the Michigan and South Dakota bills does not mention progesterone therapy or Abortion Pill Rescue at all.¹⁷² This language (“continuing your pregnancy,” “maintaining the pregnancy,” “discontinu[ing] a drug-induced abortion”) seems directly responsive to judges who found that the word “reversal” itself was misleading.¹⁷³

169. H.B. § 578, 2020 Leg., Reg. Sess. (La. 2021).

170. H.B. 5374, *supra* note 121

171. S.D. H.B. 1130 § (1)(h) & (i) (2021).

172. *Id.* at (3)(a) & (b); *see also* Assemb. B. 180, 2019-2020 Leg., Reg. Sess. (Wis. 2019) (“If the woman is considering or planning to have an abortion induced by an abortion-inducing drug regimen that includes mifepristone, that the ingestion of the first drug in the abortion-inducing drug regimen may not result in an immediate abortion and that, if the woman changes her mind after ingesting the first drug, *the woman may be able to continue the pregnancy but time is of the essence* and she should contact a physician to discuss options or consult the information provided in the materials under part (d) to locate a health care professional that can assist in counteracting the effects of the drug.”) (emphasis added). While the South Dakota bill does not directly reference the Abortion Rescue Hotline, it does require providers to duplicate the statement above and point patients to a “phone number, website, and any other contact information provided to the department by physicians or other entities, who or that have indicated their ability and willingness to provide assistance, twenty-four hours per day, seven days a week, to a woman seeking to discontinue an abortion.” Presumably, the department would have to reference APR to comply with this requirement.

173. Tenn. Prelim. Inj. Ord. at 1141-42, 1145-46 (“The pool of women reading the mandated message, however, will undoubtedly include patients whose pregnancies will

Many of the critiques made by the Arizona plaintiffs have been addressed; the more recent bills, like Louisiana's 2021 bill, specify that the technique applies only to medication abortions affected by mifepristone. The Louisiana bill does not require physicians to literally speak the government-mandated message; instead, the patients receive the printed information upon discharge. Critically, the timing of the message alleviates potential concerns about the prospect of reversal pushing uncertain abortion patients to take mifepristone under the misguided idea that they can reverse its effects later.¹⁷⁴ The bill does not include penalties for providers that do not comply.

At their core, these bills still suffer from one fundamental problem: they promote a therapy that has not been proven to be safe or effective. As a subject of litigation, judges—especially those who are not sympathetic to abortion or see the abortion decision as emotionally wrought—might look more favorably on bills that simply present information about the option of progesterone therapy after a patient has taken mifepristone.

III: CHALLENGING ABORTION REVERSAL AS LAW

Abortion reversal bills typically amend or supplement abortion-specific informed consent statutes.¹⁷⁵ Although the substance of abortion reversal bills is relatively new, the anti-choice strategy of forcing providers to “disclose” unnecessary or misleading information to abortion patients as part of the informed consent process is not.¹⁷⁶ Indeed, reversal bills fit neatly

terminate after taking the first pill, and it is undisputed that progesterone therapy will not “reverse” the abortions of those patients. The word “reversal” makes the mandated message untruthful and/or misleading because it promises more than progesterone therapy has even attempted to deliver. Additionally, the term “reverse” does not accurately describe the theory underlying Dr. Delgado’s progesterone therapy”); N.D. Prelim. Inj. Ord. at 1149 (“First, the statement that ‘it may be possible to reverse the effects of an abortion-inducing drug’ is misleading at best. The State’s own expert, Dr. Obritsch, admits that: ‘The term ‘abortion reversal’ is somewhat misleading in that an abortion is not reversed but rather, abortion is prevented from occurring . . . by preventing the antiprogesterone effect of mifepristone from exerting its effect upon the pregnancy.’”).

174. See, e.g., Tenn. Prelim. Inj. Ord. at 1138 (“Finally, the timing of this message—requiring that it be conveyed before the patient makes the decision to begin the procedure—contributes to its misleading nature.”).

175. See, e.g., S.B. 341, 92d Gen. Assemb., 2019 Reg. Sess. (Ark. 2019). (“An Act To Amend The Woman’s Right To Know Act; To Provide Information on Reversing The Effects of Abortion-Inducing Drugs; And For Other Purposes”); S.B. 1243, 64th Leg., 2d Reg. Sess., (Idaho 2018). (“In order to provide assistance in assuring that the consent to an abortion is truly informed consent”); H.F. 53, 89th Leg., Reg. Assemb. Leg. (Iowa 2021). (“An Act relating to informed consent for medication abortions.”).

176. See, e.g., *Mandatory Counseling for Abortion*, GUTTMACHER INST. (Jan. 2020),

within a decades-old framework that paints abortion patients as indecisive, desperate, and easily swayed by outside influence.¹⁷⁷ Ironically, as several federal judges have pointed out when striking down abortion reversal bills, the claim that abortion can be reversed could actually lead an uncertain patient to take mifepristone because she thinks she can “reverse” its effects if she changes her mind. Thus, rather than ensuring that patients are making the abortion decision with all the information they need, reversal bills mislead patients about the impact of mifepristone on their pregnancy. The handful of courts that have considered reversal mandates have expressed deep concern about laws requiring that physicians speak a government message against their best medical judgment and held that these laws likely violate the First Amendment’s prohibition against compelled speech. This section provides the legal and medical background for First Amendment challenges to reversal laws on the ground that they compel misleading and untruthful speech by physicians and offers a potential novel challenge on the ground that the laws also violate a patient’s complementary right not to listen.

A. *Informed Consent and Decisional Certainty*

Informed consent plays a crucial role in the doctor-patient relationship and reflects respect for patient autonomy—one of the “four main principles that should guide the practice of medicine.”¹⁷⁸ Patient autonomy and self-determination “preserve[] an individual’s ability to make and carry out informed decisions that arise from unbiased and thoughtful deliberation.”¹⁷⁹

<https://www.guttmacher.org/evidence-you-can-use/mandatory-counseling-abortion>. (listing inaccurate information included in biased counseling, like the non-existing link between abortion and breast cancer or the existence of “post-abortion stress syndrome.”).

177. See, e.g., Our Passion, Heartbeat Int’l, <https://www.heartbeatinternational.org/about/our-passion> (“Heartbeat’s life-saving mission . . . We RENEW broken cities around the world, by developing pregnancy centers where abortion clinics are the only alternative for abortion-vulnerable women.”); see also Maya Manian, *The Irrational Woman: Informed Consent and Abortion Decision-Making*, 16 DUKE J. GENDER L. & POL’Y 223, 225 (2009); Reva B. Siegel, *The New Politics of Abortion: An Equality Analysis of Woman-Protective Abortion Restrictions*, U. ILL. L. REV. 991 (2007) (“South Dakota’s [abortion counseling] statute illustrates the shift from fetal-focused to gender-based justifications for abortion restrictions. The legislative history gives a lengthy account of how abortion hurts women, sometimes explaining these harms in the language of public health, sometimes in the language of informed consent, and sometimes in the language of natural law . . . [T]hese justifications rest on gender stereotypes about women’s capacity and women’s roles.”).

178. Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 435 (2006).

179. *Id.*

As experts in their fields, healthcare providers often have significantly more information about a patient's condition or the risks and benefits of any treatment plan. Because of the power dynamic and knowledge gap between doctors and patients, violating informed consent constitutes medical malpractice.¹⁸⁰ The first informed consent claim was famously recognized by Justice Cardozo in *Schloendorff v. New York General Hospital*.¹⁸¹ Cardozo wrote, “[e]very human being of adult years and sound mind has a right to determine what shall be done with his body; and a surgeon who performs an operation without his patient's consent, commits an assault.”¹⁸² One hundred years later, all fifty states have codified informed consent requirements and offer legal recourse to patients who did not properly consent to treatment.¹⁸³

Abortion is no different from any other medical procedure or treatment. Before choosing a medication or surgical abortion, doctors must present their patients with all the relevant medical information about their choice, including the risks and benefits of each option. For example, abortion providers should always tell their patients about risks from infection or ectopic pregnancy.¹⁸⁴ The informed consent process is meant to provide patients with “sufficient knowledge regarding their medical condition and treatment choices to make an autonomous medical decision.”¹⁸⁵ The process is *not* meant to sway the patient to choose a particular course of treatment.

Precisely because abortion is not reversible, abortion providers—like all medical professionals guiding their patients through a particular treatment—employ safeguards to ensure that each abortion patient is sure of her decision and isn't being pressured to have the abortion. Quality providers screen for intimate partner violence (“IPV”) and coercion.¹⁸⁶ In addition to screening

180. *Canterbury v. Spence*, 464 F.2d 772, 780-81 (D.D.C. 1972). In the United States, about half of states use a patient-based standard for informed consent claims—*i.e.*, that what a reasonable patient would expect to be told before treatment determines the scope of informed consent. Other states use a physician-based standard, which “require[s] physicians to inform a patient of the risks, benefits and alternatives to a treatment in the same manner that a ‘reasonably prudent practitioner’ in the field would.” King & Moulton, *supra* note 178, at 430.

181. *Schloendorff v. Soc’y of N.Y. Hospital*, 211 N.E. 125 (N.Y. 1914).

182. *Id.* at 126.

183. Manian, *supra* note 177, at 235–37.

184. See, e.g., Cleland et al., *supra* note 14, at 5 and Upadhyay et al., *supra* note 14, at 176.

185. King & Moulton, *supra* note 178, at 435.

186. *Number 518, Committee on Health Care for Underserved Women*, (Feb. 2012), <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2012/02/intimate-partner-violence>.

for outside influence, the standard of care for abortion providers is to assess patients for what's known as "decisional conflict" and "decisional certainty":

Decisional conflict is defined as a state of uncertainty about a course of action when the choices involve risk, loss, regret, or a challenge to personal values. Assessing and responding to decisional conflict—and its corollary, decisional certainty—is routine in health care, particularly in fields such as obstetrics and oncology where decisions often require balancing complex benefits and risks which are sensitive to patients' preferences and values.¹⁸⁷

Qualitative scales have been developed to determine the level of certainty a patient feels before undergoing treatment. For example, the Decisional Conflict Scale measures four domains that reflect levels of certainty in decision-making: "[U]nderstanding of the different health care options available; clarity about which risks and benefits matter most; level of support or pressure felt in making a decision; and difficulty in choosing a course of action."¹⁸⁸ In a study of patients subject to state laws that required waiting periods before abortion—allegedly a way to enhance certainty in the abortion decision-making process—researchers found that abortion patients typically experience very little decisional conflict.¹⁸⁹ Indeed, abortion patients experience less decisional conflict than patients undergoing knee surgery, prostate cancer treatment, prenatal testing after infertility, or mastectomy.¹⁹⁰

Decisional conflict and decisional certainty are important concepts in the reversal context for obvious reasons. First, very few abortion patients "regret" their abortions and most rank relatively high on measurements of decisional certainty, including how stable that decision remains after the abortion.¹⁹¹ So while "[e]valuating how certain a woman is about her

187. See, e.g., Lauren J. Ralph et al., *Measuring Decisional Certainty Among Women Seeking Abortion*, 95 CONTRACEPTION 269, 269 (2017).

188. See, e.g., Iris Jovel et al., *Abortion Waiting Periods and Decision Certainty Among People Searching Online for Abortion Care*, 137 OBSTETRICS & GYNECOLOGY 597, 599 (2021).

189. *Id.* at 597.

190. Advancing New Standards in Reproductive Health, *Women Are Certain About Their Decision to Have an Abortion* (Oct. 10, 2016), <https://www.ansirh.org/research/research/women-are-certain-about-their-decision-have-abortion>.

191. Jovel et al., *supra* note 189, at 601 ("Overall, in this sample of people searching for abortion information online, those who had obtained abortions by follow-up had the most stable levels of decision certainty over time, which is consistent with previous literature."); Corrine H. Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLOS ONE (2015) ("Instead, as

decision to obtain an abortion is . . . an important component of abortion care,” abortion reversal laws (and other biased “informed consent” laws) promote the idea “that women experience more conflict about abortion than other healthcare decisions and require additional time or information” beyond the standard informed consent process, which is simply not true.¹⁹² Moreover, for a patient who *is* experiencing high decisional conflict about her abortion, information about abortion reversal may cause her to push through that uncertainty and take mifepristone if she believes that reversing mifepristone’s effects is possible, with potentially tragic results.

B. Informed Consent, Professional Speech, & The First Amendment

Although litigators have challenged abortion reversal mandates on multiple constitutional grounds,¹⁹³ the most common—and successful—challenges have been claims that reversal laws violate the First Amendment by compelling physicians to speak a government message. The First Amendment free speech right encompasses both the right to speak and the right *not* to speak.¹⁹⁴ The compelled speech prohibition protects against three “distinct evils of government speech regulation: incompetence, entrenchment, and intolerance.”¹⁹⁵ Content-based regulations are “presumptively unconstitutional” and require the government to satisfy strict scrutiny (*i.e.*, demonstrate that the law is narrowly tailored to serve a compelling state interest) before a court will uphold the law.¹⁹⁶ As Justice

previous analyses of earlier subsets of the data analyzed here show, feelings of relief predominate among women who have obtained an abortion in the week following the abortion . . . and all emotions decline in intensity over the three years after the abortion This same study also found no evidence that significant numbers of women regret their abortion decisions; 95% of women reported that abortion was the right decision three years after their abortion.”) (citations of previous publications of the author’s work omitted)).

192. Ralph, *supra* note 187, at 3.

193. Other claims include Equal Protection (in Tennessee, Oklahoma, and Indiana), Procedural Due Process (in Oklahoma and North Dakota), and Substantive Due Process (in Arizona and Indiana). All of the courts to review reversal mandates have ruled on free speech grounds. Substantive due process claims on behalf of patients are discussed later in this Part.

194. N.D. Prelim. Inj. Order at 1148 (citing *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)).

195. Caroline Mala Corbin, *The First Amendment Right Against Compelled Listening*, 89 B.U.L. REV. 939, 996 (2009) (quoting Dale Carpenter, *The Antipaternalism Principle in the First Amendment*, 37 CREIGHTON L. REV. 579, 635 (2004)).

196. *Id.* (quoting *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2226 (2015) and *NIFLA v. Becerra*, 138 S. Ct. 2361, 2371 (2018)).

Clarence Thomas noted in *National Institute of Family & Life Advocates* (“NIFLA”) v. *Becerra*, the right to free speech is particularly important in the realms of medicine and public health, “where information can save lives.”¹⁹⁷

Abortion reversal bills are part of a broader, decades-long trend that attempts to use the informed consent dialogue to talk patients out of abortion. Since *Roe v. Wade*, states have proposed and passed abortion-specific “informed consent” laws that direct physicians to present abortion patients with misleading information meant to sway them in favor of childbirth. Some of these laws misrepresent the physical risks of abortion by claiming that abortion causes breast cancer and infertility.¹⁹⁸ Others focus on the “humanity” of the embryo or fetus by requiring physicians to show their patients an ultrasound of their fetus in real-time, or to describe fetal development in detail.¹⁹⁹

Before *Planned Parenthood v. Casey*, the Supreme Court struck down the substance of such anti-choice informed consent laws on multiple occasions and stressed the importance of insulating the informed consent process from anti-choice state influence.²⁰⁰ For example, in *Akron Center for Reproductive Rights v. City of Akron*, the Supreme Court struck down a statute that required physicians to give their patients inaccurate information about abortion, including statements that abortion “can result in severe emotional disturbances” and cause “sterility and miscarriage and prematurity in subsequent pregnancies.”²⁰¹ The law also required physicians to make a statement that “the unborn child is a human life from the moment of conception” and describe “the anatomical and physiological characteristics

197. *NIFLA v. Becerra*, 138 S. Ct. 2361, 2374 (2018).

198. *Roe v. Wade*, 410 U.S. 113, 166 (1973); see Mandatory Counseling for Abortion, *supra* note 44; see also *American College of Obstetricians and Gynecologists, Committee Opinion No. 434: Induced Abortion & Breast Cancer Risk*, 113 OBSTETRICS & GYNECOLOGY 1417 (2009) (reaffirmed 2019); Jen Gunther, *Can An Abortion Affect Your Fertility?*, N.Y. TIMES (May 30, 2019), <https://nyti.ms/3azPWck>.

199. CAROL SANGER, ABOUT ABORTION: TERMINATING PREGNANCY IN TWENTY-FIRST-CENTURY AMERICA 115 (The Belknap Press of Harvard University Press 2017); CAROL SANGER, *Seeing and Believing: Mandatory Ultrasound and The Path to a Protected Choice*, 56 UCLA L. REV. 351, 387 (2008) [hereinafter Sanger, *Seeing and Believing*].

200. See *Planned Parenthood v. Casey*, 505 U.S. 833, 838-41 (discussing Section 3205’s informed consent provision, which discusses abortion under Pennsylvania statute).

201. 462 U.S. 416, 423 (1983); see also *Thornburgh v. Am. Coll. of Obstetricians and Gynecologists*, 476 U.S. 747, 760 (1986) (striking down informed consent regulations “designed to influence the woman’s informed choice between abortion and childbirth.”)

of the particular unborn child at the gestational point of development at which time the abortion is to be performed”²⁰² Although the Court recognized the state had an interest in protecting maternal health after the first trimester, that interest did not allow for regulations that “depart from accepted medical practice”²⁰³ or “justify abortion regulations designed to influence the woman’s informed choice between abortion or childbirth.”²⁰⁴ In striking down the informed consent provisions, the Court stressed the importance of the doctor-patient relationship and the physician’s role in facilitating medical decision-making:

The Court also has recognized, because abortion is a medical procedure that the full vindication of the woman’s fundamental right necessarily requires that her physician be given the room he needs to make his best medical judgment. . . . The physician’s exercise of this medical judgment encompasses both assisting the woman in the decision-making process and implementing her decision should she choose abortion.²⁰⁵

In *Planned Parenthood v. Casey*, the Supreme Court departed from its post-*Roe* stance on pro-life informed consent and held that “truthful, non-misleading information about the nature of the procedure, the attendant health risks and those of childbirth” was not a constitutional violation.²⁰⁶ This was true “even when in doing so the State expresses a preference for childbirth over abortion.”²⁰⁷ Under this rubric, even laws that blatantly espouse anti-choice ideology (like the idea that life begins at conception) may survive constitutional scrutiny.²⁰⁸

Scholars and litigators have suggested myriad ways that biased counseling laws might violate the rights of both doctors and patients—by compelling physicians to provide inaccurate information to their patients,²⁰⁹ by

202. 462 U.S. 416, 424 (1983).

203. *Id.* at 430–31.

204. *Id.* at 444.

205. *Id.* at 427.

206. 505 U.S. 833, 882 (1992); *see also* Manian, *supra* note 177, at 250.

207. *Casey*, 505 U.S. at 883.

208. *See, e.g.,* *Planned Parenthood Minn., N.D., S.D., v. Rounds*, 530 F.3d 724, 726 (8th Cir. 2008) (upholding a statute requiring that physicians tell patients “[t]hat the abortion will terminate the life of a whole, separate, unique, living human being.”)

209. Vandewalker, *supra* note 8, at 8; Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. ILL. L. REV 939, 940 (2007); David Orentlicher, *Abortion and Compelled Physician Speech*, J.L. MED. & ETHICS 9, 13 (2015).

compelling patients to hear inaccurate information,²¹⁰ by relying on improper gender stereotypes,²¹¹ and by interfering with the abortion decision-making process.²¹² Unfortunately, courts are split about the constitutional viability of these laws as either complying with *Casey*'s "truthful, non-misleading information" mandate or impermissibly interfering with an abortion patient's decision-making.²¹³

The challenge, then, for advocates who hope to attack abortion reversal requirements through constitutional law is to demonstrate that abortion reversal is both false and misleading under *Casey* and its progeny.²¹⁴ In 2018, advocates opposing abortion pill reversal found an unlikely (and inadvertent) ally in Justice Clarence Thomas, who wrote the majority opinion in *NIFLA v. Becerra*, which struck down a California law that required Crisis Pregnancy Centers ("CPCs") to give their patients information about low-cost state reproductive services provided by the state, including abortion.²¹⁵ Although *NIFLA* was perceived to be an anti-choice decision written by an anti-choice justice, both opinions striking down abortion reversal bills—written by federal judges in North Dakota and Tennessee, respectively—have treated *NIFLA* as supportive precedent.²¹⁶

NIFLA challenged the California Reproductive Freedom, Accountability, Comprehensive Care, and Transparency ("FACT") Act, which required both unlicensed and licensed "covered facilities" to "disseminate a government-drafted notice" stating that "California has public programs that provide immediate free or low-cost access to comprehensive family planning

210. Corbin, *supra* note 195, at 996 (arguing that biased counseling bills violate an as-yet-unrecognized right against compelled listening).

211. Siegel, *supra* note 171, at 993.

212. Sanger, *Seeing and Believing*, *supra* note 192, at 387.

213. *Compare* *Planned Parenthood v. Casey*, 505 U.S. 833, 881; *with Rounds*, 530 F.3d at 726; *and* *Stuart v. Camnitz*, 774 F.3d 238, 242 (4th Cir. 2014) (striking down a requirement that physicians show abortion patients a real-time image of an ultrasound and describe the image as a violation of free speech). As discussed in the next subsection, trying to fit *physician* First Amendment claims into the *Casey* undue burden framework (which presumes that patients' abortion rights are at stake) often obscures the free speech right of the physician, independent of the abortion context.

214. *See* 505 U.S. at 838.

215. 138 S. Ct. 2361 (2018).

216. A state district court in Oklahoma also temporarily enjoined the reversal mandate, which was challenged as a violation of free speech, procedural due process, and Oklahoma's "special law" (*i.e.*, state Equal Protection). The judgment summarily granted Plaintiffs' Motion for a Temporary Injunction but did not outline its reasoning for doing so. Okla. Judgment.

services. . . prenatal care, and abortion for eligible women.”²¹⁷ Although the bill technically covered abortion providers, the legislation was clearly aimed at curbing CPCs.²¹⁸ The legal question at issue in *NIFLA* was whether the notice requirement, as applied to both the licensed and unlicensed facilities, constituted compelled speech by the government in violation of the First Amendment. The Ninth Circuit denied plaintiffs’ motion for a preliminary injunction, holding that the licensed notice would survive a lower level of scrutiny applied to “professional speech” and that the unlicensed notice would survive any level of scrutiny.²¹⁹

The majority opinion rejected California’s argument (and Ninth Circuit precedent) that the licensed notice should survive a lower level of scrutiny applied to “professional speech.” Indeed, Justice Thomas rejected the idea that “professional speech” was an appropriate category to carve out of broader First Amendment protections at all.²²⁰ In so doing, the *NIFLA* decision invoked the ways that “governments have manipulated the doctor-patient discourse to increase state power and suppress minorities,” including Chinese physicians who were “dispatched to the countryside to convince peasants to use contraception” and Soviet physicians who, at the government’s request, “reject[ed] requests for medical leave” from workers constructing the Siberian railroad.²²¹

217. *NIFLA v. Becerra*, 138 S. Ct. 2361, 2369 (2018). Licensed covered facilities included those with the “primary purpose of providing family planning or pregnancy-related services” and satisfied at least two of six other requirements, including those that (1) offer ultrasounds, (2) provide or counsel about contraception, (3) offer pregnancy tests or diagnosis, (4) “advertise[] or solicit[] patrons with offers to provide prenatal sonography, pregnancy tests, or pregnancy options counseling,” (5) offer abortion services, or (6) collect health information from clients. The bill also required unlicensed covered facilities (those that provide pregnancy-related services and satisfy two of four requirements) to provide a “government-drafted notice” on site and in advertising materials stating that the facility is not licensed by the State of California and does not have a licensed medical provider on site. *Id.* at 2368–70.

218. See, e.g., Amy Everitt, *Unmasking Fake Clinics: The Truth About Crisis Pregnancy Centers in California*, NARAL PRO-CHOICE CALIF. FOUND. 1, 2 (2010), <https://www.sfcityattorney.org/wp-content/uploads/2015/08/Unmasking-Fake-Clinics-The-Truth-About-Crisis-Pregnancy-Centers-in-California.pdf> (finding after investigation that a majority of CPCs promoted false statements about links between abortion and breast cancer, infertility, and mental health problems).

219. *NIFLA*, 138 S. Ct. at 2370 (citing Nat’l Inst. of Fam. & Life Advoc. v. Harris, 839 F.3d 823, 845 (9th Cir. 2016)).

220. *Id.* at 2371–72.

221. *Id.* at 2374 (citing Paula Berg, *Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice*, 74 B.U.L. REV. 201 (1994)). Ironically, Berg’s article argues that the informed consent scripts upheld

The doctrine of “professional speech” developed in the circuit courts in the context of California’s ban on “sexual orientation change efforts” for children in *Pickup v. Brown*, and Florida’s ban on healthcare providers asking or recording information about firearm ownership in *Wollschlaeger v. Governor of Florida*.²²² The professional speech doctrine generally stands for the proposition that free speech rights are diminished when a doctor is acting “within the confines of a professional relationship” and lower still when “the regulation [is] of professional conduct . . . even though such regulation may have an incidental effect on speech.”²²³ The “fundamental premise” of the professional speech doctrine is that the government’s power to license professionals like doctors “necessarily contemplates a lesser-included power to significantly regulate the speech of professionals.”²²⁴

After rejecting the professional speech doctrine as a way to uphold the FACT Act,²²⁵ the majority also discussed and rejected the application of two narrow exceptions to free speech protection that arise in commercial settings: laws requiring disclosure of “purely factual and uncontroversial information about the terms under which . . . services will be available” per *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*,²²⁶ and laws that regulate professional conduct, even though that conduct incidentally involves speech per *Casey*.²²⁷ The *Zauderer* exception did not apply because the notice did not disclose anything about the CPCs’ provided services, and because it “requires these clinics to disclose information about . . . abortion, anything but an ‘uncontroversial’ topic.”²²⁸

The second exception also did not apply because the California notice did not involve the “practice” of medicine, which would be “subject to reasonable licensing and regulation by the State.” The majority clarified that

by *Casey* in the abortion context violate the First Amendment. *Id.* at 206 (“[T]his Article strives to succeed where . . . *Casey* failed by developing a First Amendment theory of doctor-patient discourse that appreciates and protects patients’ interests in receiving complete, unbiased medical information and advice.”)

222. See *Pickup v. Brown*, 728 F.3d 1042, 1048 (9th Cir. 2013); *Wollschlaeger v. Governor of Florida*, 760 F.3d 1195, 1203 (11th Cir. 2014).

223. Rodney A. Smolla, *Professional Speech and the First Amendment*, 119 W. VA. L. REV. 67, 72 (2016) (quoting *Pickup*, 740 F.3d at 1053-55).

224. *Id.* at 69.

225. See *NIFLA v. Becerra*, 138 S. Ct. 2361, 2365 (2018) (stating the California Reproductive Freedom, Accountability, Comprehensive Care, and Transparency Act [FACT Act] was enacted to regulate anti-choice pregnancy centers that offer pregnancy-related services).

226. 471 U.S. 626, 651 (1985).

227. *NIFLA*, 138 S. Ct. at 2372 (citing *Casey*, 505 U.S. at 884).

228. *Id.* at 2372.

the restrictions on free speech at issue in *Casey* were permissible under the First Amendment because they were part of the informed consent process for a particular procedure—an example of “longstanding torts for professional malpractice,” which falls under the “traditional purview of state regulation of professional conduct.” The California notices, on the other hand, did not “facilitate informed consent to a particular procedure” and thus “regulate [] speech as speech.”²²⁹

C. *Speaking & Listening*

1. *A Physician’s Right Not to Speak*

Although this decision was perceived as a win for anti-choice principles, courts have already invoked *NIFLA*’s reasoning about “professional speech” to protect abortion providers from spreading information they think is inaccurate and misleading and declined to apply mere rational basis review to the statutes.²³⁰ In Tennessee, a judge invoked *NIFLA* as “reject[ing] special rules for separate categories of speech” and noting the Supreme Court’s “reluctan[ce] to mark off new categories of speech for diminished constitutional protection.”²³¹ Ultimately, the Tennessee order concluded that plaintiffs were likely to succeed on their First Amendment claim, and the law should be preliminarily enjoined. Even though *Casey*’s informed consent holding was not technically decided on First Amendment grounds, the Tennessee Court’s First Amendment ruling explicitly relied on *Casey*’s distinction between truthful and untruthful and misleading and non-misleading information.²³²

229. *Id.* at 2373–74.

230. The *NIFLA* majority distinguished informed consent requirements tied to a specific medical procedure from the broad notices required by the FACT Act. Nonetheless, lower federal courts have interpreted *NIFLA*’s rejection of a “professional speech” carve out to apply equally to laws that use informed consent as a mechanism to require doctors to speak a government message. *See All-Options. v. Atty. Gen. of Ind.*, 2021 U.S. Dist. LEXIS 122138, at *21 (S.D. Ind. June 30, 2021) (citing *NIFLA v. Becerra*, 138 S. Ct. 2361, 2371 (2018), for the propositions that “required notices for medical providers are content-based regulation[s] of speech that implicate the First Amendment” and that such “speech is fundamental to the physician-patient relationship because doctors help patients make deeply personal decisions.”)

231. N.D. Prelim. Inj. Order at 1149.

232. Tenn. Prelim. Inj. Ord. at 35. The Court also cited a recent Sixth Circuit case, *EMW Women’s Surgical Ctr. v. Beshear*, 920 F.3d 421, 424 (6th Cir. 2019), which decided that courts are not required to “highly scrutinize” an informed consent statute “as long as it met three requirements: ‘(1) it must relate to a medical procedure; (2) it must be truthful and not misleading; and (3) it must be relevant to the patient’s decision whether to undertake the procedure, which may include, in the abortion context,

The Tennessee bill required physicians to share the following statement, which is similar but not identical to the AUL Model Bill:

Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately.²³³

The Court then dismantled Tennessee’s bill word-by-word to demonstrate the bill required doctors to share “untruthful and/or misleading” information. First, the judge noted that research about mifepristone’s sole efficacy was not “recent” or “developing,” but is instead “approximately 30 years old.”²³⁴ The “next sentence” was found to be “even more problematic” because of its misuse of the word “reverse.”²³⁵ The Court applied Merriam Webster’s dictionary definition of “reverse” and found that it did not “accurately describe to patients the medical research on progesterone therapy.”²³⁶ This was true both because the research itself did not support such a strong statement, and because even Delgado’s description of progesterone therapy could not accurately be called “reversal” because it implies a kind of competitive effect rather than a “neutraliz[ing]” effect where progesterone acts as an “anecdote” that can “undo” mifepristone’s effects.²³⁷ Even the relatively innocuous instruction to “consult with a healthcare professional” was found to be potentially misleading because patients would see such an instruction while they were already at a healthcare provider’s office.²³⁸

In North Dakota, the District Court judge also adopted the reasoning in *NIFLA* to strike down a reversal mandate. The State argued their reversal bill “regulate[d] professional conduct that incidentally burdens speech”—the same argument that California made in support of the FACT Act.²³⁹ The District Court assumed without deciding that this exception applied to the reversal mandate and held that intermediate review was the appropriate

information relevant to the woman’s health risks, as well as the impact on the unborn life.”

233. Tenn. Code Ann. § 39-15-218(b).

234. *Id.* at 40.

235. *Id.* at 41.

236. *Id.*

237. *Id.* at 42-43 (“Simply put, Defendants’ argument is hoist on Dr. Delgado’s petard.”)

238. *Id.* at 44.

239. N.D. Prelim. Inj. Ord. at 1148-1149.

standard to apply, noting that the *NIFLA* court did not prescribe a standard of review for professional speech.²⁴⁰ Under intermediate scrutiny, North Dakota had to demonstrate that the reversal mandate furthered a substantial government interest and was sufficiently tailored to that interest.²⁴¹ The Court strongly rejected the argument that the reversal mandate was tailored to any legitimate state interest and held that it would not survive *any* level of scrutiny:

Legislation which forces physicians to tell their patients, as part of informed consent, that ‘it may be possible’ to reverse or cure an ailment, disease, illness, surgical procedure, or the effects of any medication—in the absence of any medical or scientific evidence to support such a message—is unsound, misplaced, and would not survive a constitutional challenge under any level of scrutiny. State legislatures should not be mandating unproven medical treatments, or requiring physicians to provide patients with misleading and inaccurate information. The provisions of H.B. 1336 violate a physician’s right not to speak and go far beyond any informed consent laws addressed by the United States Supreme Court, the Eighth Circuit Court of Appeals, or other courts to date.²⁴²

Most of the claims brought against reversal focus on the rights of physicians to practice medicine ethically without threat of fines, professional ramifications, and civil or criminal penalties.²⁴³ Each of the challenges so far has been brought by abortion providers. This makes sense: each abortion reversal bill directly regulates physicians. Abortion reversal bills obviously impact patients too, though. Each patient that undergoes an abortion, no matter how certain she is of her decision, must hear and receive information about reversal. In many states, as the Arizona plaintiffs pointed out, this includes patients undergoing surgical abortions or medication abortions without mifepristone. One can imagine the heartache and confusion, for example, that a patient undergoing a procedure to terminate a wanted pregnancy for medical reasons might feel after hearing that she could “reverse” her abortion. The physician’s right not to speak a government message is thus intimately intertwined with the patient’s experience of listening to that message.

240. *Id.* at 1148.

241. *Id.* at 1149 (citing *NIFLA v. Becerra*, 138 S. Ct. 2361, 2375 (2018)).

242. *Id.* at 1151.

243. *Id.* at 1139-44.

2. *A Patient's Right Not to Listen*

Of the five reversal lawsuits that have been brought, plaintiffs in Arizona and Indiana are the only two who have brought claims on behalf of patients. In both instances, the claim derived from the Fourteenth Amendment and *Casey's* prohibition on state regulation of abortion informed consent that forces physicians to share “untruthful, misleading, or irrelevant” information.²⁴⁴ The core of the claim itself makes sense—it should not be controversial to say that patients have a “right” to accurate information from their doctors, especially when doctors are sharing a state-sponsored message—but the way it fits into *Casey's* constitutionalized informed consent framework feels disjointed. *Casey* held that “truthful, non-misleading information about the nature of the procedure, the attendant health risks and those of childbirth” did not constitute an undue burden—a holding that allowed biased counseling requirements that were specifically meant to dissuade women from abortion to remain in effect.²⁴⁵ Although reversal is inflected with pro-life ideology, the reversal message is not meant to dissuade patients from undergoing an abortion at that moment; indeed, as discussed in Part III, the message could actually persuade unready patients to choose abortion. Thus, arguing that reversal constitutes an undue burden under *Casey* makes little sense.²⁴⁶

The First Amendment provides a potential alternative—albeit novel—

244. Complaint at 108, *All-Options, Inc. v. Atty. Gen. of Ind.*, No. 1:21-CV-1231 (S.D. Ind. June 30, 2021) ([t]he Abortion Reversal Disclosure Requirement requires the provision of untruthful or misleading information to pre-viability abortion patients in violation of the Due Process Clause of the Fourteenth Amendment.”).

245. 505 U.S. at 882.

246. This critique addresses only the legal logic behind the claim, not the utility in bringing an undue burden claim or litigators' judgment in framing their arguments this way. As Professor Caitlin Borgmann has convincingly argued, even claims that should not fall under the undue burden standard (like physician First Amendment claims) get “preempted” by the undue burden standard when judges decide their constitutionality. Caitlin E. Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047, 1055 (2014). In the abortion context, virtually every claim gets decided by reference to the undue burden standard. *Id.* at 1069 (“*Casey* by no means compels or even justifies undue burden preemption of free speech claims in the abortion context. But the joint opinion is sufficiently confusing in its treatment of physicians' First Amendment claims to have sowed confusion among lower courts as to whether or how the undue burden standard and compelled speech doctrine intersect. For example, the U.S. Court of Appeals for the Fifth Circuit has held that compelled speech claims against pre-abortion ultrasound requirements and other mandated pre-abortion disclosures are essentially coextensive with undue burden claims against these laws. As with bodily integrity and equal protection claims, this results in a weakening of First Amendment compelled speech claims when they are raised in the context of abortion.”)

claim that focuses on the patient's experience of a reversal mandate. In her article *The First Amendment Right Against Compelled Listening*, Professor Caroline Mala Corbin proposes a correlative right against compelled speech that would encompass, among other things, biased counseling laws that target abortion patients.²⁴⁷ A right against compelled listening would target reversal mandates in a more coherent way. Corbin articulates two approaches to this proposed speech right: what she calls the categorical approach and the contextual approach.²⁴⁸ Under the former approach, "the right against compelled listening is implicated any time the government forces its message onto an unwilling captive audience."²⁴⁹ If a court applied the categorical approach to reversal mandates, they would have to pass strict scrutiny, which requires the government to offer a compelling interest towards which the mandate was narrowly tailored. Given the mandates' failure to pass even intermediate scrutiny in North Dakota, it seems unlikely that a state would be able to do so. Under the contextual approach, government-mandated speech may be permissible if it enhances autonomy.²⁵⁰ Just like biased counseling laws, abortion reversal mandates arguably "abrogate a woman's autonomy to a significant degree . . . by assuming she has not adequately thought through the . . . repercussions [of an abortion] and cannot do so without state intervention."²⁵¹

Although a right from compelled listening has not been recognized by any U.S. jurisdictions, reversal presents an interesting and unique opportunity to set a precedent for recognition of such a right. Generally, judges seem extremely troubled by reversal mandates' impact on patient decision-making and receptive to the idea that patients should not have to hear information about reversal.²⁵² For example, the North Dakota plaintiffs did not bring any claims on behalf of their patients, but the court nonetheless focused on the abortion patient's right to an informed consent process that accurately reflects the risks and benefits of abortion. The North Dakota court found the mandate "violates the First Amendment rights of physicians. . . [by] express[ing] ideological beliefs essentially designed to make it more difficult

247. Corbin, *supra* note 195, at 998–1007.

248. *Id.* at 1007–09.

249. *Id.* at 1007.

250. *Id.* at 1009.

251. *Id.* at 1010.

252. *See, e.g.,* Tenn. Prelim. Inj. Ord. at 46 ("But it is undisputed that a portion of patients who change their mind will not be able to save their pregnancies. In the Court's view, misleading an undecided patient into beginning a procedure that may have unalterable consequences by suggesting she can "reverse" it later is not a result desired by either side.")

for women to choose an abortion.”²⁵³ Similarly, the Tennessee order enjoining reversal focused primarily on the *patients’* experience of reversal-related speech.²⁵⁴ The reasoning behind First Amendment claims is a bit disjointed: the mandate violates *physicians’* free speech rights because it burdens *patients’* abortion decisions. A right against compelled listening addresses the actual harm caused by the patients’ experience in a coherent, clear way.

PART IV: CHALLENGING ABORTION REVERSAL AS MEDICAL PRACTICE

The last section analyzed the problems with requiring that physicians share information about abortion reversal—in other words, the issues that arise when reversal is *law*. Although the impact litigation discussed in Part III bills has been enormously effective,²⁵⁵ litigation—especially constitutional litigation in federal court that requires a team of expert witnesses—is expensive and time-consuming. Moreover, litigation only targets abortion reversal as *law* while it continues to proliferate as *medical practice*.

This section proposes challenges to abortion reversal as a medical “therapy” and “unmonitored experiment.” Two features of abortion reversal make it ripe for challenge as *medicine* rather than just law: the misleading statement that abortion reversal is safe and effective and the lack of oversight of the research that supposedly supports that statement. The group Abortion Pill Rescue claims to have “reversed” (and tracked) over 1,000 abortions,²⁵⁶ and that work has two related functions: medical practice and human subjects research, both of which implicate the ethical obligations of the physicians and other medical professionals involved. When physicians treat patients—in the context of either research or a clinical relationship—they have both legal and professional obligations to uphold the Hippocratic oath and other ethical duties. Both governmental bodies and professional organizations

253. N.D. Prelim. Inj. Ord. at 1150.

254. Order at 46, *Planned Parenthood of Tenn. & N. Miss.*, No. 3:20-cv-00740.

255. As explained in Section II, the Arizona preliminary injunction was the result of a stipulation between the parties, which included a guarantee that the Arizona legislature would repeal the statute. While the suit was ultimately dismissed, the litigation forced the legislature’s hand. As of May 31, 2021, Indiana’s abortion reversal bill has also been challenged in court, but only the Complaint has been filed.

256. Boles Decl. at 3-4, *Planned Parenthood Tenn. & Tennessee N. Miss. North Mississippi v. Slatery*, 2021 WL 765606, at *1 (M.D. Tenn. Feb. 26, 2021) (“The Abortion Pill Reversal network has tracked more than 1,000 living, healthy babies with no increased risk of birth defects who have been delivered because patients interacted with the APR network.”)

enforce these ethical duties in a variety of ways, including licensing, oversight, civil and/or criminal penalties, and claims of individual patients who were harmed by a treatment. This section proposes ways to ensure that reversal is subject to an appropriate level of oversight and that patients know what they are getting when they encounter a provider who claims to reverse medication abortion.

A. *Human Subjects Research on Reversal*

To prove that abortion reversal is effective and safe, Dr. Delgado and his co-authors have published three studies, two of which tracked individual patient responses to progesterone “therapy.” Part I mentioned the questionable oversight of reversal research conducted by Drs. Delgado and Davenport in the context of the two articles they published: the 2012 case study, and the 2018 case study series. As Drs. Grossman and White noted in the *New England Journal of Medicine*, both studies likely fall under the federal definition of “research.”²⁵⁷ And, because abortion reversal proponents are conducting human subjects research, they should be subject to a certain level of oversight. Unfortunately, as demonstrated in this section, that oversight appears to be limited or non-existent.

Unethical human subjects research has a dark history in the United States, especially in the realm of reproductive health. In the antebellum South, Black women who were enslaved were forced to undergo horrific gynecological and obstetric experimentation by doctors who were later hailed as leaders in reproductive health.²⁵⁸ In the mid-twentieth century, American researchers intentionally exposed Guatemalan women to sexually transmitted diseases in order to study their effects.²⁵⁹ In 1966, a researcher named Henry Beecher published an article in the *New England Journal of Medicine* detailing unethical research conducted by top researchers at prestigious institutions in the United States.²⁶⁰ That report, in addition to revelations about the horror of Nazi research, eventually led to federal

257. Grossman & White, *supra* note 9, at 210.

258. See, e.g., DEIDRE COOPER OWENS, *MEDICAL BONDAGE: RACE, GENDER, & THE ORIGINS OF AMERICAN GYNECOLOGY* (University of Georgia Press 2017).

259. See, e.g., Susan S. Lee & Aurora J. Grutman, *Seeking Justice for Victims of the Guatemalan Sexually Transmitted Disease Experiments 1946–1948*, 39 COLUM. J. GENDER & L. 54 (2020).

260. Henry K. Beecher, *Ethics and Clinical Research*, 274 N.E.J.M. 1354 (1966), reprinted in WORLD HEALTH ORGANIZATION, *BULLETIN OF THE WORLD HEALTH ORGANIZATION* (2001); see also DAVID J. ROTHMAN, *STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW & BIOETHICS TRANSFORMED MEDICAL DECISION MAKING* at 72, 72–75 (1991).

regulations promulgated to prevent researchers from exploiting individual human subjects in support of the greater good.

Current federal law requires researchers to follow what is known as the “Common Rule,” which defines human subjects research and outlines requirements for federally-funded research.²⁶¹ “Research” is defined as a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”²⁶² Pursuant to the Federal Code of Regulations, all non-exempt human subjects research has to meet certain requirements, including informed consent by any human subjects and prospective review by an ethics oversight board.²⁶³

1. *Ethical Oversight*

Prospective review of research is typically accomplished by IRBs attached to universities or hospitals. Not all research is attached to an institution, though; for-profit independent review boards also exist. In addition to prospective oversight, there is also “after the fact” oversight in the form of investigations by governmental bodies like the Office of Research Integrity.²⁶⁴ Moreover, in some jurisdictions, researchers may owe their subjects a “special duty of care” that could result in civil liability.²⁶⁵

The medical professionals associated with Abortion Pill Rescue have almost certainly violated crucial tenets of ethical research, if not federal law.²⁶⁶ The two published articles on reversal reflect problematic research practices. For example, there is no indication that Delgado or Davenport sought or received IRB or ethics board approval for the initial 2012 case report.²⁶⁷ As Grossman and White point out, however, the ways the case

261. 45 C.F.R. § 46.101.

262. 45 C.F.R. § 46.102(l).

263. This applies only to researchers who receive federal funding. § 46.101(a). Those who conduct totally private research with no connection to federal funding technically are not subject to these rules, although peer-reviewed publications will often require adherence.

264. U.S. DEP’T HEALTH & HUM. SERVS., OFF. RES. INTEGRITY, INVESTIGATIONS, <https://ori.hhs.gov/investigations>.

265. See, e.g., *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 858 (Md. 2001) (holding that researchers owed a duty of care to children who were subjected to lead poisoning as part of an experiment).

266. Whether Drs. Delgado and Davenport violated federal law depends on the source of their funding. If they have received any funding from the National Institutes of Health or another federal body, they are legally bound by the human subjects research provisions of the CFR. See § 46.101.

267. Delgado & Davenport, *supra* note 45; Bhatti, *supra* note 60, at 3; Grossman et

report was conducted meets the federal definition of ‘research’ requiring oversight.”²⁶⁸ Grossman’s reasoning for concluding that the case report “extends into the realm of research” includes its “prospective nature” (*i.e.*, that Delgado and the other Abortion Reversal (ABR) providers prospectively provided a treatment rather than analyzing retrospectively) and the clear goal of “assess[ing] a specific new treatment regimen.”²⁶⁹ Moreover, Delgado and Davenport recommend a “suggested protocol” for “treating women who have ingested mifepristone and then wish to continue the pregnancy” at the end of the article.²⁷⁰ While some low-risk research is exempt from a fulsome IRB review, that research is still subject to a limited IRB review, done by a single board member who determines whether the research is eligible for exemption.²⁷¹

The 2018 study is even more problematic. In 2018, the case study was briefly retracted because language in it implied the University of San Diego Institutional Review Board (“USD IRB”) approved the study.²⁷² The University of San Diego (“USD”) asked Dr. Delgado and his co-authors to “withdraw this paper and submit a corrected version for publication because the wording regarding [Institutional Review Board] approval in the paper was ambiguous, leading many readers to incorrectly conclude that the USD IRB had reviewed and approved the entire study.”²⁷³ The USD IRB had not approved the study; instead, Delgado had been granted an IRB *waiver* because the research he proposed was a backward-looking review of abortion

al., *supra* note 34, at 210 (“Delgado and Davenport do not report that their study had an ethics board or institutional review board (IRB) approval.”)

268. Grossman et al., *supra* note 34, at 210.

269. *Id.*

270. Delgado & Davenport, *supra* note 4, at 3.

271. See *Institutional Review Board (IRB) Proposals*, ABDUL LATIF JAMEEL POVERTY ACTION LAB, <https://www.povertyactionlab.org/resource/institutional-review-board-irb-proposals> (“*Exempt research* involves minimal risk and fits under one of the exempt review categories described in the Common Rule. Exempt status means the study is exempted from some (but not all) regulatory review, though not from ethics review, and IRBs may still place conditions on exempt research. It is up to the IRB, not the researcher, to determine whether the study qualifies for exempt status.”)

272. See Oransky, *supra* note 77; see also Tenn. Prelim. Inj. Ord. at 19. (“Dr. Delgado also explained that, before the case series was published, he sought approval from the Institutional Review Board (“IRB”) at the University of San Diego and received an exemption. But after the case series was published, the IRB at that university asked Dr. Delgado to withdraw the case series. Dr. Delgado then sought and obtained approval from another IRB for the withdrawn case series.”)

273. Oransky, *supra* note 77 (citing interview with Thomas Herrinton, provost of the University of San Diego (USD)).

reversal treatment rather than a forward-looking experiment.²⁷⁴ The original study was described as “an observational case series with data analysis that received an institutional review board waiver,” with a footnoted reference to USD IRB.²⁷⁵ The republished study recharacterized the study as “a retrospective analysis of clinical data of a group of pregnant women who took progesterone in an effort to reverse the effects of mifepristone.”²⁷⁶

As Dr. Courtney Schreiber pointed out in the Oklahoma litigation, upon republication, “the authors altered the description of their methods but not the results or discussion.”²⁷⁷ She also noted that the paper was *not* merely observational or a retrospective analysis “because instead of just observing the impact of a treatment on patients, the researchers actively enlisted participants to undergo an *experimental* intervention—here, the administration of progesterone after mifepristone”²⁷⁸ Schreiber harshly critiqued the republished paper, stating that “[i]t is unheard-of to withdraw a paper, rewrite its methods to describe an entirely different study design, and republish the remainder of the paper unchanged.”²⁷⁹

The new protocol was not reviewed by USD IRB but instead by a for-profit independent review board called Aspire IRB.²⁸⁰ While there is nothing inherently unethical about using a for-profit review board, a report by the Government Accountability Office (“GAO”) demonstrated real ethical vulnerabilities of for-profit research oversight.²⁸¹ The undercover GAO officers both “succeeded in getting approval from an actual IRB to test a fictitious medical device on human subjects” and “created a Web site for a bogus IRB.”²⁸² A real medical research company reached out to the fake IRB and attempted to “get approval to join ongoing human trials involving invasive surgery,” even though the investigators in the fake IRB “had no medical expertise whatsoever.”²⁸³ In the latter scenario, the GAO noted that

274. *Id.*

275. *Id.*

276. Delgado et al., *supra* note 67, at 24.

277. Decl. of Dr. Courtney Schreiber in Supp. Pl. Mot for Prelim. Inj. at ¶ 31, *Amer. Med. Assoc. v. Stenehjem*, No. 1:19-cv-00125-DLH-CRH (D.N.D. June 19, 2019),

278. *Id.*

279. *Id.*

280. *See* Oransky, *supra* note 77.

281. *See generally* U.S. GOV’T ACCOUNTABILITY OFFICE., GAO-09-448T, HUMAN SUBJECTS RESEARCH: UNDERCOVER TESTS SHOW THE INSTITUTIONAL REVIEW BOARD SYSTEM IS VULNERABLE TO UNETHICAL MANIPULATION (2009), <https://www.gao.gov/products/gao-09-448t>.

282. *Id.*

283. *Id.*

the IRB did not verify any of the submitted information, which “included false information that the FDA had already cleared” the fictional device.²⁸⁴ The GAO noted that because “the transaction involved privately funded human subjects research and did not involve any FDA-regulated drugs or devices, GAO’s bogus IRB could have authorized this testing to begin without needing to register with any federal agency.”²⁸⁵ These scenarios “show[] the potential for unethical manipulation in the IRB system.”²⁸⁶

2. *Informed Consent for Research Subjects*

In addition to oversight requirements, Section 46.116 of the CFR also outlines the “general requirements for informed consent” in human subjects research, starting with “the information that a reasonable person would want to have in order to make an informed decision about whether to participate.”²⁸⁷ The code also requires that researchers “identif[y] . . . any procedures that are experimental” and describe “reasonably foreseeable risks or discomforts,” any benefits to the subject or other people, a “disclosure of appropriate alternative procedures or courses of treatment,” and a statement describing whether subject records will be kept confidential.²⁸⁸

The 2012 study does not mention whether patients gave informed consent to the treatment or to be research subjects. The 2018 study notes that “[t]he women gave written informed consent for treatment to their respective treating medical professionals that included permission to track their data.”²⁸⁹ Although consent to collect data is part of informed consent, that only scratches the surface of what the federal law requires. The study does not note whether the subjects were told that the treatment was experimental, what the standard of care is when a patient decides to discontinue a medication abortion, or what the potential risks of progesterone are.

The Abortion Pill Rescue website serves to recruit patients for reversal research and may provide a glimpse into the way reversal is presented to prospective patients. The 2018 study explicitly states that patients were recruited after “call[ing] an informational hotline linked to an informational website”—a clear reference to Abortion Pill Rescue.²⁹⁰ The information on the website is hardly measured—indeed, the general tone is one of certainty

284. *Id.*

285. *Id.*

286. *Id.*

287. 45 C.F.R. § 46.116(a)(4).

288. 45 C.F.R. § 46.116(b)(2)-(5).

289. Delgado et al., *supra* note 67, at 24.

290. *Id.*

that reversal works, and a constant sense that “time is of the essence.” The homepage features this language:

There is an effective process called *ABORTION PILL REVERSAL*. Contact us and we can talk to you and offer you help.

We know that an unplanned pregnancy can be scary, and many women make decisions to abort when they are terrified and stressed. We know that after some time, many women change their minds about a chemical abortion. *IT MAY NOT BE TOO LATE TO SAVE YOUR PREGNANCY*.

This language does not create an environment that would allow a potential patient to make a reasoned decision about the experimental nature of the treatment and its respective costs and benefits. This is not just a problem for the patients involved in the previous two studies; research regarding reversal is ongoing. In addition to the two published articles, Drs. Delgado and Davenport run the Steno Institute in California—an organization dedicated to life-affirming research, including studying reversal.²⁹¹ The Steno Institute is currently sponsoring further research on reversal: “[t]o convince the healthcare community of the efficacy and safety of abortion pill reversal, Dr. Delgado is designing a clinical randomized control trial (“RCT”) study; it will compare leading progesterone protocols regarding efficacy and side effects to determine the best reversal method.”²⁹² It is unclear how Dr. Delgado proposed to conduct a randomized trial with a control group in an ethical manner without engaging patients who actually plan to follow through with their abortions. As Delgado et al. noted in their 2018 study, for physicians who truly believe that progesterone enhances a pregnancy’s chance of survival after mifepristone, giving a placebo to a control group of real patients who wish to undo their abortions would be unethical.²⁹³

B. Unethical Medical Practice & Informed Consent

Abortion reversal also requires the practice of medicine. In addition to conducting and overseeing reversal research, Drs. Delgado and Davenport are both licensed as physicians by the Medical Board of California—Delgado as a family practice physician, and Davenport as an obstetrician and gynecologist.²⁹⁴ Both doctors have administered progesterone themselves as

291. See *Research*, STENO INST., <https://stenoinstitute.org/research> (last visited July 31, 2021).

292. *Id.*

293. Delgado et al., *supra* note 67, at 28–29.

294. See Med. Bd. of Cal., *Licensing Details for: G 66807*, CAL. DEP’T CONSUMER

part of their medical practice.²⁹⁵ The Abortion Pill Rescue hotline also claims that a team of “professional healthcare providers” is on call 24/7 to assist patients who change their minds about pregnancy.²⁹⁶ Several doctors have spoken publicly (and/or under oath) about administering progesterone to patients who wish to reverse their abortions. For example, Dr. Allan Sawyer of California described a young woman who “walked into a Glendale[, California] abortion clinic” but changed her mind “after taking the deadly pill.”²⁹⁷ Dr. Sawyer gave the patient an ultrasound and “immediately started her on the reversal protocol medications,” to alleged success.²⁹⁸ Dr. Brent Boles, an obstetrician and gynecologist in Tennessee and member of the Abortion Pill Rescue medical advisory board, wrote in a declaration in support of Tennessee’s reversal bill that he “do[es] not keep a list,” but “would estimate that [he has] prescribed natural progesterone to more than [twenty] women who wanted to reverse their abortion processes—some right here in Tennessee who then had healthy babies.”²⁹⁹ Even in states that have failed to pass abortion reversal bills, the *practice* of abortion reversal proliferates and compromises patient safety.³⁰⁰

AFFS., <https://search.dca.ca.gov/details/8002/G/66807/57f209a342bfa8dd26734294bfeada9b> (last visited July 31, 2021) (George Delgado’s license); Med. Bd. of Cal., *Licensing Details for: G 33883*, CAL. DEP’T CONSUMER AFFS., <https://search.dca.ca.gov/details/8002/G/33883/df37aee70faa4d8804de0d48dbfe038d> (last visited July 31, 2021) (Mary Davenport’s license).

295. See *Dr. Delgado’s Story*, ABORTION PILL RESCUE, <https://abortionpillreversal.com/abortion-pill-reversal/success-stories/2-dr-delgado> (last visited Oct. 26, 2021) (“They wanted to know what they could do to reverse the mifepristone. I explained to Rhonda the risks of the situation and offered her progesterone therapy since mifepristone functions as a progesterone antagonist”); see also *Our Services*, Mary L. Davenport, MD, MS, FACOG, <https://drmaryldavenport.com/our-services/> (listing “Abortion Pill Reversal” as an available service at her ob/gyn office).

296. *The Abortion Pill Reversal Team*, ABORTION PILL RESCUE, <https://abortionpillreversal.com/about-us> (last visited Oct. 26, 2021).

297. *Abortion Reversal Works!* CTR. FOR ARIZ. POL’Y. (Apr 20, 2018), <https://www.azpolicy.org/2018/04/20/abortion-pill-reversal-works/>. Despite its neutral name, the Center for Arizona Policy “is a nonprofit advocacy group whose mission is to promote and defend the foundational values of life, marriage and family, and religious freedom.” *Our Mission*, CTR. FOR ARIZ. POL’Y, <https://www.azpolicy.org/>.

298. *Id.*

299. Boles Decl., *supra* note 256, ¶ 10.

300. See, e.g., *Abortion Reversal Near Grayson*, GA, OBRIA MED. CLINICS, <https://www.obria.org/areas-served/grayson-ga/abortion-pill-reversal/>; *Abortion Pill Reversal*, GATEWAY WOMEN’S CARE, <https://gatewaywomens.care/abortion-info/abortion-pill-reversal/>; *Abortion Pill Reversal*, COLO.SPRINGS PREGNANCY CTR., <https://www.cspregnancycenter.com/services/abortion-pill-reversal/>; *Abortion*

1. *Informed Consent Claims by Patients*

Much of the conversation around informed consent and reversal has focused on the impact of forcing abortion providers to steer their patients towards reversal. Importantly, though, informed consent also plays a role in the actual medical practice of providing progesterone to patients who contact the Abortion Rescue hotline and become patients of the “professionals” affiliated with the group. A patient who was told by one of these professionals that progesterone therapy was safe and effective and was harmed by the procedure could sue the provider directly under the relevant medical malpractice and/or informed consent statute in her state. The point of medical malpractice and informed consent claims is, of course, to compensate the patient for harm done to them and encourage providers to behave in accordance with acceptable medical practice.

The requirements to bring an informed consent claim vary by state, but a typical informed consent statute requires a patient to demonstrate that a provider had a duty of care to a patient, that they breached that duty of care by failing to provide material information about the treatment, that the patient’s decision to undergo the treatment was caused by the lack of information, and that the patient was subsequently harmed.³⁰¹ How courts assess which information is “material” depends on the state; about half of states’ informed consent statutes refer to what a reasonable physician would disclose, and the other half depend on what a reasonable patient would expect.³⁰² Some states allow informed consent as a freestanding claim; others require that the patient bring their informed consent claim in conjunction with a medical malpractice claim.³⁰³

A patient seeking to sue a reversal provider would likely be able to demonstrate the first three elements of an informed consent claim. Physicians owe their patients a duty of care by entering a treatment relationship with them.³⁰⁴ Depending on what information the reversal provider actually disclosed, a patient could likely demonstrate that material information about the procedure was not disclosed under a physician or patient-based standard. At least some states require physicians to disclose

Pill Reversal, PREGNANCY HEALTH CLINIC, <https://www.pregnancyhelpclinic.com/free-services/abortion-pill-reversal>.

301. See, e.g., Timothy J. Paterick et al., *Medical Informed Consent: General Considerations for Physicians*, 83 MAYO CLINIC PROCS. 313 (2008), <https://mayocl.in/3bQ9Lwx> (last visited Oct. 23, 2021).

302. See King & Moulton, *supra* note 178, at 430.

303. BARRY R. FURROW, ET AL., *HEALTH LAW: CASES, MATERIALS & PROBLEMS* (8th ed. 2018).

304. *Id.* at 132–34.

when procedures are experimental or when providers have adopted a new technique; this disclosure requirement includes both the “experimental nature” of the procedure and the “known or projected most likely risks.”³⁰⁵ Based on the way abortion reversal is advertised, providers do not disclose any potential risks. To the contrary, abortion reversal advocates claim with certainty that progesterone is safe for the patient and her baby.

Moreover, reversal proponents have consistently overstated the effectiveness/results of their research. For example, a Colorado-based clinic advertises a 65% efficacy rate for abortion reversal on their website.³⁰⁶ As discussed in Part I, advocates frequently promote the 64-68% efficacy rate that came from two sub-groups of the research subjects from Delgado’s 2018 study—which, as demonstrated above, does not establish efficacy.

The final element of an informed consent claim—harm for which the patient can be compensated—would likely be the hardest to prove. In a jurisdiction that allows standalone informed consent claims, a court might be amenable to a claim that a patient would not have received progesterone injections without being given inaccurate information. Progesterone is expensive, and injections are painful, and physicians who do this work stand to benefit financially from a protocol that requires multiple administrations of progesterone. There is one other obvious potential “harm” that a patient who undergoes progesterone therapy might suffer. The results of Dr. Creinin’s halted study on reversal are a frightening indication of what could happen when patients do not follow the two-drug regimen. Because reversal therapy necessarily stops patients from taking misoprostol, the risk of hemorrhage that accompanies taking mifepristone alone might cause compensable “harm.” Although patients cannot typically bring claims for pain and emotional harm without accompanying physical injury, a patient who was physically harmed could also tack on an emotional harm claim if she was inaccurately promised that the doctor could “save her baby.”³⁰⁷

One challenge of litigating individual patient claims is, of course, to find patients who were harmed in compensable ways by abortion reversal therapy

305. See, e.g., *Estrada v. Jaques*, 321 S.E.2d 240 (N.C. Ct. App. 1984).

306. *Abortion Pill Reversal*, COLO. SPRINGS PREGNANCY CTR., <https://www.cspregnancycenter.com/services/abortion-pill-reversal/> (last visited Oct. 22, 2021).

307. This would depend on what her individual provider told her. Presumably, reversal providers do not guarantee the success of progesterone therapy. Nonetheless, there is enough evidence of reversal advocates promoting the inaccurate 64-68% success rate drawn from Delgado and Davenport’s 2018 paper that at least some patients have likely encountered inflated descriptions of the therapy’s success rate during the informed consent process. See generally *id.*; CTR. FOR ARIZ. POL’Y, *supra* note 297.

and are both willing and able to bring an individual malpractice claim. In states where abortion providers are forced to give out information about reversal, providers could also send patients home with information about the risks of reversal and resources for legal assistance if they choose to pursue reversal and something does go wrong.

2. *Informed Consent Legislation*

One alternative to this focus on litigation is to draft and promote legislation in abortion-friendly states that create specific, informed consent requirements for abortion reversal. California, for example, is considered to be a reproductive rights friendly state, and the FACT Act (at issue in *NIFLA*) demonstrates a willingness to legislate against misinformation spread by anti-choice advocates. Nevertheless, abortion reversal proliferates widely in California. Drs. Delgado and Davenport both practice there, and presumably both conduct research on and administer progesterone therapy as part of their medical practices licensed by the state of California. Heartbeat Services offers an “Abortion Pill Rescue Network Training” that was approved by the California Board of Registered Nursing as continuing education for nurses.³⁰⁸ Notably, the Steno Institute—Delgado’s research wing—is located in Escondido, California.³⁰⁹

A significant part of the reversal operation is thus located in a state that typically seeks to regulate reproductive healthcare providers who mislead patients. A state like California can and should take action to regulate the professionals who research reversal and provide reversal as a medical treatment. The Medical Board of California has jurisdiction to investigate and take disciplinary action against providers who engage in misleading advertising and inappropriate prescribing.³¹⁰

States should also borrow a page from the anti-choice movement’s playbook and pass legislation that requires additional informed consent for any reversal provider. In states that pass reversal bills, anti-reversal advocates should seek to amend the bills to include these informed consent requirements. The language in such a bill might look something like this:

308. See Abortion Pill Rescue Network Training, HEARTBEAT INTERNATIONAL, <https://www.heartbeat-services.org/resources/store/heartbeat-academy/abortion-pill-rescue-network-training> (last visited July 31, 2021) (“Training approved by the California Board of Registered Nursing, Provider Number CEP 16061 for 3.0 contact hours.”).

309. *Contact*, STENO INSTITUTE, <https://stenoinstitute.org/contact/> (last visited July 31, 2021).

310. *Consumers*, MED. BD. CAL., <https://www.mbc.ca.gov/Consumers/Complaints/> (last visited July 31, 2021).

Any medical professional who claims to provide treatment to “reverse” or discontinue a medication abortion, or to assist a patient who seeks to “maintain” a pregnancy after ingesting mifepristone using progesterone or any other therapy not approved by the Federal Food and Drug Administration, must provide the patient with the following information—both orally and in writing—before starting any treatment:

- 1) The theory that a medication abortion may be reversed or discontinued has been rejected by the American Medical Association and the American College of Obstetricians and Gynecologists.*
- 2) The established standard of care for a patient who has changed her mind after taking mifepristone is to monitor embryonic or fetal activity.*
- 3) No long-term, double-blind, peer-reviewed experiments have established the safety or efficacy of abortion reversal.*
- 4) Of the studies that purport to establish a protocol for “reversing” abortion, the overall rate of pregnancies that continued to term after progesterone therapy was 49%. This is comparable to studies that measured the rate of pregnancies that continued after taking mifepristone without any other intervention.*

Any medical professional who violates this Act may be subject to civil penalties, including professional disciplinary action [under relevant medical malpractice laws of the State]; revocation of relevant licensure; and/or investigation by [relevant State regulatory authorities.]

In addition to any criminal or civil penalties, failure to comply with the provisions of this Act shall provide a basis for a civil malpractice action for compensatory and/or punitive damages.

Like California’s FACT Act, this informed consent bill would likely be subject to legal challenge by pro-life groups like Abortion Pill Rescue and crisis pregnancy centers. The language above is truthful, non-misleading, and specifically applies to informed consent tied to a particular medical treatment, and so should pass constitutional muster even under *NIFLA v. Becerra*.³¹¹ Unlike the FACT Act, which broadly targeted reproductive

311. See *NIFLA v. Becerra*, 138 S. Ct. 2361 2373–74 (2018) (“The licensed notice at issue here is not an informed-consent requirement or any other regulation of professional conduct. The notice does not facilitate informed consent to a medical procedure. In fact, it is not tied to a procedure at all. It applies to all interactions between a covered facility and its clients, regardless of whether a medical procedure is ever sought, offered, or performed. If a covered facility does provide medical procedures, the notice provides no information about the risks or benefits of those procedures. Tellingly, many facilities that provide the exact same services as covered facilities—such as general practice clinics, see §123471(a)—are not required to provide the licensed notice. The licensed

health providers, this legislation would be “narrowly drawn” to further the compelling government interest of ensuring that patients are informed when undergoing experimental procedures.

CONCLUSION

As this Article demonstrates, abortion reversal bills are dangerous in their own right: these bills threaten patients’ decisional certainty, manipulate the doctor-patient relationship, and encourage patients to take part in a dangerous, expensive, painful, and likely ineffective experiment. But abortion reversal bills also reflect a worrisome trend, decades in the making, of anti-choice advocates creating a body of pseudo-scientific literature to support abortion restrictions. This trend leaves the judiciary to muddle through expert reports about endocrinological mechanisms and research design and assess the credibility of physicians and their research. While judges often wade into other disciplines to make legal decisions (often quite deftly, as the decisions in Tennessee and North Dakota demonstrate), these incremental bills and granular scientific decisions—and the massive amounts of time and money it costs to litigate them—distract from bigger questions of bodily autonomy and privacy.

The strategies outlined in this Article go beyond challenging reversal as law and urge the medical community and existing oversight mechanisms to hold reversal advocates accountable as they conduct research and administer progesterone therapy. Ultimately, patients should be able to engage with reversal if they so desire, but that engagement should be fully informed about the experimental nature of the treatment, the ideology that fuels its providers, and the current standard of care for patients who change their mind during a medication abortion.

notice regulates speech as speech.”).

APPENDIX

STATE	BILL	TITLE	STATUS
AZ	S.B. 1318 (2015)	An Act Amending . . . Arizona Revised Statutes: Relating to Abortion	REPEALED by S.B. 1112 (2016); litigation dismissed in July 2016 ³¹²
AR	Act 522, S.B. 341 (2019)	An Act To Amend The Woman's Right-To- Know Act; To Provide Information on Reversing the Effects of Abortion-Inducing Drugs; And For Other Purposes.	IN EFFECT; codified at Arkansas Code § 20-16- 1703(b)
CA	AB-2134 (2016)	An act to add Section 123472.4 to the Health and Safety Code, relating to public health. ³¹³	FAILED IN COMMITTEE ³¹⁴
CO	H.B. 1086 (2017)	Abortion Pill Reversal Information Act	FAILED IN COMMITTEE ³¹⁵
GA	S.B. 239 (2017)	AN ACT To amend Chapter 9A of Title 31 of the Official Code of Georgia Annotated, relating	FAILED IN COMMITTEE ³¹⁶

312. ACLU OF ARIZONA, Press Release: *End of the Line for Anti-Abortion Law Forcing Doctors to Mislead Women* (July 23, 2016), <https://www.acluaz.org/en/press-releases/end-line-anti-abortion-law-forcing-doctors-mislead-women>.

313. Interestingly, the California legislation would amend the California FACT Act—the same legislation at issue in *NIFLA v. Becerra*, discussed at length in Part III. The FACT Act required crisis pregnancy centers (or “CPCs”) to disclose certain information to clients. See *NIFLA v. Becerra*, 138 S. Ct. 236, 2377-78 (2018).

314. *AB-2134 Clinics: Notice: Abortion Pill Reversal* (2015-2016), CALIF. LEGIS. INFO., https://leginfo.legislature.ca.gov/faces/billHistoryClient.xhtml?bill_id=201520160AB2134 (last visited July 31, 2021).

315. *Colorado House Bill 1086*, LEGISCAN, <https://legiscan.com/CO/bill/HB1086/2017> (last visited July 31, 2021).

316. *Georgia Senate Bill 239*, LEGISCAN, <https://legiscan.com/GA/bill/SB239/2017>

		to the Woman's Right to Know Act, so as to include chemical abortion under voluntary and informed consent requirements; to provide for information concerning procedures and treatment to reverse the effects of a chemical abortion; to provide for chemical abortion reversal information availability; to provide for related matters; to repeal conflicting laws; and for other purposes.	
ID	Senate Bill 1131 (2017)	AN ACT relating to Abortion; . . . to require certain information about . . . where further information can be obtained concerning chemical abortions, including any interventions that may affect their effectiveness or result in abortion reversals, to be posted on the website of the Department of Health and Welfare . . .	FAILED IN COMMITTEE ³¹⁷
ID	Senate Bill 1243 (2018)	AN ACT relating to Abortion; . . . to require certain information about . . . where further information can be obtained concerning chemical abortions, including any interventions that may affect their effectiveness or result in abortion reversals, to be posted on the website of the Department of Health and Welfare . . .	IN EFFECT; codified at Idaho Code § 18-60
IN	H.B. 1128 (2017)	Abortion Matters	FAILED TO PASS THE SENATE; passed in House ³¹⁸
IN	H.B. 1577 (2021)	Abortion Matters	IN EFFECT pending lawsuit filed May 18,

(last visited July 31, 2021).

317. 2017 Legislation, Senate Bill 1131, Idaho State Leg., 2017 Legislation, <https://legislature.idaho.gov/sessioninfo/2017/legislation/s1131> (last visited July 31, 2021) (Showing that the bill was quickly abandoned by the Senate).

318. Indiana House Bill 1128, LEGISCAN, <https://legiscan.com/IN/bill/HB1128/2017> (last visited July 31, 2021).

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			2021 ³¹⁹ ; codified at Public Law 218-2021
IA	H.F. 53/383 (2021)	An Act relating to informed consent for medication abortions, and providing penalties.	Referred to Human Resources Committee as H.F. 383 on 4/15/2021; session ended 4/30/2021 ³²⁰
KS	S.B. 67 (2019)	An Act Requiring notification to patients that the effects of a medication abortion may be reversible	VETOED BY GOVERNOR; Motion to reconsider failed veto override failed ³²¹
KS	H.B. 2274 (2020)	Requiring notification to patients that the effects of a medication abortion may be reversible.	FAILED IN COMMITTEE ³²²
KY	H.B. 115 (2018)	AN ACT relating to reporting prescriptions to terminate a pregnancy.	FAILED IN COMMITTEE ³²³
KY	S.B. 50 (2019)	AN ACT relating to abortion and informed consent	IN EFFECT; codified at Ky. Rev. Stat. 311.710-311.820.

319. Tom Davies, *Groups ask Judge to Block Indiana "Abortion Reversal" Law*, LOCAL12 (May 19, 2021), <https://local12.com/news/local/groups-ask-judge-to-block-indiana-abortion-reversal-law>; Complaint, *All-Options, Inc. v. Att'y Gen. of Ind.*, Case No. 1:21-CV-1231 (S.D. Ind., 2021).

320. Iowa House Bill 383 (In Recess), LEGISCAN, <https://legiscan.com/IA/bill/HF383/2021> (last visited Aug. 17, 2021).

321. John Hanna, *Kansas Lawmakers Fail to Override Governor's Abortion 'Reversal' Veto*, PBS NEWSHOUR NewsHour (May 1, 2019, 4:50 PM), <https://to.pbs.org/3hKHcEs>.

322. Kansas Leg., H.B. 2274, http://www.kslegislature.org/li_2020/b2019_20/measures/hb2274/ (last visited Aug. 17, 2021).

323. Kentucky House Bill 115, LEGISCAN, <https://legiscan.com/KY/bill/HB115/2018> (last visited Aug. 17, 2021).

LA	H. Conc. Res. 87 (2016)	Abortion: Requests a study and report by the Department of Health and hospitals concerning the possibility of reversing the effects of an abortion induced with drugs or chemicals	IN EFFECT as of July 1, 2021, codified at La. Rev. Stats. 40:1061.11.1. ³²⁴
LA	H.B. 578 (2021)	HEALTH CARE: Provides relative to disclosure of certain information relative to abortion pill reversal	Proposed April 2021
ME	H.P. 619/Leg. Doc. 851 (2021)	An Act To Ensure Women Are Informed of Abortion Pill Reversal	FAILED TO PASS SENATE as of June 17, 2021. ³²⁵
MI	H.B. 5374 (2020)	Amends Public Health Code § 17015 (Mich. Code Laws 331.17015)	FAILED IN COMMITTEE ³²⁶
MT	H.B. 171 (2021)	Abortion Inducing Drug Risk Protocol Act	IN EFFECT Oct. 1, 2021; codified at Mont. Code Ann. tit. 50, ch. 20 §§ 1-14.
NE	Legislative Bill 209 (2019)	A Bill for An Act Relating to Crimes and Offenses . . .	IN EFFECT; codified at Neb. Rev. Stats. Supp. § 28-327; repeal bill L.B. 872 failed in 2020 ³²⁷

324. *Legislative Report on 2016 House Concurrent Resolution 87: Study Related to Whether the Effects of an Abortion Induced with Drugs or Chemicals Can Be Reversed*, LA. DEP'T OF HEALTHLa., (Apr. 12, 2017), <https://ldh.la.gov/assets/docs/LegisReports/HCR87RS20161.pdf>.

325. Maine LD851, TRACKBILL *Maine LD851*, <https://trackbill.com/bill/maine-legislative-document-851-an-act-to-ensure-women-are-informed-of-abortion-pill-reversal/2058279/> (last visited Aug. 17, 2021).

326. H.B. 5374, *supra* note 121.

327. *Neb. Rev. Stats. Supp. § 28-327* (2010); *see also* H.B. § 578, 2020 Leg., Reg. Sess. (La. 2021).

NC	HB 62/ HB 575 (2017)	Amends “Woman’s Right to Know” statute	FAILED IN COMMITTEE ³²⁸
ND	HB 1336 (2019)	AN ACT . . . to amend and reenact subsection 11 of section 14-02.1-02 of the North Dakota Century Code, relating to informed consent requirements before an abortion.	ENJOINED as of Sept. 9, 2019; codified at N.D. Cent. Code § 14- 02.1-02(11)(a)(2).
OH	S.B. 155 (2019)	Abortion Pill Reversal Information Act “Regards Pretreatment notice of mifepristone abortion reversal . . . “	FAILED IN COMMITTEE ³²⁹
OK	S.B. 614 (2019)	An Act relating to abortion; defining terms; requiring certain signage; requiring certain informed consent; providing procedure in case of emergency; requiring State Board of Medical Licensure and Supervision to maintain certain website; providing criminal and administrative penalties; providing civil remedies; requiring certain protection of privacy in court hearings; providing severability; providing for codification; and providing an effective date.	ENJOINED as of October 29, 2019; codified at Okla. Stats. tit. 63 § 1-756.
SD	H.B. 1157 (2016)	An Act to require that a doctor provide a woman additional information as a part of informed consent prior to performing an abortion.	IN EFFECT
SD	H.B. 1130 (2021)	An Act to establish requirements for the presentation of a written statement regarding the discontinuance of a drug-induced abortion.	PASSED BOTH HOUSES as of Mar. 3, 2021; to be

328. *House Bill 575*, N.C. GEN. ASSEMB., <https://www.ncleg.gov/BillLookUp/2017/H575> (stating that bill did not progress past referral to Committee on Health).

329. *Senate Bill 155 – Status*, OHIO LEGISLATURE. Ohio Leg. <https://www.legislature.ohio.gov/legislation/legislation-status?id=GA133-SB-155>

			codified at S.D. Rev. Stats. § 34-23A-10.1
TN	S.B. 2465 (2019)	AN ACT to amend Tennessee Code Annotated, Title 11; Title 39, Chapter 15, Part 2; Title 63 and Title 68, relative to abortion.	ENJOINED as of Feb. 26, 2019; codified at Tennessee Code Annotated Section 39-15-218 (“Section 218”).
UT	H.B. 141 (2017)	Unborn Children Protection Amendments	IN EFFECT; codified at L. Utah 76-7-305 & 76-7-305.5
WV	H.B. 2982 (2021)	The Second Chance at Life Act	GOES INTO EFFECT July 9, 2021 ³³⁰ ; codified at W.V. Code §16-2I-1 through 3
WI	2019 Assembly Bill 180 (2019)	AN ACT . . . relating to: informed consent regarding a certain abortion-inducing drug regimen and reporting requirements for induced abortions.	VETOED June 21, 2019 ³³¹

330. *Bill Status – 2021 Regular Session: House Bill 2982*, W.V. LEGISLATURE, https://www.wvlegislature.gov/Bill_Status/bills_history.cfm?INPUT=2982&year=2021&sessiontype=RS (last visited July 31, 2021).

331. AB 180, VOTESMART, <https://justfacts.votesmart.org/bill/26429/67284V3524/requires-potential-abortion-reversal-drugs-be-made-available> (last visited July 31, 2021).