

# The Legal Limbo of Menstrual Regulation: Implications of Expanding Reproductive Health Options in the United States

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## ABSTRACT

*Inspired by the broader movement to expand access and autonomy in reproductive health and rights, this Paper analyzes the legal implications of re-introducing menstrual regulation in the United States. “Menstrual regulation” (MR) is the process of inducing uterine bleeding following delayed menses without confirming pregnancy status. MR is distinct from abortion because there is no confirmation of pregnancy—a critical element in the medical and legal definitions of abortion, its regulation, and its practice. MR has been used in abortion-restrictive contexts, including in the United States prior to Roe v. Wade, and internationally, such as in Bangladesh. This therapy is most readily and safely accomplished through medication (specifically, misoprostol and mifepristone or misoprostol alone). Though these medications are used for medical abortion in the United States today, they are not currently used for MR, which is rarely, if ever, offered as an alternative. Similarly, while there are many laws and regulations governing abortion and contraception, there are none that address MR specifically. This begs the question, if MR were to be offered as a distinct therapy, what laws would apply for patients and providers?*

*This Paper aims to increase awareness of what MR is, why it is not currently an option in the fertility control spectrum, why it should be, and what the legal implications would be if MR were introduced under the existing U.S. legal framework for reproductive health and rights. Part I sets the stage with more detailed information on how MR works. Part II explores how MR fits in the existing legal frameworks for contraception and abortion. Given that MR is used after intercourse but without confirming pregnancy, this process lies somewhere*

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between pregnancy prevention (contraception<sup>1</sup>) and pregnancy termination (abortion<sup>2</sup>). The analysis of how MR may be categorized legally is informed by a review of the intrauterine device (IUD) and emergency contraception (EC), for which there were similar categorization debates that are now resolved. Part III assesses the specific legal implications of MR for user and provider if it were to be introduced today, including issues such as off-label prescriptions and insurance coverage. Finally, Part IV offers concluding remarks and initial recommendations.

Through my analysis, I demonstrate that MR does not fit neatly into the existing legal dichotomy of contraception or abortion, and a third legal regime may best accommodate this therapy. Absent such a third option, contraception is the more appropriate category. In the few instances courts have considered MR, however, some dicta has categorized MR as an abortion. That there are very few cases on the subject, and the lack of consensus suggests the debate can and should be revisited. Currently, several studies are underway to explore interest in a “missed period pill”—another framing of MR—and thus this Paper seeks to update existing literature<sup>3</sup> and contribute to the discussion among reproductive health advocates and lawyers exploring this topic.

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1. Taber’s Cyclopedic Medical Dictionary defines contraception as “the prevention of conception” and “contraceptive” as “any process, device, or method that prevents conception. Categories of contraceptives include steroids; chemical; physical or barrier; combinations of physical or barrier and chemical; ‘natural’; abstinence; and permanent surgical procedures.” *TABER’S CYCLOPEDIC MEDICAL DICTIONARY* 435–36 (Clayton L. Thomas et al. eds., 18th ed. 1997) [hereinafter *TABER’S*].
  2. Taber’s Cyclopedic Medical Dictionary defines abortion as “[t]he termination of pregnancy before the fetus reaches the stage of viability.” *Id.* at 6. Merriam-Webster’s medical dictionary defines abortion as “1: the termination of a pregnancy after, accompanied by, resulting in, or closely followed by the death of the embryo or fetus: a: spontaneous expulsion of a human fetus during the first 12 weeks of gestations—compare miscarriage b: induced expulsion of a human fetus.” *Abortion*, MERRIAM-WEBSTER ONLINE DICTIONARY, <http://c.merriam-webster.com/medlineplus/abortion> (last visited Feb. 25, 2021) [<https://perma.cc/DF4V-5B2B>]. For the purpose of surveillance data, the Centers for Disease Control and Prevention (CDC) defines a legal induced abortion as “as an intervention performed by a licensed clinician (e.g., a physician, nurse-midwife, nurse practitioner, physician assistant) within the limits of state regulations that is intended to terminate a suspected or known ongoing intrauterine pregnancy and that does not result in a live birth.” *CDCs Abortion Surveillance System FAQs*, *CENTERS FOR DISEASE CONTROL & PREVENTION* (Nov. 25, 2019), [https://www.cdc.gov/reproductivehealth/data\\_stats/abortion.htm](https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm) [<https://perma.cc/5J6P-RQ3T>].
  3. There is little legal analysis literature on MR in the United States, and the few articles that do tackle this subject were written between the 1970s and the 1990s.

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## INTRODUCTION

In the United States, a woman or person who menstruates<sup>4</sup> who has missed their period and suspects, but does not desire, pregnancy may expect they have two choices: to seek an abortion or to continue the pregnancy. Confirmation of the pregnancy will occur at some point for either option.<sup>5</sup> What if a third option

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- Gender-nonconforming and non-binary people, trans men, and girls (adolescents) also require reproductive health care and could benefit from the option of MR. See Jessica A. Clarke, *They, Them, and Theirs*, 132 HARV. L. REV. 894, 954 (2019) (“People of all gender identities can be pregnant”). There is a live debate in the reproductive health and women’s rights fields about the use of gender-neutral terminology, such as “pregnant person” or “menstruators.” See *Position Statement on Gender Inclusive Language*, Midwives Alliance North America, <https://mana.org/healthcare-policy/position-statement-on-gender-inclusive-language> (last visited Feb. 26, 2021) [<https://perma.cc/TDT2-G8W5>] (adopting gender-neutral language in pregnancy, birth, and breastfeeding); compare NAT’L WOMEN’S L. CTR., *Pregnancy and Parenting*, <https://nwlc.org/issue/pregnancy-parenting/> (last visited Feb. 26, 2021) [<https://perma.cc/CEE3-ZL5D>] (using the term “women” in advocating for pregnancy-related rights and abortion access). Advocates of gender-neutral terminology argue that it separates gender from sex—a core feminist value—and provides inclusivity for all persons who become pregnant, menstruate, etc., without excluding people who do identify as “women.” See, e.g., Adrienne Saya, *The Push for “Pregnant Person”: Using Gender Inclusive Language in Reproductive Rights*, NARAL PRO-CHOICE MD (May 22, 2019), <https://prochoicecmd.medium.com/the-push-for-pregnant-person-using-gender-inclusive-language-in-reproductive-rights-54e7ed69e27c> [<https://perma.cc/Q88Y-QK9G>] (adopting gender-neutral language). Advocates of maintaining the gendered term “women” assert that reproductive health and rights cannot be divorced from gender identity, and that gender-neutral terms fail to capture reproductive health as an issue linked to the broader oppression of women as such. See, e.g., Our Readers & Katha Pollitt, *Does Talking About ‘Women’ Exclude Transgender People From the Fight for Abortion Rights?*, NATION (Apr. 22, 2015) (debating the use of “women” and gender-neutral terms in abortion). See also *Doe v. Maher*, 515 A.2d 134, 159 (Conn. Super. Ct. 1986) (“Since time immemorial, women’s biology and ability to bear children have been used as a basis for discrimination against them. . . . This discrimination has had a devastating effect upon women.”); Gloria Steinem, *If Men Could Menstruate*, 6 WOMEN’S REPROD. HEALTH 151, 151 (July 30, 2019). This Paper uses the term “women” as well as “people who menstruate/can get pregnant” to address both the link to broader gender oppression and the need to ensure inclusivity in reproductive health and rights.
  - People in the United States who suspect they may be pregnant typically use an at-home pregnancy test around twenty-eight days since their last menstrual period (LMP), or when they miss their period, followed by confirmation by a health care provider. See *Home Pregnancy Tests*, KAISER PERMANENTE (Feb. 11, 2020), <https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.home-pregnancy-tests.hw227606> [<https://perma.cc/W45M-STGK>] (noting that “[w]hile a few home pregnancy tests may be sensitive enough to show a pregnancy on the first day of a woman’s missed period, most test kits are more accurate about

existed?<sup>6</sup> Specifically, initiating uterine bleeding to ensure non-pregnancy without first confirming pregnancy status. This process, known as “menstrual regulation” (MR),<sup>7</sup> was practiced in the United States prior to the legalization of abortion.<sup>8</sup> MR fell out of use, however, largely due to the liberalization of access to abortion

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a week after a missed period.”); *Pregnancy*, FOOD & DRUG ADMIN. (Apr. 29, 2019), <https://www.fda.gov/medical-devices/home-use-tests/pregnancy> [https://perma.cc/B564-W72Y]; *Getting Pregnant*, MAYO CLINIC (Jan. 12, 2019), <https://www.mayoclinic.org/healthy-lifestyle/getting-pregnant/in-depth/home-pregnancy-tests/art-20047940> [https://perma.cc/U54J-MDQR]; Lawrence B. Finer, Lori F. Frohworth, Lindsay A. Dauphinee, Susheela Singh & Ann M. Moore, *Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States*, 74 *CONTRACEPTION* 334, 338 (2006) (“Many . . . respondents described a process of confirming the pregnancy at a doctor’s office or clinic, rather than (or in addition to) at home”). People who do not wish to be pregnant may delay confirming pregnancy in the hope that their period arrives or that they naturally miscarry. SARAH S. BROWN & LEON EISENBERG, *THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES* 66 (1995) (“Women who have mistimed or unwanted conceptions tend to initiate prenatal care later in pregnancy and to receive less adequate care. . . than women who have intended the pregnancy.”); Marianne Kjelsvik, Ragnhild J. Tveit Sekse, Asgjerd Litleré Moi, Elin M. Aasen, Catherine A. Chesla & Eva Gjengedal, *Women’s Experiences When Unsure about Whether or Not to Have an Abortion in the First Trimester*, 39 *HEALTH CARE FOR WOMEN INT’L* 784, 791 (2018) (“Even if they had verified the pregnancy by a test and the bodily signs reminded them, this new reality might feel unreal and hard to take in. Some described how they tried to keep the thoughts away, even if they were there all the time. They found thinking about the pregnancy was exhausting.”); Finer et al., *supra*, at 334, 338 (noting that minors took longer to suspect pregnancy and that minors, women below the poverty level, and women with two or more children took longer than higher educated and higher income women to confirm pregnancy). Confirming pregnancy before abortion is also standard practice. *Safe Abortion: Technical and Policy Guidance for Health Systems*, WORLD HEALTH ORG. 32 (2012), <https://www.ncbi.nlm.nih.gov/books/NBK138188/> [https://perma.cc/F4SF-WC3U] (“The first steps in providing abortion care are to establish that the woman is indeed pregnant and, if so, to estimate the duration of the pregnancy and confirm that the pregnancy is intrauterine.”).

6. “What is a woman to do if neither her plan A (birth control) nor her plan B (the morning-after pill) worked? Wouldn’t it be great if she had a plan C—a medicine similar to these other pills that would start her period and end her anxieties? Such a thing exists, and it should be available to all women.” Francine Coeytaux & Victoria Nichols, *Plan C: The Safe Strategy for a Missed Period When You Don’t Want to Be Pregnant*, REWIRE NEWS (Feb. 7, 2014, 4:23 PM), <https://rewire.news/article/2014/02/07/plan-c-safe-strategy-missed-period-dont-want-pregnant/> [https://perma.cc/8MZ4-FXCW].
7. Claudia Pap Mangel, *Legal Abortion: The Impending Obsolescence of the Trimester Framework*, 14 *AM. J. L. & MED.* 69, 79 (1988). Taber’s *Cyclopedic Medical Dictionary* defines menstrual regulation as “vacuum or suction curettage of the uterus done within the first two weeks following the expected date of the onset of menstruation. If amenorrhea was due to pregnancy, the procedure is classed as a form of fertility control.” TABER’S, *supra* note 1 at 1193. *See also* Wendy R. Sheldon, Meighan Mary, Lisa Harris, Katherine Starr & Beverly Winikoff, *Exploring Potential Interest in Missed Period Pills in Two U.S. States*, *CONTRACEPTION* 1, 1 (2020), [https://www.contraceptionjournal.org/article/S0010-7824\(20\)30337-1/fulltext](https://www.contraceptionjournal.org/article/S0010-7824(20)30337-1/fulltext) [https://perma.cc/WGV4-KEAN] (explaining that missed period pills, a method of MR, “are uterine evacuation medications used for treatment of delayed menses without prior pregnancy confirmation”).
8. *Medicine: Unofficial Abortion*, *TIME* (Sept. 11, 1972) (referring to menstrual regulation as “menstrual extraction” and describing its use); Laurie Johnston, *Abortion Clinics in City Face Rising Competition*, *N.Y. TIMES*, Mar. 19, 1973, at 4; William E. Brenner, David A. Edelman & Elton Kessel, *Menstrual Regulation in the United States: A Preliminary Report*, 26 *FERTILITY AND STERILITY* 289, 289 (1975); Diane Curtis, *Doctored Rights: Menstrual Extraction, Self-Help Gynecological Care, and the Law*, 20 *N.Y.U. REV. L. & SOC. CHANGE* 427, 435 (1994) (“In the United States, ‘bringing it down’ and ‘removing a menstrual obstruction’ have been common practices since the colonies were first established.”).

and advancements in testing that permitted pregnancy to be confirmed sooner and even at home, reducing the window in which pregnancy may be suspected but impossible to confirm. Elsewhere in the world, MR is still in use and has adapted from aspiration methods to modern medical options. “Bringing down” one’s period to ensure non-pregnancy is documented in Mexico and Cuba.<sup>9</sup> MR is permitted and occurs formally in Bangladesh, where abortion is illegal except to save the life of the mother.<sup>10</sup> While MR uses the same methods as an abortion—vacuum aspiration or curettage or, modernly, medication—it is distinct from abortion because pregnancy status is not first confirmed. MR induces bleeding that may or may not terminate a pregnancy, depending on the reason for their delayed menses. Abortion, by definition and practice, requires confirmation of pregnancy. MR is not an abortion because pregnancy is never confirmed, though the result would be the same if the MR user was pregnant.

Reviving MR in the United States could offer an appealing additional opportunity for women and people who menstruate to control their fertility. In a survey by Gynuity Health Projects, 42 percent of women who presented for a pregnancy test at a clinic said they would be interested in a “missed period pill,” including 70 percent of those who “would be unhappy if pregnant.”<sup>11</sup> It is easy to see the appeal. Imagine the scenario where someone is a few days late for their period. Instead of continuing to wait anxiously for it to begin or going out to buy a pregnancy test, they take a pill to induce bleeding and cramping. After a few days, as usual, their bleeding subsides and they can be confident they are not pregnant. It’s a simple, safe intervention at home that allows them to take control of the situation.

Beyond interest, MR could fill a critical gap in fertility control by adding an additional point along the reproductive health timeline for people to act. They may engage in MR immediately after a missed period, before pregnancy can be confirmed, and possibly before an abortion could be procured. For women in states with limited health facilities, especially limited abortion clinics, such an option could be a game changer. It would reduce the time and expense of obtaining an abortion later and avoid more degrading requirements, such as forced ultrasounds, while allowing people to control their reproductive health outcomes.<sup>12</sup> Because

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9. Coeytaux & Nichols, *supra* note 6 (“Currently, in Cuba, where abortion is legal, a woman whose period is two weeks late is offered menstrual extraction without a pregnancy test . . . [I]n Mexico, women often purchase misoprostol from pharmacies to effectively ‘bring down their periods’ (bajar la regla).”).

10. Fauzia Akhter Huda, Hassan Rushekh Mahmood, Anadil Alam, Faisal Ahmmed, Farzana Karim, Bidhan Krishna Sarker, Nafis Al Haque & Anisuddin Ahmed, *Provision of Menstrual Regulation with Medication among Pharmacies in Three Municipal Districts of Bangladesh: A Situation Analysis*, 97 *CONTRACEPTION* 144, 144 (2018) (In Bangladesh, where abortion is illegal, “a medical doctor can provide MR up to 12 weeks from the first day of the last menstrual period (LMP), and midlevel providers, such as family welfare visitors (FWVs), can provide MR up to 10 weeks from LMP.”).

11. Sheldon et al., *supra* note 7, at 4.

12. *Requirements for Ultrasound*, GUTTMACHER INST., (Sept. 1, 2020),

MR is no longer commonplace in the United States, and many people lack awareness of MR, this is an opportune moment to consider the legal implications of reviving MR and its benefits.

This Paper identifies the legal implications of MR in the United States for user and provider, with a particular emphasis on criminal law in light of recent attempts to use criminal statutes to punish women for their reproductive choices.<sup>13</sup> The purpose of this review is to inform decision-making in the reproductive health and policy community on the feasibility and advisability of re-introducing MR from a legal perspective.

Part I sets the stage with more detailed information on how MR works. Part II explores how MR fits in the existing legal framework of contraception and abortion. Given that MR ensures non-pregnancy without first confirming pregnancy, this process lies somewhere between pregnancy prevention (contraception<sup>14</sup>) and pregnancy termination (abortion<sup>15</sup>). The analysis of how MR may be categorized legally is informed by a review of the intrauterine device (IUD) and emergency contraception (EC), for which there were similar categorization debates that are now resolved. Part III assesses the specific legal implications of MR, for user and provider, if it were to be introduced today. Finally, Part IV offers concluding remarks and initial recommendations.

This Paper does not seek to answer medical or normative questions about whether MR is a good or bad therapy for patients or for the reproductive health movement generally. The aim is to outline the legal implications should this additional reproductive option become available again. Reproductive health and rights advocates must consider multiple approaches to expand fertility control access and options in an increasingly restrictive environment. This Paper hopes to contribute to one element of what will undoubtedly be a complex discussion that also considers the social and political implications of MR, which are beyond the scope of this Paper.

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<https://www.guttmacher.org/state-policy/explore/requirements-ultrasound>  
[<https://perma.cc/JTL8-7VMU>].

13. For example, in Arkansas, Anne Bynum was charged with “concealing birth” after delivering a thirty-plus-week fetus at home after allegedly taking misoprostol. She was sentenced by a jury to six years in prison, and served fifty-nine days before the conviction was reversed and remanded by the Court of Appeals of Arkansas. The court found that the trial court abused its discretion by allowing the prosecutor to introduce evidence of Bynum’s abortion history and evidence that she ingested medicine prior to giving birth. *Bynum v. State*, 546 S.W.3d 533, 536 (Ark. Ct. App. 2018). See also The Editorial Board, *How My Still Birth Became a Crime*, N.Y. TIMES (Dec. 28, 2018), <https://www.nytimes.com/interactive/2018/12/28/opinion/abortion-pregnancy-pro-life.html> [<https://perma.cc/97TS-8ENA>]; *Patel v. State*, 60 N.E.3d 1041, 1044 (Ind. Ct. App. 2016) (vacating a feticide conviction on the grounds that the state legislature did not intend feticide laws to apply to illegal abortions or to prosecute women for their own abortions).
14. Taber’s Cyclopedic Medical Dictionary defines contraception as “the prevention of conception” and “contraceptive” as “any process, device, or method that prevents conception. Categories of contraceptives include steroids; chemical; physical or barrier; combinations of physical or barrier and chemical; ‘natural’; abstinence; and permanent surgical procedures.” TABER’S, *supra* note 1, at 435–436.
15. Taber’s Cyclopedic Medical Dictionary defines abortion as “[t]he termination of pregnancy before the fetus reaches the stage of viability.” TABER’S, *supra* note 1, at 6.

### I. BACKGROUND ON MENSTRUAL REGULATION

MR is the process of inducing uterine bleeding without confirming pregnancy status for people with delayed menses.<sup>16</sup> It is colloquially known as “bringing down” or “bringing on” a period. The concept of MR has ancient roots<sup>17</sup> and a fifty-year history in modern reproductive care.<sup>18</sup> Since the 1970s, MR has evolved from primarily a vacuum aspiration procedure<sup>19</sup> to contemporary medication methods.<sup>20</sup> Though the vacuum methods most commonly used in the 1970s enjoyed high success and safety rates, modern medical methods have made MR even safer and simpler.<sup>21</sup>

This Paper focuses on the possibility of *medical* MR. Medical MR can be achieved through the use of misoprostol in conjunction with mifepristone at sixty-three days or less after last menstrual period (nine weeks since LMP), with a dosage of 200 mg of mifepristone followed by 800 µg of buccal (placed inside the cheek to dissolve) misoprostol twenty-four hours later.<sup>22</sup> Misoprostol may also be

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16. WORLD HEALTH ORG., *supra* note 5, at 66 (“uterine evacuation without laboratory or ultrasound confirmation of pregnancy for women who report recent delayed menses”); *Menstrual Extraction*, MERRIAM-WEBSTER MEDICAL DICTIONARY, <https://www.merriam-webster.com/medical/menstrual%20extraction> (last visited Feb. 26, 2021) [<https://perma.cc/L45H-RW96>] (“a procedure for early termination of pregnancy by withdrawing the uterine lining and a fertilized egg if present by means of suction”); Leonard E. Laufe, *The Menstrual Regulation Procedure*, 8 STUDIES IN FAMILY PLANNING 253, 253 (Oct. 1977) (“Menstrual regulation is the induction of uterine bleeding that has been delayed up to 14 days from its anticipated date of onset”); Elton Kessel, William E. Brenner & George H. Stathes, *Menstrual Regulation in Family Planning Services*, 65 AM. J. OF PUB. HEALTH 731, 731 (July 1975) (“Menstrual regulation (MR) is the term applied to any treatment which is administered within 14 days of a missed menstrual period to ensure that a woman either is not pregnant or does not remain pregnant”).
  17. Hippocrates, BCE 460–377, taught “herbal recipes to induce menstruation.” *A History of Birth Control Methods*, PLANNED PARENTHOOD FED’N OF AM. 11 (Jan. 2012). Thesaurus Pauperum (Treasure of the Poor), written by Peter of Spain (later Pope John XXI) in the 13<sup>th</sup> century “offered advice on birth control and how to provoke menstruation.” *Id.* at 8.
  18. *See, e.g.*, Laufe, *supra* note 16.
  19. *See, e.g.*, Laufe, *supra* note 16, at 253 (“By far the most common method of performing menstrual regulation is by mini-vacuum aspiration.”).
  20. Medical MR may be accomplished through combination mifepristone-misoprostol. *See* Cui-Lan Li, Dun-Jin Chen, Yi-Fan Deng, Li-Ping Song, Xue-Tang Mo & Kai-Jie Liu, *Feasibility and Effectiveness of Unintended Pregnancy Prevention with Low-Dose Mifepristone Combined with Misoprostol before Expected Menstruation*, 30 HUM. REPROD. 2794, 2795 (2015). It may also be accomplished through misoprostol alone. Huda et al., *supra* note 10, at 146–47.
  21. Medical MR is accomplished through the use of mifepristone and misoprostol or misoprostol alone. Both regimens enjoy high safety rates. *See* Li et al., *supra* note 20, at 2794 (“Low-dose mifepristone and misoprostol administered at the time of expected menstruation was effective and safe in maintaining or restoring non-pregnant status, with no obvious menstrual disturbance.”).
  22. Anadil Alam, Hillary Bracken, Heidi Bart Johnston, Sheila Raghavan, Noushin Islam, Beverly Winikoff & Laura Reichenbach, *Acceptability and Feasibility of Mifepristone-Misoprostol for Menstrual Regulation in Bangladesh*, 39 INT’L PERSPECTIVES ON SEXUAL & REPROD. HEALTH 80 (2013); *see also* M-L. Swahn, M. Bygdeman, Chen Jun-kang, K. Gemzell-Danielsson, Song Si, Yang Qiu-ying, Yang Pei-juan, Qian Mei-ling & Chang Wei-fang, *Once-a-Month Treatment with a Combination of Mifepristone and the Prostaglandin Analogue*

used alone for medical MR.<sup>23</sup> Misoprostol is an inexpensive prescription medication used both for ulcer treatment and prevention<sup>24</sup> and a range of gynecological purposes,<sup>25</sup> available by prescription. The mifepristone-misoprostol combination is also available by prescription, but subject to particular restrictions, as it is currently used for medical abortion.<sup>26</sup> Both the misoprostol alone and the mifepristone-misoprostol combination part of a cocktail are acceptable for medical MR, though the World Health Organization considers mifepristone-misoprostol the gold standard.<sup>27</sup>

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*Misoprostol*, 14 HUM. REPROD. 485–488 (1999) (exploring appropriate dosages for medical MR).

23. A study in Bangladesh found 86 percent of pharmacy workers mentioned misoprostol (as opposed to 78 percent who mentioned mifepristone-misoprostol combo) for MR, though “mystery client visits found that the mifepristone-misoprostol combination (69 percent) was suggested over misoprostol (51 percent) by the pharmacy workers.” Huda et al., *supra* note 10, at 144.
24. See *Cytotec (misoprostol)*, FOOD & DRUG ADMIN. 1, 6 [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2002/19268slr037.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf) (last visited Sept. 8, 2020) [<https://perma.cc/Y485-6RKF>].
25. A common gynecological off-label use of misoprostol is to soften the cervix, also called “cervical ripening.” These purposes include: to induce contractions for at-term labor, Rebecca Allen & Barbara M. O’Brien, *Uses of Misoprostol in Obstetrics and Gynecology*, 2 REVIEWS IN OBSTETRICS & GYNECOLOGY 159, 165 (2009), to prepare for a surgical procedure including surgical abortion, WORLD HEALTH ORG., *supra* note 5, at 5, and to prepare for insertion of an IUD, Allen & O’Brien, *supra*, at 163. Finally, misoprostol is used to prevent or treat postpartum hemorrhage. Jennifer Templeton Dunn, Jennifer Mraz, Erin Cassard Schultz, Eleanor A. Drey & Karen R. Meckstroth; *Abortion in California: A Medical-Legal Handbook* 30 (2012), <https://californiaabortionlaw.com/wp/wp-content/uploads/2012/03/AIC-Handbook1.pdf> [<https://perma.cc/88PN-XHTX>]. *But see Misoprostol (marked as Cytotec) Information*, FOOD & DRUG ADMIN. (July 2015), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/misoprostol-marketed-cytotec-information> [<https://perma.cc/NZ3G-FMB5>] (“Misoprostol is sometimes used to decrease blood loss after delivery of a baby. These uses are not approved by the FDA. No company has sent the FDA scientific proof that misoprostol is safe and effective for these uses.”).
26. See *Mifeprex (mifepristone) tablet label*, FOOD & DRUG ADMIN. 6 (2016), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/020687s020lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf) [<https://perma.cc/XP97-3J5C>] (requiring that prescribers be certified with the Mifeprex Risk Evaluation and Mitigation Strategy program; that patients sign a Patient Agreement Form; and that Mifeprex be dispensed only in certain healthcare settings, specifically in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare providers, rather than a pharmacy); Luisa Torres, *Restrictions on Abortion Medication Deserve a Second Look, Says a Former FDA Head*, NAT’L PUB. RADIO (Aug. 20, 2019, 11:04 AM), <https://www.npr.org/sections/health-shots/2019/08/20/740809772/restrictions-on-abortion-medication-deserve-a-second-look-says-a-former-fda-head> [<https://perma.cc/Y8ZN-QSL7>] (Dr. Jane Henney, who was FDA commissioner when the Mifeprex restrictions were imposed, explaining that “[t]he current restrictions impose a lot of burden [sic] on women who have to go to a clinic and [on] the certified physician. If some of those restrictions were lifted, you could possibly go to your own physician who might write a prescription that you could get filled in your pharmacy and take this medication at home right now. Women, particularly in rural areas and suburbs, have to travel long distances for this, and it’s just a real burden on them to do that. It’s also a burden on the physicians, who have to register and keep extensive records.”) (alteration in original).
27. As explained above, MR is accomplished using the same methods as medical abortion. The WHO recommends mifepristone followed by misoprostol for medical abortion, as “safe and effective up to 9 weeks (63) days of pregnancy” and notes that “limited evidence also suggests the safety and effectiveness of a regimen with repeated doses of misoprostol between 9 and 12



### A. History of Menstrual Regulation in the United States

Prior to *Roe v. Wade*, medical providers offered MR, also known at the time as menstrual evacuation, to treat unwanted and unconfirmed pregnancies, but the procedure slowly fell out of practice after abortion was decriminalized.<sup>28</sup> Small “self-help” clinics, organized by then-called “Militant Women’s Liberationists,” also performed menstrual extractions outside of the formal health sector.<sup>29</sup> Since the medications for medical MR were not available, the most common method of MR in the 1970s was vacuum aspiration.<sup>30</sup> In the medical field, the procedure was seen as both a simple and effective therapy and a workaround to the criminalization of abortion. A *TIME* article in 1972 summarized, “[menstrual regulation] is becoming medically respectable; more and more physicians are studying it as a possibly practical method of avoiding the legal and physical hardships of abortions done later in pregnancy.”<sup>31</sup> In 1975, an article in the *Journal of Family Law* predicted “the development of menstrual regulation may make restrictive abortion laws obsolete.”<sup>32</sup>

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weeks of gestation.” WORLD HEALTH ORG., *supra* note 5, at 38; see Kelly Cleland and Nicole Smith, *Aligning Mifepristone Regulation with Evidence: Driving Policy Change Using 15 Years of Excellent Safety Data*, 92 *CONTRACEPTION* 179, 179 (2015) (“Currently, the most common evidence-based protocols involve 200 mg mifepristone and 800 mcg misoprostol, and allow for use up to at least 63 days of gestation; these regimens are recommended by the World Health Organization, the American College of Obstetricians and Gynecologists and the Society of Family Planning and the Planned Parenthood Federation of America”). Misoprostol, though less effective than when used in combination with mifepristone, may also be used safely alone. See Elizabeth G. Raymond, Margo S. Harrison & Mark A. Weaver, *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, 133 *OBSTETRICS & GYNECOLOGY* 137, 137 (2019) (“Misoprostol alone is effective and safe and is a reasonable option for women seeking abortion in the first trimester”).

28. Cindy Pearson, *Self Help Clinic Celebrates 25 Years*, NAT’L WOMEN’S HEALTH NETWORK (Mar./Apr. 1996), <https://www.fwhc.org/selfhelp.htm> [<https://perma.cc/72H9-BWDF>] (describing how menstrual extraction self-help groups shifted to in-clinic abortion provision after *Roe v. Wade*); Coeytaux & Nichols, *supra* note 6 (explaining that menstrual regulation “did not take hold in the United States,” though it did in Bangladesh, where abortion remains strictly regulated).
29. *TIME*, *supra* note 8; Coeytaux & Nichols, *supra* note 6 (MR “began in California in 1971, when a group of self-help feminists developed a technique that allowed women to safely suction out menstrual blood and tissue. Referring to it as ME (menstrual extraction), these early self-helpers advocated that women join self-help groups and practice extracting each others’ menses around the time of their expected periods”); Pearson, *supra* note 28 (“The techniques eventually developed by Rothman and Downer were entitled menstrual extraction, to differentiate them from abortion in the medical setting. Menstrual Extraction, or ME, was never envisioned as a service that lay women practitioners would provide to other women who needed an abortion. Rather, the early self helpers advocated that women join self help groups and practice extracting each other’s menses around the time of their expected periods. If a pregnancy happened to be present, it would be extracted along with the contents of the uterus. The self helpers believed that their experience with each other, the modified nature of the equipment they were using, and the fact that they were ending pregnancies far earlier than was typical during an abortion would make menstrual extraction safe.”).
30. *TIME*, *supra* note 8 (noting that vacuum aspiration had “remarkably few complications in some 2,500 doctor-performed procedures”).
31. *Id.*
32. Luke T. Lee & John M. Paxman, *Legal Aspects of Menstrual Regulation: Some Preliminary Observations*, 14 *J. FAM. L.* 181, 191 (1975).

The procedure was seen as a legal workaround precisely because pregnancy was not first confirmed, creating a situation where “an abortion in fact is not an abortion officially.”<sup>33</sup> However, MR prior to *Roe* did not always, in fact, terminate a pregnancy. Reports of tissue examinations from the era showed that only “between 50% and 85% of the women who elect[ed] to have extractions [we]re pregnant.”<sup>34</sup> Though MR acceptance increased in the United States in the early 1970s, the context quickly shifted with the legalization of abortion.

After *Roe*,<sup>35</sup> MR became gradually less relevant, in part due to the liberalization of abortion laws, which meant the legal benefit of the grey space provided by MR was no longer necessary.<sup>36</sup> As scholars at the time explained, “[b]efore the US Supreme Court decision which legalized abortion on Jan. 22, 1973, the performing of uterine evacuations before pregnancy could be diagnosed was suggested as a way of avoiding abortion laws.”<sup>37</sup> Once abortion was legalized, MR was no longer the only legal post-conception fertility control method. Even so, the framework of MR was not immediately seen as irrelevant. A 1973 journal hypothesized that MR in a post-*Roe* world might “return[] us to the rule in effect until the nineteenth century; namely, the legal definition of abortion did not apply until the ‘quickening’ of the fetus.”<sup>38</sup> In the mid-1970s, it thus seemed possible that MR might continue as a method for post-coital fertility control early in a pregnancy and not “count” as abortion.<sup>39</sup> Ultimately, the liberalization of abortion laws contributed to a general abandonment of MR in the formal medical framework in the United States.<sup>40</sup>

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33. TIME, *supra* note 8.

34. *Id.*

35. The Supreme Court has recognized the constitutional right to an abortion since *Roe v. Wade* in 1973, confining state abortion bans to post-viability and holding that regulations before viability must be to protect the life and health of the mother. *Roe v. Wade*, 410 U.S. 113, 163 (1973). In 1992, in *Planned Parenthood v. Casey*, the court did away with the *Roe* trimester framework, and set out the undue burden standard, which prevents states from placing a significant obstacle before a woman seeking an abortion. 505 U.S. 833, 874 (1992). *Whole Woman’s Health v. Hellerstedt* clarified this standard and outlined that courts must review the tangible benefits as compared to the restrictions caused by a challenged regulation in an undue burden analysis. 136 S. Ct. 2292, 2309 (2016).

36. Curtis, *supra* note 8, at 441 (“After *Roe v. Wade* was decided, the interest in menstrual extraction waned as women turned more consistently to the newly legal and available clinical abortion providers, almost always physicians”).

37. Jane E. Hodgson, Roxanne Smith & Daniella Milstein, *Menstrual Extraction: Putting It and All Its Synonyms into Proper Perspective as Pseudonyms*, 228 JAMA 849, 849 (1974).

38. Anne-Marie Dourlen-Rollier, *Legal Problems Related to Abortion and Menstrual Regulation*, 7 COLUM. HUM. RTS. L. REV. 120, 134–35 (1975).

39. Lee & Paxman, *supra* note 32, at 183 (outlining that prostaglandins—the category in which misoprostol falls—“may be used to remedy a menstrual delay of not more than ten days or as a menstrual regulator when administered between the 25th to 28th day of the cycle. If fertilization has taken place, the prostaglandins will bring about the elimination of the ovum. There is also the possibility that the prostaglandins can be used in mid-cycle as an implantation inhibitor and a post-coital contraceptive.”).

40. Self-help MR appears to have continued on a small scale, with a revival in the 1980s as abortion restrictions began to crop up. See Pearson, *supra* note 28. However, there is generally little data on MR in the United States, so the extent to which MR continued to exist either in

Another contributing factor for the gradual movement away from MR was the improved accuracy of early pregnancy tests. One feature of MR that was a particular benefit when it first came into practice was that it is “performed without a positive pregnancy test during the interval before conventional pregnancy testing is reliable.”<sup>41</sup> Because abortions require a confirmed pregnancy, MR fills the gap between missing a period and being able to obtain a pregnancy test. This allows a woman to ensure she is not pregnant before confirming her status and begin the process to obtain an abortion.<sup>42</sup> Over time, pregnancy tests have become increasingly reliable at earlier stages in the pregnancy.<sup>43</sup> Today, even at-home tests claim to be able to provide a diagnosis the first day after a missed period; accuracy increases with time, however, and, generally, tests are the most accurate a week after a missed period.<sup>44</sup> Even so, as late as 1977, when tests were becoming more advanced, MR was still seen as having a place in the reproductive options spectrum. One journal hailed MR as a “simple technique, which has already gained international acceptance as an appropriate treatment of amenorrhea [the absence of menstruation], especially when unwanted pregnancy is the suspected

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the formal medical sector or informally in the period after *Roe* is unclear. Given the lack of studies, scholarly literature, or medical association attention, the practice at the very least likely faded from the general reproductive health and rights sphere.

41. Laufe, *supra* note 16, at 253; TIME, *supra* note 8 (“Vacuum-aspiration abortions are generally performed between the eighth and twelfth weeks of pregnancy, when tests can establish whether a woman is in fact pregnant. Menstrual extraction is designed to be done no later than six weeks after the woman’s last menstrual period, when proof of pregnancy by ordinary tests is sometimes difficult to establish”); Lee & Paxman, *supra* note 32, at 183–84 (“[M]any proponents are now urging that menstrual regulation be used during this so-called “gray area”—five to six weeks from LMP—when it cannot be medically determined, whether embryonic development has begun”).
42. Laufe, *supra* note 16, at 253 (noting pregnancy tests are most accurate two weeks after a missed period). See also *The Thin Blue Line: The History of the Pregnancy Test*, NAT’L INST. HEALTH, <https://history.nih.gov/display/history/Pregnancy+Test+Timeline> (last visited Feb. 26, 2021) [<https://perma.cc/EZ5L-N64W>] (noting that in the 1970s tests performed by doctors could be done “as early as four days after a missed period,” but also that tests were most accurate two weeks after a missed period. The first at-home pregnancy test became available in 1977.).
43. *Id.*
44. *Home Pregnancy Tests: Can You Trust the Results?*, MAYO CLINIC (Jan. 12, 2019), <https://www.mayoclinic.org/healthy-lifestyle/getting-pregnant/in-depth/home-pregnancy-tests/art-20047940> [<https://perma.cc/W6W3-J2QV>] (“The earlier after a missed period that you take a home pregnancy test, the harder it is for the test to detect hCG. For the most accurate results, repeat the test one week after a missed period. If you can’t wait that long, ask your health care provider for a blood test”). See also *Pregnancy*, FOOD & DRUG ADMIN. (Dec. 28, 2017), <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitro-diagnostics/homeusetests/ucm126067.html> [<https://perma.cc/AS82-9BFV>] (“Most pregnancy tests have about the same ability to detect hCG, but their ability to show whether or not you are pregnant depends on how much hCG you are producing. If you test too early in your cycle or too close to the time you became pregnant, your placenta may *not* have had enough time to produce hCG.”) (emphasis in original); *Pregnancy Tests*, PLANNED PARENTHOOD (last visited Apr. 22, 2019), <https://www.plannedparenthood.org/learn/pregnancy/pregnancy-tests> [<https://perma.cc/KCE8-RJNG>] (“You can take a pregnancy test anytime after your period is late—that’s when they work the best . . . [i]f your periods are very irregular, or you don’t get periods at all for one reason or another, your best bet for accurate results is to take a pregnancy test 3 weeks after sex”).

cause.”<sup>45</sup> However, starting in the 1980s, the procedure declined due, in part, to the legalization of abortion<sup>46</sup> and increasingly accurate early pregnancy tests. The latter reduced the time needed to confirm pregnancy, thereby making it possible to obtain an abortion sooner.

In considering the decline of MR, it is important to keep in mind that medical MR was not even possible until the late 1990s. The only methods available were curettage—scraping of the uterus, which required someone to perform the procedure—or vacuum aspiration, which self-help groups argued a woman could safely perform at home but required some equipment and training. The mifepristone-misoprostol combination for medical abortion did not become available in the United States until 2000.<sup>47</sup> In 2015, medical MR began in Bangladesh, where vacuum MR had been in use for several decades.<sup>48</sup> Now, with decades of data on the safety and efficacy of misoprostol-mifepristone and misoprostol alone for medical abortion, and lessons from contexts like Bangladesh, the possibility of a simple and safe at-home medical MR experience is clear.<sup>49</sup>

### B. Potential Benefits of Re-Introducing Menstrual Regulation in the United States

There are many potential benefits of re-introducing MR in the contemporary spectrum of fertility control options in the United States. First, “[p]erhaps the most cogent argument for use of menstrual regulation is its safety and simplicity.”<sup>50</sup> Generally, the earlier an intervention for a potential pregnancy, the safer it is for the patient. “In contrast to first-trimester abortions performed by vacuum aspiration after seven menstrual weeks’ gestation, the complications associated with menstrual regulation among pregnant women appeared to be less frequent and less severe.”<sup>51</sup> Safety and simplicity are benefits not only in terms of health outcomes, but also because they may increase access as lower-level health providers,<sup>52</sup> or pregnant people themselves, might be able to successfully and

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45. Laufe, *supra* note 16, at 255.

46. The “raison d’être” of MR ended with *Roe*, though it still continued for some time after among women’s groups. Hodgson et al., *supra* note 37, at 849.

47. Luran Neergaard, *FDA Approves Abortion Pill*, WASH. POST (Sept. 28, 2000, 11:57 AM) [<https://perma.cc/JVY3-QX7G>].

48. Huda et al., *supra* note 10, at 145.

49. Mary Gatter, Kelly Cleland & Deborah L. Nucatola, *Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days*, 91 *CONTRACEPTION* 269, 269 (2015) (“An evidence-based regimen of 200 mg of mifepristone orally followed by home use of 800 mcg of buccal misoprostol 24–48 h later is safe and effective through 63 days estimated gestational age. Further, the need for aspiration for any reason was low, and hospitalization was rare”); Raymond et al., *supra* note 27, at 143 (analyzing forty-two studies of thirteen-thousand women who used misoprostol alone for first trimester abortion and concluding the method “can be effective and safe for inducing abortion in the first trimester”).

50. Laufe, *supra* note 16, at 255.

51. Brenner et al., *supra* note 8, at 293.

52. Laufe, *supra* note 16, at 255.

safely manage MR.<sup>53</sup>

Second, the concept of regulating menstruation remains relevant in the modern era and could resonate with potential users. There is evidence that some populations in the United States already use a framework of “bringing down one’s period.”<sup>54</sup> Many women are familiar with the concept of regulating menses through oral contraceptives, which are frequently prescribed for that purpose or offer regular periods as a positive side effect. Post-coital fertility control, generally, is also not a new idea. “Throughout the world many women rely on postconception fertility control methods either because their preconception method has failed or because they do not use a preconception method. This will probably continue to be the case for the foreseeable future.”<sup>55</sup> Whether through Plan B or abortions, the fertility control spectrum already includes post-coital options; MR could be added to provide further choice and opportunity for intervention.

Third, and perhaps most significantly, MR provides a new opportunity window to control reproduction. Proceeding with MR before confirming pregnancy allows people who can become pregnant to take action after the window for emergency contraception has passed—up to three days after unprotected sex for over the counter emergency contraceptive pills (ECPs)<sup>56</sup> and up to five days for prescription ECPs or Paragard<sup>57</sup>—but sooner than they might be able to obtain an abortion, which providers may delay until five to six weeks LMP (last

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53. Katharine Footman, Rachel Scott, Fahmida Taleb, Sally Djikerman, Sadid Nuremowla, Kate Reiss & Kathryn Church, *Feasibility of Assessing the Safety and Effectiveness of Menstrual Regulation Medications Purchased from Pharmacies in Bangladesh: a Prospective Cohort Study*, 97 *CONTRACEPTION* 152, 152 (“This paper assesses the outcomes of women who self-manage menstrual regulation medications purchased from pharmacies. The methodology requires further development, but our study provides preliminary positive evidence on the safety and effectiveness of self-management despite low information provision from pharmacy workers”); Megan K. Donovan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, 21 *GUTTMACHER POL’Y REV.* (Oct. 17, 2018), <https://www.guttmacher.org/gpr/2018/10/self-managed-medication-abortion-expanding-available-options-us-abortion-care> [https://perma.cc/H68R-JNSD].
54. The concept of bringing down one’s period appears tied to the practices of some populations, particularly in the state of Texas. See Liza Fuentes, Sarah Baum, Brianna Keefe-Oates, Kari White, Kristine Hopkins, Joseph Potter & Daniel Grossman, *Texas Women’s Decisions and Experiences Regarding Self-Managed Abortion*, 20 *BMC WOMEN’S HEALTH* 1, 2 (2020) (“In a 2014 national survey of abortion patients, 2.2% had ever tried to end a pregnancy or bring back their period on their own”); John Burnett, *Legal Medical Abortions Are Up in Texas, But So Are DIY Pills from Mexico*, *NAT’L PUB. RADIO* (June 9, 2016, 4:46 AM), <https://www.npr.org/sections/health-shots/2016/06/09/481269789/legal-medical-abortions-are-up-in-texas-but-so-are-diy-pills-from-mexico> [https://perma.cc/4ZFN-7PL7].
55. Laufe, *supra* note 16, at 255–56.
56. Coeytaux & Nichols, *supra* note 6 (“Plan B emergency contraceptive only provides a short window of opportunity—it is most effective if taken no later than 72 hours after unprotected sex”).
57. *Emergency Contraception*, *KAISER FAMILY FOUND.* (Sept. 6, 2018), <https://www.kff.org/womens-health-policy/fact-sheet/emergency-contraception/> [https://perma.cc/D4EP-EGGH].

menstrual period)<sup>58</sup> or which may be further delayed by state-mandated waiting periods.<sup>59</sup> Obtaining an abortion generally requires in-clinic pregnancy confirmation through methods typically available at thirty-five to forty-two days LMP (e.g. urine tests, bloodwork, or ultrasound) or roughly one to two weeks following a missed period. To illustrate the window in which MR could function, imagine a person who seeks fertility control four days after a missed period. This person is seeking care two and a half to three weeks after unprotected sex and roughly a week (or longer) before they could obtain an abortion.<sup>60</sup> They take medication which safely induces bleeding and cramps similar to a period, and thereafter can be assured they are not pregnant. For the patient who is past the point for EC (three to five days after unprotected sex) but does not want further delay, MR offers the opportunity to control fertility in a window that is currently overlooked in available reproductive methods.

Fourth, there is evidence that demand for MR would be substantial.<sup>61</sup> In a recent study of women presenting at health clinics for pregnancy tests, a sizeable portion said they would be interested in a “missed period pill.” This includes 70 percent of women who said they would be unhappy if they were pregnant, and 12 percent of women who said they would be happy if they were pregnant.<sup>62</sup> Some women may feel more comfortable pursuing early MR but not a later abortion. Others may prefer the option of taking action without confirming pregnancy for personal reasons. A participant in the “missed period pill” study commented, “[i]t would be easier on my emotional wellbeing to not know I was actually pregnant but to alleviate the issue which is my missed period.”<sup>63</sup>

The psychological benefits, though potentially great, should not be pursued at the cost of providing clear, informed consent. A patient obtaining MR must

58. *How Early in a Pregnancy Can You Get an Abortion?*, PLANNED PARENTHOOD (Dec. 1, 2010, 9:51 PM), <https://www.plannedparenthood.org/learn/teens/ask-experts/2572> [<https://perma.cc/47UN-L3LK>].

59. Twenty-six states impose a waiting period between state-mandated counseling and obtaining an abortion. Most waiting periods are twenty-four hours, such as those in Arizona, Georgia, and Ohio, but can be as long as seventy-two hours, as in South Dakota, Utah, Oklahoma, Missouri, North Carolina, and Arkansas. These waiting periods require patients to make multiple visits to a health care provider to obtain an abortion, which poses particular challenges in states where patients must often travel far distances to reach a provider, such as in Texas and Mississippi. *Counseling and Waiting Periods for Abortion*, GUTTMACHER INST. (Sept. 1, 2020), <https://www.guttmacher.org/state-policy/explore/counseling-and-waiting-periods-abortion> [<https://perma.cc/SE7M-LR5S>].

60. Emily Bazelon, *The Dawn of the Post-Clinic Abortion*, N.Y. TIMES MAG. (Aug. 28, 2014), <https://www.nytimes.com/2014/08/31/magazine/the-dawn-of-the-post-clinic-abortion.html> [<https://perma.cc/7ZLN-BZDF>] (“A medical abortion in the United States usually involves two office visits. At the first, a woman often has an ultrasound, to date the pregnancy. She is given mifepristone in the office and misoprostol to take at home 24 hours later. Then, at a follow-up visit, the woman has an examination to make sure the abortion is complete. (The F.D.A. protocol, however, calls for three visits and recommends that the misoprostol be taken under medical supervision; Texas requires four visits.)”).

61. Sheldon et al., *supra* note 7, at 6.

62. *Id.* at 4.

63. *Id.* at 5. See also Laufe, *supra* note 16, at 255 (“For many women, not knowing whether amenorrhea is a result of conception may be of great psychological value and may permit them to avoid confronting the issue of abortion”).

understand that in the case that they are pregnant, the therapy would terminate the pregnancy. Additionally, earlier literature on the psychological benefits of MR sometimes contains undertones of sexism around what information and decisions women are able to cope with, which both assumes the decision is emotional or difficult and reflects a paternalism that should remain in the pre-*Roe* era.<sup>64</sup> Finally, while MR may be acceptable to women who would object to abortion, or whose communities would object,<sup>65</sup> the reproductive health community should interrogate whether this framing will come at a cost of further stigmatizing abortion or simply serve as another option to increase access to reproductive healthcare. MR's psychological elements may provide an additional space for autonomy in controlling fertility and providers should ensure patients are fully informed so that they are empowered in the active choice to not confirm pregnancy before pursuing fertility control.

Finally, with *Roe* increasingly under attack, exploring MR as an additional fertility control method is important to potentially increase access to care and choice in restrictive states. It's possible that MR could again serve as a workaround in a legally restrictive environment. For example, MR could allow providers and patients to avoid hoops such as waiting periods, ultrasound requirements, and forced speech that accompany some abortion statutes. This could allow providers to provide MR sooner than they would be able to provide an abortion, or might make fertility control possible for people who otherwise would not be able to navigate restrictive requirements. The potential for MR to increase one's ability to control their fertility in restrictive states could be especially beneficial to women in rural areas, women of color, poor women, gender non-binary people, and trans men who face additional challenges to accessing reproductive care in general and abortion care in particular.<sup>66</sup> MR could even expand access for those who receive health care through Medicaid, whose coverage of post-coital fertility control at this point only goes through emergency contraception and does not cover abortion as a result of restrictions imposed by the Hyde amendment. However, it's unclear how courts would interpret MR. Thus, the benefits outlined in this paragraph could be temporary should courts categorize MR as an abortion, a categorization that would, I argue in Part III, be inaccurate.

There could also be negative consequences to reviving MR. Providers may

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64. TIME, *supra* note 8 (“Since we have no real, definitive knowledge of pregnancy, a woman does not have to face all the conflicting emotions that go into that situation”) (internal quotations omitted).

65. Sheldon et al., *supra* note 7, at 5–6.

66. The American College of Obstetricians and Gynecologists, *Health Disparities in Rural Women*, 586 COMM. OP. 1, 2 (2014), <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2014/02/health-disparities-in-rural-women.pdf> [<https://perma.cc/3K33-RHQS>]; Christine Dehlendorf, Maria Isabel Rodriguez, Kira Levy, Sonya Borrero & Jody Steinauer, *Disparities in Family Planning*, 202 AM. J. OBSTETRICS & GYNECOLOGY 214, 215–17 (2010); Laura Nixon, *The Right to (Trans) Parent: A Reproductive Justice Approach to Reproductive Rights, Fertility, and Family-Building Issues Facing Transgender People*, 20 WM. & MARY J. WOMEN & L. 73, 76–78 (2013).

raise concerns, such as disagreeing with providing a potentially unnecessary procedure<sup>67</sup> if a patient is not pregnant. This concern, however, should be balanced against the benefits of ensuring people have autonomy over their bodies and clashes with trends in the reproductive movement to put power over reproductive health into the hands of people who can become pregnant. Providers may also be unwilling to provide a therapy that is in a legal grey zone or has similarities to abortion due to the potential increased costs for doing so. These costs could range from fear that state actors may seek to penalize providers of MR to increased malpractice insurance costs if insurance companies treat MR similarly to abortion, for which there are often (unnecessary) premium increases.<sup>68</sup> Finally, formally re-introducing MR could bring scrutiny to the practice and lead to regulation of the medications used for MR that would ultimately decrease access. While we lack data on how often people currently obtain misoprostol and then use it for MR purposes, such self-help could become unavailable should the process formally revive and likely elicit responsive regulation in states hostile to reproductive rights. These issues need further analysis, particularly by the medical field.

## II. HOW DOES MR FIT IN THE EXISTING LEGAL FRAMEWORK?<sup>69</sup> MR OCCUPIES A LEGAL LIMBO BETWEEN ABORTION AND CONTRACEPTION.

MR does not fit neatly into the current U.S. framing of fertility control as a dichotomy of contraception and abortion. At the outset, it is unclear which category is appropriate for MR. This therapy occurs later along the reproductive timeline than existing contraceptives but explicitly does not confirm pregnancy which is part of the standard “abortion” process. However, whether and how MR would fit in the existing categories of abortion and contraception is the first step required to analyze which laws might be implicated by the re-introduction of MR. Looking to other reproductive therapies, the IUD (intrauterine device) and EC (emergency contraception), helps inform how MR may not be classified as an abortion. At the same time, MR also has elements that distinguish it from existing contraceptives. Case law is little help in this area, as few courts have confronted MR let alone its legal classification, and the decisions that have touched on MR

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67. Hodgson et al., *supra* note 37, at 850 (arguing that the medical field should interrogate whether unnecessary procedures should be encouraged: “When a patient is fully informed of her options and risks, she can usually be guided toward making the proper medical choice, but in helping her to arrive at that choice, should we lower our standards of medical care, or indulge in semantics? Let us eliminate such inaccurate terminology as ‘menstrual extraction,’ ‘menstrual planning,’ ‘endometrial aspiration,’ ‘menstrual induction,’ or ‘menstrual regulation.’”).

68. Already, medical malpractice insurers sometimes increase costs for off-label therapies or prohibit some off-label uses altogether. Additionally, insurers may attach disproportionate-to-risk “abortion riders” costing \$10,000–\$15,000. Christine E. Dehlendorf & Kevin Grumbach, *Medical Liability Insurance as a Barrier to the Provision of Abortion Services in Family Medicine*, 98 AM. J. PUB. HEALTH 1770, 1770 (2008).

69. This analysis will use California law where state law is necessary.



are inconsistent.<sup>70</sup> If MR were to be revived today, it should, at the very least, not be categorized legally as an abortion and may be best addressed in a category of its own.

### A. Lessons from IUDs and Emergency Contraception

Two types of contraceptives—the IUD and EC—provide insight into how reproductive therapies are classified. There are two types of IUDs, a non-hormonal copper IUD (Paragard)<sup>71</sup> and hormonal IUDs (Mirena, Skyla, Kyleena, and Liletta).<sup>72</sup> When IUDs first came to market there was some debate as to whether they should be classified as contraceptives.<sup>73</sup> A fringe argument posited that IUDs should be classified as abortifacients as an egg could theoretically be fertilized but fail to implant due to the IUD creating a thinner uterine lining.<sup>74</sup> Current scientific

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70. There are only a handful of court decisions that address MR, and the cases that do exist are generally several decades old and predate many important modern reproductive health and abortion cases. The Supreme Court briefly mentioned MR in *Roe v. Wade*, 410 U.S. 113, 161 (1973) (“Substantial problems for precise definition of [when life begins] are posed, however, by new embryological data that purport to indicate that conception is a ‘process’ over time, rather than an event, and by new medical techniques such as menstrual extraction, the ‘morning-after’ pill, implantation of embryos, artificial insemination, and even artificial wombs”). See also *Planned Parenthood Ass’n v. Ashcroft*, 483 F. Supp. 679, 697–698 (W.D. Mo. 1980), *aff’d* 665 F.2d 848 (8th Cir. 1980) (state statutory requirement that physicians inform a patient both that she is pregnant and how long she has been pregnant prior to performing an abortion fails to pass rational basis review because it has the effect of outlawing menstrual extraction); *Planned Parenthood Ass’n v. Fitzpatrick*, 401 F. Supp. 554, 573–574 (E.D. Penn. 1975), *vacated* 428 U.S. 901, *modified* 1977 U.S. Dist. LEXIS 13980, *aff’d* 439 U.S. 379 (1975) (finding constitutional a state statute requiring determination of pregnancy prior to abortion, and that such a requirement would bar menstrual regulation); *Planned Parenthood of the Heartland v. Heineman*, 724 F. Supp. 2d 1025, 1032 (D. Nev. 2010) (enjoining enforcement of amendment to Nebraska statute to define “self-induced abortion means any abortion or menstrual extraction attempted or completed by a pregnant woman on her own body”).
71. *Copper IUD (ParaGard)*, MAYO CLINIC (Feb. 11, 2020), <https://www.mayoclinic.org/tests-procedures/paragard/about/pac-20391270> [<https://perma.cc/WD4V-3WX8>].
72. *Levonorgestrel (Intrauterine Route)*, MAYO CLINIC (Aug. 1, 2020), <https://www.mayoclinic.org/drugs-supplements/levonorgestrel-intrauterine-route/description/drg-20073437> [<https://perma.cc/DB2E-DRE2>].
73. Lee & Paxman, *supra* note 32, at 184–86 (“Much discussion was devoted to the question whether the IUD was an abortifacient or a contraceptive . . . [and] [s]everal authors have argued that both the IUD and the ‘morning after’ pill violate the criminal abortion statutes. There is, however, no literature suggesting that any successful criminal abortion prosecutions have ever been brought on that theory”); *Copper IUD (ParaGard)*, *supra* note 71 (“Copper wire coiled around the [IUD] produces an inflammatory reaction that is toxic to sperm and eggs (ova), preventing pregnancy.”); Irving Sivin, *IUDs are Contraceptives, Not Abortifacients: A Comment on Research and Belief*, 20 *STUD. FAM. PLAN.* 355, 357 (1989) (“Today, however, the weight of scientific evidence indicates that IUDs act as contraceptives. They prevent fertilization, diminishing the number of sperm that reach the oviduct and incapacitating them. IUDs, particularly copper devices, decrease the likelihood that ova can be found in the Fallopian tube shortly after ovulation.”).
74. Dr. John C. Wilke, former president of the National Right to Life Committee, championed the IUD-as-abortifacient argument, arguing that contraceptives such as IUDs and morning-after pills produce “micro-abortions.” See John C. Wilke, *American College of OB/GYN Changes*

literature, however, emphasizes that IUDs primarily work by preventing fertilization,<sup>75</sup> not by preventing implantation. Though the IUD-as-abortifacient argument has been revived in recent years,<sup>76</sup> since the initial classification and through today the medical field is clear that IUDs are contraceptives and not abortifacients.

The legal regime has followed suit, and IUDs are squarely in the “contraceptive” bucket of regulations. This remains true even as IUDs have also come to be used for EC.<sup>77</sup> The copper IUD, for example, is effective *as an EC* when inserted up to five days following intercourse. The American College of Obstetricians and Gynecologists still classifies copper IUDs as contraceptives, writing that because copper IUDs “prevent rather than disrupt pregnancy, they too are properly classified as contraceptives, not abortifacients.”<sup>78</sup> The classification of IUDs as contraception suggests that the fact that a method could in theory expel a fertilized egg is not sufficient to categorize it as an abortion.

Emergency contraception pills (ECPs) have also generated categorization debates, but have come to be classified as contraceptives.<sup>79</sup> EC is birth control

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*Definition*, LIFE ISSUES INST. (last visited July 31, 2020), <https://www.lifeissues.org/2000/11/american-college-obgyn-changes-definition/> [<https://perma.cc/TP58-FSL7>]. This argument was advanced by Hobby Lobby before the Supreme Court in 2014 as well. See Brief for Respondent at 4–5 n.2, 14–15, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014) (No. 13-354) (arguing that the Affordable Care Act’s requirement of coverage of IUDs and morning-after pill violates the Religious Freedom Restoration Act of 1993 because petitioners believe providing this coverage would violate their religious beliefs, which prohibits them from facilitating abortion).

75. Beverly Anderson & Mishka Terplan, *Understanding the IUD*, NAT’L CTR. FOR HEALTH RSCH. (last visited Sept. 13, 2020), <http://www.center4research.org/understanding-the-iud/> [<https://perma.cc/T9YT-G3GD>]; *Intrauterine Device (IUD)*, DEPT. OF HEALTH & HUM. SERVS. (last visited Aug. 3, 2020), <https://opa.hhs.gov/reproductive-health?pregnancy-prevention/birth-control-methods/iud/index.html> [<https://perma.cc/QAZ2-HMSM>]; Joerg Dreweke, *Contraception is Not Abortion: The Strategic Campaign of Antiabortion Groups to Persuade the Public Otherwise*, 17 GUTTMACHER POL’Y REV. 14, 15 (2014) (“Both the hormonal and copper IUDs work primarily by preventing sperm from reaching and fertilizing an egg. Of all these methods, only the copper IUD, when used as an emergency contraceptive, appears capable of preventing implantation of a fertilized egg. However, even then it would not be considered an abortion under standard medical and legal definitions”); Irving Sivin, *supra* note 73, at 357 (“Today, however, the weight of scientific evidence indicates that IUDs act as contraceptives. They prevent fertilization, diminishing the number of sperm that reach the oviduct and incapacitating them. IUDs, particularly copper devices, decrease the likelihood that ova can be found in the Fallopian tube shortly after ovulation”).

76. See generally Dreweke, *supra* note 75; Olga Khazan, *Here’s Why Hobby Lobby Thinks IUDs Are Like Abortions*, ATLANTIC (Mar. 12, 2014), <https://www.theatlantic.com/health/archive/2014/03/heres-why-hobby-lobby-thinks-iuds-are-like-abortions/284382/> [<https://perma.cc/3ESV-4CCS>].

77. *Copper IUD (ParaGard)*, *supra* note 71; Sivin, *supra* note 73.

78. *Id.*

79. *Emergency Contraception*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (Aug. 2019), <https://www.acog.org/womens-health/faqs/emergency-contraception> [<https://perma.cc/T335-87XH>] (“Using EC does not cause an abortion. An abortion ends an existing pregnancy. EC prevents pregnancy from occurring”); Dreweke, *supra* note 75 (“A contraceptive method, by definition, prevents pregnancy by interfering with ovulation, fertilization or implantation. Abortion ends an established pregnancy, after implantation. This scientific definition of pregnancy—which reflects the fact that most fertilized eggs naturally

used within three to five days after unprotected sex to prevent pregnancy.<sup>80</sup> ECPs in the United States include levonorgestrel (for example, Plan B One-Step), ulipristal acetate (ella), and combined regimens.<sup>81</sup> Objections to ECPs often relate to a misconception that EC causes an abortion.<sup>82</sup> However, ECPs prevent ovulation and may prevent implantation but do not affect an established pregnancy.<sup>83</sup> Therefore, ECPs have been classified as a contraceptive.

Though ECPs have come to be classified as contraception,<sup>84</sup> there are regulatory hurdles that reflect the perception of EC as closer to an abortion—terminating pregnancy—than simply preventing pregnancy. Common legal barriers include refusal and conscience clauses allowing pharmacists to refuse to dispense EC if they object on religious grounds,<sup>85</sup> and “excluding emergency contraception from state Medicaid family planning eligibility expansions or contraceptive coverage mandates.”<sup>86</sup> While levonorgestrel ECPs are available over the counter and may be used up to three days after unprotected sex, ulipristal ECPs, which may be used up to five days after unprotected sex, require a prescription.<sup>87</sup> Since the Hobby Lobby decision in 2015, some employers may also

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fail to implant in the uterus—is also the legal definition, and has long been accepted by federal agencies (during administrations both supportive of and opposed to abortion rights), and by U.S. and international medical associations . . . both Plan B and ella work primarily by preventing ovulation; they can work for up to five days after sex, because sperm can survive in a woman’s body for that long”).

80. *Emergency Contraception*, HEALTH & HUM. SERVS. (Feb. 9, 2017), <https://opa.hhs.gov/reproductive-health?pregnancy-prevention/birth-control-methods/emergency-contraception/index.html> [<https://perma.cc/Q427-YZWR>].

81. *Id.*

82. *Legal & Opposition Issues*, INT’L CONSORTIUM FOR EMERGENCY CONTRACEPTION (last visited Aug. 15, 2018), <https://www.cecinfo.org/ec-issues/legal-opposition-issues/#national> [<https://perma.cc/P2BP-KPGQ>].

83. *Emergency Contraception: An Affirmative Agenda to Improve Access*, CTR. FOR REPROD. RTS. (2003), [https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/pdf\\_adv\\_ec\\_I\\_0.pdf](https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/pdf_adv_ec_I_0.pdf) [<https://perma.cc/8627-3KDW>] (“According to both medical science and legal convention, pregnancy begins only after implantation of a fertilized egg in the uterus. EC therefore acts to prevent a pregnancy. Studies show that EC has no effect on established pregnancies”); *Emergency Contraception*, WORLD HEALTH ORG. (Feb. 2, 2018) <https://www.who.int/news-room/fact-sheets/detail/emergency-contraception> [<https://perma.cc/VB2K-9D3Z>] (“Emergency contraceptive pills prevent pregnancy by preventing or delaying ovulation and they do not induce an abortion. The copper-bearing IUD prevents fertilization by causing a chemical change in sperm and egg before they meet. Emergency contraception cannot interrupt an established pregnancy or harm a developing embryo.”).

84. Courts in California classify EC as contraception. See Heather M. Field, *Increasing Access to Emergency Contraceptive Pills Through State Law Enabled Dependent Pharmacist Prescribers*, 11 UCLA WOMEN’S L.J. 141, 150-51 (2000). See also, e.g., *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405, 412–13 (1989) (finding that EC is not an abortifacient).

85. Claire A. Smearman, *Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 473 (2006); *Emergency Contraception*, GUTTMACHER INST. (Sept. 1, 2020), <https://www.guttmacher.org/state-policy/explore/emergency-contraception> [<https://perma.cc/6SVF-QPUQ>].

86. WORLD HEALTH ORG., *supra* note 83.

87. *Id.*

refuse to include ECPs (and IUDs) in their employee insurance benefits for contraception if they believe doing so would conflict with their religious beliefs against abortion. The Supreme Court, however, did not itself agree with the assertion that ECPs or IUDs in fact cause abortions.<sup>88</sup> The categorization of ECPs as contraception, and not abortion, further elongates the timeline for fertility methods to count as contraceptives but also demonstrates that lawmakers are more willing to regulate methods the farther they extend on the reproductive timeline.

### B. Menstrual Regulation: Between Contraception and Abortion

How does MR fit within the U.S. legal system's dichotomy of contraceptive or abortion? At first glance, MR does not fit neatly into either category. In the 1970s, commentators already noted that in light of MR, "the distinction between contraception and abortion is becoming more and more tenuous."<sup>89</sup> The legal question of categorizing MR may have seemed unnecessary in the new regime of decriminalized abortion in the late 70s. One author noted, categorization "is not of great interest in those countries which have adopted liberal legislation on abortion, but it is of capital importance in those countries where repressive laws still exist."<sup>90</sup> Compared to the post-*Roe* 1970s, MR categorization could be "of capital importance" in the current, increasingly restrictive, environment in the United States.<sup>91</sup>

MR does not fit neatly into the legal category of abortion. While the medical definition of abortion is not contested, it generally constitutes a termination of a pregnancy before fetal viability,<sup>92</sup> and some definitions do not distinguish between induced and spontaneous termination (miscarriage). Based on this type of definition, MR could result in an abortion if a user is in fact pregnant. In practice, and in legal definitions, the critical element, however, is knowledge of pregnancy status. The Planned Parenthood consent form states that "'abortion' means the use of any means to terminate the pregnancy of a female *known by the*

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88. *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 691 (2014) ("Since RFRA applies in these cases, we must decide whether the challenged HHS regulations substantially burden the exercise of religion, and we hold that they do. The owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions, and if they do not comply, they will pay a very heavy price—as much as \$1.3 million per day, or about \$475 million per year, in the case of one of the companies. If these consequences do not amount to a substantial burden, it is hard to see what would.").

89. Dourlen-Rollier, *supra* note 38, at 132.

90. *Id.*

91. T.J. Raphael & Amber Hall, *In the 45 Years Since Roe v. Wade, States Have Passed 1,193 Abortion Restrictions*, PUB. RADIO INT'L (Jan. 22, 2018, 4:30 PM), <https://www.pri.org/stories/2018-01-22/45-years-roe-v-wade-states-have-passed-1193-abortion-restrictions> [<https://perma.cc/KT4P-PT8Y>]; Colleen Shalby & Priya Krishnakumar, *For Many Women Across the U.S., It's Already a Post-Roe vs. Wade Reality*, L.A. TIMES (Sept. 4, 2018), <https://www.latimes.com/projects/la-na-abortion-laws-roe-wade/> [<https://perma.cc/7WV9-DBDG>].

92. Taber's Medical Dictionary defines abortion as "[t]he termination of pregnancy before the fetus reaches the stage of viability." TABER'S, *supra* note 1, at 6.

*attending physician to be pregnant.*”<sup>93</sup> As a medical journal noted in 1974: “[a] positive pregnancy test thus converts the procedure into an early abortion . . . in that case, it is no longer a menstrual extraction.”<sup>94</sup> The confirmation—or lack thereof—of pregnancy becomes the critical element in determining whether a procedure is MR or an abortion.

Legally, the definition of abortion in the United States varies at the state level. The proposed Uniform Abortion Act outlined in *Roe* defined abortion as “the termination of human pregnancy *with an intention* other than to produce a live birth or to remove a dead fetus.”<sup>95</sup> For an example of a state definition, in California, the Reproductive Privacy Act<sup>96</sup> defines “abortion” as “any medical treatment *intended* to induce the termination of a pregnancy except for the purpose of producing a live birth.”<sup>97</sup> The Center for Disease Control and Prevention defines “a legal induced abortion” for surveillance purposes as “an intervention performed by a licensed clinician (e.g., a physician, nurse-midwife, nurse practitioner, or physician assistant) within the limits of state regulations that is *intended* to terminate a suspected or known ongoing intrauterine pregnancy and that does not result in a live birth.”<sup>98</sup> Intent to terminate a pregnancy is a key part of the legal definition.

Because MR by definition includes no confirmation of pregnancy, see *supra* Part I, it seems that there could be no knowledge with respect to terminating a pregnancy and thus it would not meet the definition of an abortion.<sup>99</sup> It is possible that the mens rea, the intent, of a provider would be closer to recklessness as to the possibility of pregnancy, rather than knowledge or purpose. Some commentators have argued that if MR is “employed with the intention of bringing about an abortion, it is likely” that it constitutes abortion.<sup>100</sup> Even in this case, “the difficulty, of course, lies in the definition of the offense and in the proof of the intention.”<sup>101</sup> Methods of MR have uses besides ensuring non-pregnancy.<sup>102</sup> If the

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93. *DISCLOSURE AND CONSENT FORM for MEDICAL, SURGICAL, AND DIAGNOSTIC PROCEDURES*, PLANNED PARENTHOOD TEX., [https://www.plannedparenthood.org/files/6114/0168/3065/C107e\\_Disclosure\\_and\\_Consent\\_for\\_Medical\\_Surgical\\_Diagnostic\\_ProcedureTexas.pdf](https://www.plannedparenthood.org/files/6114/0168/3065/C107e_Disclosure_and_Consent_for_Medical_Surgical_Diagnostic_ProcedureTexas.pdf) [<https://perma.cc/G6QP-DUC9>] (emphasis added).

94. Hodgson et al., *supra* note 37, at 849.

95. *Roe v. Wade*, 410 U.S. 113, 146 (1973) (emphasis added).

96. CAL. HEALTH & SAFETY CODE §§ 123460–68 (Deering 2018).

97. 1 CAL. FORMS OF PLEADING AND PRACTICE—ANNOTATED § 4.10 (2018); CAL. HEALTH & SAFETY CODE § 123464(a) (Deering 2018) (emphasis added).

98. *CDCs Abortion Surveillance System FAQs*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 25, 2019), [https://www.cdc.gov/reproductivehealth/data\\_stats/abortion.htm](https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm) [<https://perma.cc/Ry2R-6AT9>] (emphasis added).

99. In 1975, authors Luke T. Lee and John M. Paxman recognized this definitional issue when they asked, “Can medical intervention be classified as abortion in the absence of proof of a pre-existing pregnancy?” See Lee & Paxman, *supra* note 32, at 185.

100. Dourlen-Rollier, *supra* note 38, at 133.

101. *Id.*

102. *Id.* (“Prostaglandins, as well as the technique of uterine aspiration, also offer a duality of uses. They may be used for diagnostic purposes or therapeutic purposes, as well as for the regulation

intent is to regulate menses, then a secondary outcome of pregnancy elimination would not constitute knowledge or purpose.<sup>103</sup> For example, condoms similarly have dual uses—disease prevention and pregnancy prevention.<sup>104</sup> In light of the lack of knowledge due to unknown pregnancy status and difficulties proving intent, MR does not fit easily in the legal definition for abortion.

Few courts have looked at the element of confirmation of pregnancy and intent with respect to abortion. In *Planned Parenthood Association v. Fitzpatrick*, since vacated, a district court upheld a statute requiring positive determination of pregnancy prior to abortion with criminal enforcement, banning MR.<sup>105</sup> The court, persuaded by “possible risks to the health of the female patient from infection and hemorrhage,” upheld the ban.<sup>106</sup> The court explained, “[w]e do not believe that *Roe* precludes the state from requiring a positive determination of pregnancy prior to the performance of an abortion procedure in furtherance of its interest in protecting nonpregnant females from undergoing unneeded abortion procedures.”<sup>107</sup> With more evidence now on the safety of MR, it’s possible a similar case today would be resolved differently. Regardless of how the safety evaluation would proceed today, this case is interesting because it demonstrates that a court considered MR without confirmed pregnancy to not constitute an abortion per se, but understood the goal of MR to be similar to abortion such that a state may have a reasonable interest in regulating it.

In *Planned Parenthood Association v. Ashcroft*, the Eighth Circuit more directly addressed the categorization of MR. The case concerned a statute mandating that a “woman must sign a consent form to acknowledge that she has been informed by the attending physician of the following: (1) That according to the best medical judgment of her attending physician she is pregnant . . .”<sup>108</sup> The District Court found that because of the informed consent requirement, the statute “could cause a woman seeking an early abortion [by menstrual extraction] to wait until such time as current technology enabled her physician to determine that she is in fact pregnant. A regulation which has the effect of outlawing a safe abortion technique utilized in the very early stages of pregnancy” is unconstitutional for lack of rational basis.<sup>109</sup>

On appeal, Ashcroft argued that the “statute does not affect menstrual extraction because a menstrual extraction is not an abortion.”<sup>110</sup> Thus, in seeking to limit reproductive rights access (the statute imposed barriers to obtaining and

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of the menstrual cycle. Thus, one has good grounds to argue that their use does not, in itself, constitute the proof of an intention to commit an abortion.”).

103. Lee & Paxman, *supra* note 32, at 197 (“where the menstrual regulators are used for therapeutic reasons linked strictly to the induction of the menses, or for other medical reasons, no violation of the statute can occur.”).

104. Dourlen-Rollier, *supra* note 38, at 133.

105. *Planned Parenthood Ass’n v. Fitzpatrick*, 401 F. Supp. 554, 574 (E.D. Pa. 1975).

106. *Id.*

107. *Id.*

108. *Planned Parenthood Ass’n v. Ashcroft*, 483 F. Supp. 679, 694 (W.D. Mo. 1980).

109. *Id.* at 697–98.

110. *Planned Parenthood Ass’n v. Ashcroft*, 655 F.2d 848, 868 (8th Cir. 1981).

providing abortions), Ashcroft sought to place MR outside the abortion regulatory scheme. The court, however, rejected Ashcroft's argument, stating "it is a reasonable medical certainty that 85% of women with a menstrual period 10 days late are pregnant" and therefore "it is entirely possible that a physician would perform the procedure with intent to terminate a pregnancy."<sup>111</sup> This reasoning suggests that a court could find intent for an abortion to be met by a showing of the likelihood of pregnancy in general and not the specific intent of a provider in a given instance.

In *Ashcroft*, the Court of Appeals ultimately affirmed the District Court's finding that the statute was unconstitutional, agreeing that MR was indeed an abortion, and as such the statute unconstitutionally prohibited abortion.<sup>112</sup> Thus, in classifying MR as an abortion, the court expanded reproductive rights. This case is now nearly forty years old, but it provides some interesting hints as to how courts may grapple with the ambiguities of MR. First, although abortion requires confirmed pregnancy, courts may find constructive or implied knowledge in the case of MR. Second, a court may interpret MR as an abortion when striking down restrictive statutes, and it is possible today a court would find that MR is not an abortion in order to similarly protect abortion rights. Of course, the inverse is also true. Because there are so few cases addressing MR, it is difficult to say whether courts—especially the current Supreme Court and increasingly conservative District and Circuit Courts—would continue to classify MR as an abortion today, and to what effect in terms of increasing or restricting access.

MR may fit better, but still not perfectly, in the contraception category. Contraception is "[a] product or medical procedure that interferes with reproduction from acts of sexual intercourse."<sup>113</sup> Contraceptives include barrier methods, hormonal methods, permanent methods, intrauterine devices, and fertility awareness methods.<sup>114</sup> The placement of IUDs and ECs in this category suggests that MR too could fall in this zone. Though modern science demonstrates both IUDs and ECs function primarily by preventing fertilization, it is possible they may lead to the expulsion of a fertilized but not implanted egg. It is also worth noting that fertilized eggs are frequently expelled naturally.<sup>115</sup> MR allows "a

111. *Id.* at 868.

112. *Id.* at 868–69 (affirming District Court holding that the informed consent requirement including pregnancy confirmation is unconstitutional because it would in effect prohibit menstrual regulation, and the court found "no justification for such a prohibition").

113. David Hubacher & James Trussell, *A Definition of Modern Contraceptive Methods*, 92 *CONTRACEPTION* 420 (2015), <http://www.track20.org/download/pdf/Article%20-%20Hubacher%20and%20Trussell%20Contraception%202015.pdf> [https://perma.cc/9DN3-2GZ5]; *Contraception*, MERRIAM-WEBSTER MED. DICTIONARY (last visited Apr. 22, 2019), <https://www.merriam-webster.com/dictionary/contraception> [https://perma.cc/5WPG-Z6PR] ("deliberate prevention of conception or impregnation").

114. *Contraception*, *CTRS. FOR DISEASE CONTROL & PREVENTION* (Aug. 13, 2020), <https://www.cdc.gov/reproductivehealth/contraception/index.htm> [https://perma.cc/XZ8A-2THR].

115. *Conception: How It Works*, UNIV. CAL. S.F. (last visited Jul 31, 2020),

woman to eliminate an ovum and to regulate her menstrual cycle before she herself is certain whether that ovum has been fertilized.”<sup>116</sup> The parallels between IUDs, ECs, and MR suggest that MR is close to falling in the contraceptive category.<sup>117</sup>

However, MR is able to function later in a pregnancy, and thus it is not exactly parallel to IUDs and ECs. If an IUD or EC expelled a fertilized egg, it would occur before implantation, which occurs five to six days after an egg is fertilized.<sup>118</sup> MR, by contrast, occurs after a missed period, roughly fourteen or more days after fertilization. Notwithstanding the later time frame for use, because MR does not meet the abortion definition, in the dichotomy it would seem to be a contraceptive by default, and the similarities to IUDs and ECs further support this classification.<sup>119</sup> Thus, though imperfect, MR as a post-coital method of fertility control may be “classified as having a contraceptive function, unless a special intermediate category is created between contraception and abortion.”<sup>120</sup>

An intermediary category may indeed be most appropriate. MR could be classified as a “Plan C”<sup>121</sup> or “missed period pill,”<sup>122</sup> acknowledging it is beyond existing contraceptive options, but also does not fit in the abortion framework. Alternatively, it could simply be used as a method of pregnancy prevention “without specifying whether it is a matter of contraception or abortion.”<sup>123</sup> MR could also fall in a category “referred to merely as ‘post-conceptive’ methods for regulating fertility.”<sup>124</sup> In sum, MR highlights how fertility control occurs on a continuum and challenges the black and white boxes of our existing legal framework.

Courts have acknowledged that reproductive therapies often have multiple purposes or effects and may not fit neatly into the dichotomy. In *Gurski v. Wyeth-Ayerst*, a medical malpractice suit, the court acknowledged that the dual uses of OCPs for contraception and “the regulation of menstrual cycles,” here, to relieve cramping and bleeding associated with menstruation, “might blur any legal

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<https://www.ucsfhealth.org/education/conception-how-it-works> [https://perma.cc/2CDD-FJCH] (“In nature, 50 percent of all fertilized eggs are lost before a woman’s missed menses.”).

116. Dourlen-Rollier, *supra* note 38, at 132.

117. Lee & Paxman, *supra* note 32, at 218 (“an argument may be made that the menstrual regulators fall within the definition of typical contraceptive functions, like the IUD and the ‘morning after pill’”).

118. Dreweke, *supra* note 75, at 15 (“Of all these methods, only the copper IUD, when used as an emergency contraceptive, appears capable of preventing implantation of a fertilized egg.”); *Conception: How It Works*, *supra* note 115 (“Once the embryo reaches the blastocyst stage, approximately five to six days after fertilization, it hatches out of its zona pellucida and begins the process of implantation in the uterus.”).

119. Lee & Paxman, *supra* note 32, at 218.

120. Dourlen-Rollier, *supra* note 38, at 132; Lee & Paxman, *supra* note 32, at 185 (“It is not improbable, then, that the menstrual regulators will either be looked on as ‘contraceptives’ or placed in a special category somewhere between contraceptives and abortifacients and referred to simply as post-conceptive fertility control devices.”)

121. Coeytaux & Nichols, *supra* note 6.

122. Sheldon et al., *supra* note 7.

123. Dourlen-Rollier, *supra* note 38, at 134.

124. Lee & Paxman, *supra* note 32, at 218–19.



distinction” between such uses.<sup>125</sup> In *Roe*, the Court also acknowledged that MR challenges the dichotomy. In considering how to define viability, the Court commented on how blurry the lines can be, noting definitional problems posed by “new embryological data that purport to indicate that conception is a ‘process’ over time, rather than an event, and by new medical techniques such as menstrual extraction, the ‘morning-after’ pill, implantation of embryos, artificial insemination, and even artificial wombs.”<sup>126</sup> Accepting a more fluid conception of fertility control could best accommodate MR, by not asking (nor wanting) the law to wade into a medical and personal part of life. If MR does become an option in the near future, however, it will likely be legally categorized as abortion, contraception, or a Plan C. How MR is categorized will impact what laws apply for patients and providers, the issue we turn to next.

### III. THE CURRENT LEGAL FRAMEWORK CAN ACCOMMODATE MR AS ANOTHER FERTILITY CONTROL OPTION.

Were MR to be reintroduced in the United States today, this therapy could implicate a range of laws for both users and providers. Prior to *Roe*, when MR was more commonplace, the legality of the therapy went largely untested.<sup>127</sup> Though the above analysis finds that MR could be classified, at the very least, as *not* an abortion, this Paper analyzes the legal implications were MR to be, for whatever reason, classified as an abortion. The below analysis uses California as a sample for state law purposes, as California has a generally progressive legal environment for reproductive rights and could be envisioned as an early adopter of MR. As such, this analysis may not be comprehensive for states with very different or especially restrictive laws.

#### A. Legal Implications for Users

Criminal sanctions would likely not apply to MR users. If MR is *not* categorized as an abortion and the medication is obtained legally from a health care provider, there would be little criminal risk for patients. One potential risk could be through enforcement of statutes that mandate certain disposal methods for fetuses.<sup>128</sup> However, these statutes generally apply to a fetus over twenty-

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125. The court ultimately did not reach a decision (“It is unnecessary, however, to make such fine distinctions at this stage of the proceedings”) on any legal distinction between oral contraceptives used for birth control versus for a therapeutic purpose but found the manufacturer did have a duty to warn patients of risks directly. *See Gurski v. Wyeth-Ayerst Div. of Am. Home Prods. Corp.*, 953 F. Supp. 412, 416 (D. Mass. 1996).

126. *Roe v. Wade*, 410 U.S. 113, 160 (1973).

127. *TIME*, *supra* note 8 (“The legality of the procedure has yet to be tested in any court.”).

128. CAL. HEALTH & SAFETY CODE § 7054.3 (Deering 2018) mandates that a fetus of under twenty weeks be disposed of by interment or incineration (“Notwithstanding any other provision of law, a recognizable dead human fetus of less than 20 weeks uterogestation not disposed of by interment shall be disposed of by incineration.”). In fact, improper disposal at any stage of a

weeks LMP,<sup>129</sup> and MR would be used much earlier in a pregnancy (likely four-to-twelve-weeks LMP). Additionally, there have been very few prosecutions<sup>130</sup> for improper fetal disposal, with the notable example of Purvi Patel, who was charged with abuse of a corpse for improper disposal of a fetus that was beyond twenty weeks.<sup>131</sup>

The second potential type of sanction that could apply to MR users even if MR is not categorized as an abortion is that related to purchases from unlicensed online pharmacies. Some medications that can be used for MR, such as misoprostol, can be easily purchased over the internet from unregistered online pharmacies. Such a purchase would technically violate drug import laws,<sup>132</sup> but Food and Drug Administration<sup>133</sup> and Drug Enforcement Administration<sup>134</sup> enforcement guidelines reflect that individual consumer purchases are generally not targeted. A Pennsylvania woman, however, was prosecuted for ordering mifepristone-misoprostol pills online that her sixteen-year-old daughter took to induce a miscarriage of an unplanned pregnancy.<sup>135</sup> Thus there is low, but potential, criminal liability for MR users who obtain their medication through

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pregnancy could be prosecuted as a misdemeanor under California Penal Code § 643 (Deering 2018), which states “No person knowingly shall dispose of fetal remains in a public or private dump, refuse, or disposal site or place open to public view. For the purposes of this section, ‘fetal remains’ means the lifeless product of conception regardless of the duration of the pregnancy.” The only case found that implicated § 7054.3 is *Feminist Women’s Health Ctr. v. Philibosian*, 157 Cal. App. 3d 1076 (1984), in which a district attorney and Catholic organization sought to obtain fetal material from an abortion clinic that was incorrectly following this statute. The court found this unconstitutional, holding for the health center.

129. Ashley Collette, *Concern or Calculation: An Examination of State Law Mandating the Burial or Cremation of a Fetus*, 9 WAKE FOREST L. REV. ONLINE 1, 1 (“Traditionally, states have refrained from intervening in the disposition of a fetus under 20 weeks uterogestation.”).
130. In Arkansas, Anne Bynum was charged with concealing a birth after delivering a roughly thirty-week stillborn at home. The case has been reversed and remanded. *See Bynum v. State*, 546 S.W.3d 533, 536 (Ark. Ct. App. 2018). In Virginia, a woman was charged with a felony for improperly concealing a dead body when she disposed of her stillborn fetus (30-32 weeks). *See Christina Cauterucci, Virginia Woman Given a Jail Sentence for “Concealing a Dead Body” After Her Stillbirth*, SLATE (May 10, 2018), <https://slate.com/news-and-politics/2018/05/virginia-woman-given-a-jail-sentence-for-concealing-a-dead-body-after-her-stillbirth.html> [<https://perma.cc/R25E-YW8Z>].
131. *Patel v. State*, 60 N.E.3d 1041 (Ind. Ct. App. 2016).
132. The United States Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs (last updated Aug. 25, 2015) [<https://perma.cc/BUX9-DGQU>]; *See also* Phil Ayers, *Comment: Prescribing a Cure for Online Pharmacies*, 72 TENN. L. REV. 949, 962–63 (2005) (citing Yoo; *see* 21 U.S.C. § 331 (2000) (“If the patient does not have a valid prescription, then the drug is considered misbranded” and the “introduction or distribution of misbranded drugs into interstate commerce violates the FDCA.”)).
133. Marvin A. Blumberg, *Information on Importation of Drugs Prepared by the Division of Import Operations and Policy*, FOOD & DRUG ADMIN. (last updated Aug. 25, 2015), [<https://perma.cc/BUX9-DGQU>].
134. *Id.* *See also* *People v. Duke*, No. A134692, 2012 LEXIS 7453, 5–6 (Cal. Ct. App. Oct. 16, 2012) (discussing a defendant who ordered large quantity of valium online from Thailand. This quantity is not comparable to a woman ordering four to eight misoprostol tablets for personal use.).
135. Bazelon, *supra* note 60 (Whalen was charged “with a felony for offering medical consultation about abortion without a medical license and with three misdemeanors: for endangering the welfare of a child, dispensing drugs without being a pharmacist and assault.”).

illicit online pharmacies. For users who obtain the medication through a provider and properly dispose of any fetal remains, there would be no criminal liability.

Were MR to be classified as an abortion, there could potentially be more criminal liability for users. Criminal statutes regulating abortion distinguish between legal and illegal abortion with legal abortions requiring an authorized provider.<sup>136</sup> If a physician or other approved provider, such as a nurse practitioner, physician's assistant, or certified nurse-midwife (depending on the state), prescribes the MR treatment in compliance with abortion laws, criminal sanctions would not apply.

If a woman herself induces MR, classified as abortion, outside of the formal healthcare setting, however, she would technically not be an "authorized" provider.<sup>137</sup> Criminal prosecution of non-physicians who perform abortions has been held constitutional in light of a state's interest in protecting maternal health.<sup>138</sup> However, no U.S. Supreme Court precedent suggests third-party criminal liability would extend to a pregnant woman herself who obtains an abortion in a manner inconsistent with state abortion statutes.<sup>139</sup> The Ninth Circuit, for example, overturned the conviction of a woman who self-induced an abortion in violation of a statute which required abortions be performed by physicians.<sup>140</sup>

Additionally, laws penalizing improper provision of abortion would require an *actus reus*—the abortion—that would be difficult to prove in the case of MR. By definition, MR does not confirm pregnancy, so there would be no positive pregnancy test and thus it would be difficult to "prove the actual existence of the pregnancy."<sup>141</sup> It is difficult to imagine that police or prosecutors would obtain the product of the MR—which in many cases would look no different than heavy bleeding—in order to conduct further analysis. MR outside the health sector would also likely occur in the home. Were a woman to present for care following complications, there would be no proof she had used MR as treatment since the

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136. *Id.* ("In 39 states, it's against the law to perform an abortion if you're not a doctor.") *See, e.g.*, 1 CAL. FORMS OF PLEADING AND PRACTICE—ANNOTATED § 4.12 (2018); CAL. HEALTH & SAFETY CODE § 123405; CAL. BUS. & PROF. CODE § 2253(b)(1) (Deering 2018). *See also* *People v. Barksdale*, 8 Cal. 3d 320, 335 (1972) (holding it is constitutional to limit authority to perform abortions to physicians and surgeons).

137. Curtis, *supra* note 8, at 432, 445 ("[M]enstrual extraction arguably violates both physician-only abortion requirements and state medical practice acts."). *But see id.* at 446–48 (arguing that MR may not constitute "the practice of medicine" when the user self-administers the process depending on the state statutes governing medical practice).

138. *Connecticut v. Menillo*, 423 U.S. 9, 11 (1975); 1 CAL. FORMS OF PLEADING AND PRACTICE—ANNOTATED § 4.12 (2018).

139. 1 CAL. FORMS OF PLEADING AND PRACTICE—ANNOTATED § 4.12 (2018). *See, e.g.*, Ashcroft, 483 F. Supp. at 684 ("This Court is unaware of any case in which the prohibition on abortion by nonphysicians was ever applied to the pregnant woman herself.") The court, however, under the theory of constitutional avoidance, declined to reach a conclusion on whether it would be unconstitutional for the statutes to do so, opting instead to interpret the statute as not applying to the woman self-inducing an abortion.

140. *McCormack v. Hiedeman*, 694 F.3d 1004 (9th Cir. 2012).

141. Dourlen-Rollier, *supra* note 38, at 133.

result “is the same as it would be for a spontaneous miscarriage.”<sup>142</sup> Because treatment is the same “there is no medical reason for women to tell a health care provider that they’ve taken the pills,”<sup>143</sup> and if a patient did, HIPAA would prevent the doctor from reporting them.<sup>144</sup>

Finally, it’s possible that the mens rea for unauthorized abortions would be lacking for MR specifically. A person inducing MR, and thus not confirming pregnancy, would not necessarily have the intent to terminate a pregnancy.<sup>145</sup> In *Patel*, the court discussed the issue of intent, in relation to whether Patel knew the fetus was born alive. The relevant abortion statute included a twenty-week mark, and progress of pregnancy was used in discussion of Patel’s knowledge.<sup>146</sup> In the trial court, Patel was charged with class B felony feticide, alleging that she “knowingly terminated her pregnancy with the intention other than to produce a live birth or to remove a dead fetus.”<sup>147</sup> Though this charge was vacated because the court found “the legislature did not intend for the feticide statute to apply to illegal abortions,”<sup>148</sup> a charge for neglect of a dependent was upheld, based on Patel being “subjectively aware that the baby was born alive and that she knowingly endangered the baby by failing to provide medical care.”<sup>149</sup> Though the facts from *Patel* are extremely far from a “textbook” MR case, it suggests that a court could analyze a woman’s intent with respect to the progress of her pregnancy, which would be difficult to do in the case of MR where pregnancy is merely suspected. In summary, while criminal sanctions are theoretically possible if MR is categorized as an abortion, there would be significant enforcement barriers.

Beyond criminal law, another notable implication for MR users is insurance coverage. For misoprostol alone or the mifepristone-misoprostol combination, MR would be an off-label use. Off-label prescriptions require a further step of analysis by private insurance before they are reimbursed, though, for the most part, they will be covered. Insurers, including Medicaid, will typically determine whether to cover an off-label use by looking to medical compendia, which outline drug uses beyond those approved by the FDA.<sup>150</sup> These compendia often include abortion as a use of misoprostol, either directly under “indications” or in an “off-

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142. Bazelon, *supra* note 60.

143. *Id.*

144. 45 C.F.R. § 164.512.

145. Lee & Paxman, *supra* note 32, at 194–95. This 1975 article reviewed foreign court decisions and noted that in jurisdictions where intent to end a pregnancy was an element of criminalized abortion, menstrual regulation completed after delayed menses without confirmed pregnancy was not prosecutable: “the lack of proof of the certainty of pregnancy, at the moment that the operation was performed, precluded any possibility of a violation of the statute.”

146. *Patel v. State*, 60 N.E.3d 1041, 1045–46 (Ind. Ct. App. 2016).

147. *Id.* at 1048.

148. *Id.* at 1056.

149. *Id.* at 1044.

150. William S. Comanor & Jack S. Needleman, *The Law, Economics, and Medicine of Off-Label Prescribing*, 91 WASH. L. REV. 119, 138 (2016).

label” use category, but do not include “menstrual regulation,” as yet.<sup>151</sup> However, an inclusion of a drug and its off-label uses (or failure to warn against off-label uses) in an insurance company formulary does not necessarily reflect coverage or benefits.<sup>152</sup> As an off-label use in general, there is no barrier to MR coverage,<sup>153</sup> but until MR is added to more medical compendia, there could be coverage denial. Additionally, insurers are able to deny coverage for off-label uses that are experimental or investigational. Being off-label, however, does not itself connote the use is experimental or investigational.<sup>154</sup>

For women insured by Medicaid, which covers one in five women of reproductive age,<sup>155</sup> the categorization of MR will be particularly important. The Hyde Amendment<sup>156</sup> limits reimbursements for abortion medication to cases of

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151. See, e.g., Misoprostol, DRUG CENT., <https://drugcentral.org/drugcard/1817?q=misoprostol> (last visited Oct. 2, 2020) [<https://perma.cc/ACY9-CPCU>] (Indications: postpartum hemorrhage, prevention of NSAID-induced gastric ulcers, prevention of CMV disease after organ transplant, osteoarthritis in patients at high ulcer risk, rheumatoid arthritis in patient at high ulcer risk. Off-label uses include: cervical ripening procedure, pregnancy with abortive outcome); ChEBI:63610 - misoprostol, CHEBI (Feb. 22, 2017), <https://www.ebi.ac.uk/chebi/searchId.do?chebiId=CHEBI:63610> [<https://perma.cc/3J38-2KVP>] (Indications: anti-ulcer, oxytocic (“Oxytocics are used to induce labour, obstetric at term, to prevent or control postpartum or postabortion hemorrhage, and to assess foetal status in high risk pregnancies. They may also be used alone or with other drugs to induce abortions (abortifacients)”), and abortifacient); AHFS Monograph, <https://www.drugs.com/monograph/misoprostol.html> (last visited Oct. 2, 2020) [<https://perma.cc/5MUY-B4BN>] (Uses: prevention of NSAIA-induced ulcers, gastric ulcer, duodenal ulcer, termination of pregnancy (but notes “use as an adjunct to mifepristone”), labor induction, postpartum hemorrhage (prevention or treatment). Other compendia include: US Pharmacopeia, National Formulary, WHO, and Drugdex.
  152. See, e.g., *Borreani v. Kaiser Found. Hosps.*, 875 F. Supp. 2d 1050, 1058 (N.D. Cal. 2012). Relatives of deceased patient filed suit against Kaiser for withholding information on the safety of prescription drugs Neurontin and gabapentin in its formulary. The court stated that “Kaiser will pay for off-formulary prescriptions and, therefore, the list does not implicate benefits decisions. Kaiser’s decision to provide these formularies presumably stems from its desire to provide medical care not from its need to regulate coverage or administer benefits under the plan.”
  153. See, e.g., *McCormack v. Hiedeman*, 900 F. Supp. 2d 1128, 1137 (D. Idaho 2013) (describing how off-label uses of mifepristone and misoprostol for medical abortion pose no legal issue simply by being “off-label: “After the FDA approves a drug for use, and absent any state regulation to the contrary, doctors may prescribe that drug for indications, in dosages, and following treatment protocols different than those expressly approved by the FDA. This practice is commonly known as “off-label” use. The off-label use of drugs approved by the FDA does not violate federal law or federal regulations, because the FDA regulates the marketing and distribution of drugs, not the practice of medicine. . . . The medical community recognizes off-label, non-FDA-approved alternatives to mifepristone-misoprostol regimens, two of which include combining methotrexate and misoprostol, or simply taking misoprostol alone” (internal citations omitted)).
  154. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD DRUG L.J. 71, 72 (1998).
  155. Medicaid and Reproductive Health, PLANNED PARENTHOOD ACTION FUND, <https://www.plannedparenthoodaction.org/issues/health-care-equity/medicaid-and-reproductive-health> (last visited Jul. 31, 2020) [<https://perma.cc/DPF2-ARFM>].
  156. The Hyde Amendment prohibits federal funding for abortion except in cases of rape, incest, or danger to the life of the woman. It applies to programs including Medicaid, Peace Corps,

rape, incest, or threat to the life of the woman. Thus, were MR to be categorized as abortion, it could be excluded from Medicaid coverage. However, where that occurs, state-funded programs may step in to cover medical abortion, as is the case in California.<sup>157</sup> Conversely, were MR to be categorized as *not* an abortion and thus not subject to Hyde, it could increase reproductive health options, autonomy, and improve outcomes for Medicaid recipients. Given that women of color are more likely to have coverage through Medicaid, and face disproportionate barriers to reproductive health care in general,<sup>158</sup> MR could be a step towards providing equitable access to care.

Finally, beyond looking to compendia or whether a use is investigational, private insurers may have special rules regarding reimbursement for abortion. Some insurers may not cover medical abortion (off-label or not). California requires most private insurers to cover abortions, though this does not apply to Marketplace multi-state plans or employers that self-fund their plans.<sup>159</sup>

In sum, if MR is reintroduced in the United States, the legal implications for users will depend on how it is classified, whether they obtain the medication legally, and their insurance coverage. Assuming MR is not classified as abortion, many of the restrictive implications outlined above would not apply, and users would not face sanctions.

## B. Legal Implications for Providers

Legal implications for providers of MR are slightly more complex. If MR is classified in a way that does not implicate abortion, then legal implications would largely be the same as any medical practice liability. If MR is classified as an abortion, then more restrictions would apply.

In the case that MR is not classified as an abortion, there are still legal implications for providers. First, in order to prescribe the mifepristone-misoprostol combination for MR, providers would need to ensure they follow the specific requirements for this medication. Some states require that providers use the FDA protocol,<sup>160</sup> as opposed to the alternate protocol that is often preferred. The

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the military, prisons, disability services, and Indian Health Services. See Alyssa Engstrom, *Note: The Hyde Amendment: Perpetuating Injustice and Discrimination After Thirty-Nine Years*, 25 S. CAL. INTERDIS. L.J. 451 (2016).

157. *California Abortion Coverage in Medi-Cal and Private Insurance*, ACCESS WOMEN'S HEALTH JUST. (last visited Oct. 3, 2020) [<https://perma.cc/7UKY-WD4U>].

158. Medicaid and Reproductive Health, *supra* note 155.

159. *California Abortion Coverage in Medi-Cal and Private Insurance*, *supra* note 157.

160. Ohio, Texas, and North Dakota have passed laws mandating the use of the FDA protocols for inducing abortion with Mifeprex. See Laura Britton & Amy Bryant, *When Off-Label is Illegal: Implications of Mandating the FDA-Approved Protocol for Mifepristone-induced Abortions*, 25 WOMEN'S HEALTH ISSUES 433 (2015). See also *Medication Abortion*, GUTTMACHER INST. (Aug. 1, 2020), <https://www.guttmacher.org/state-policy/explore/medication-abortion> [<https://perma.cc/Q8GH-LB72>]. The Mifeprex protocol, approved for up to 70 days LMP, is 200 mg of Mifeprex taken by mouth; 24 to 48 hours after taking Mifeprex: 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient; About seven to fourteen days after taking Mifeprex: follow-up with the healthcare provider.

Supreme Court of Oklahoma upheld a law that confined misoprostol with mifepristone use to the on-label regimen outlined by the FDA, finding it did not violate the state constitution on legislative authority or special laws.<sup>161</sup> Other states have similar restrictions, including Texas and North Dakota,<sup>162</sup> and the issue has not been addressed by the Supreme Court of the United States.<sup>163</sup>

A significant area of law that would be implicated by MR is medical malpractice. For both the mifepristone-misoprostol and misoprostol<sup>164</sup> alone methods, MR will be an off-label use. However, this does not incur special liability. Physicians have wide discretion to write prescriptions for off-label uses and are not limited to approved uses.<sup>165</sup> In fact, “40 percent to 60 percent of prescription drugs [are] dispensed for unapproved uses.”<sup>166</sup> The term “off-label” simply connotes the FDA “regulatory status” of the use, and does not reflect risk or suggest that the use is experimental or investigational.<sup>167</sup>

As with any prescription, the ability to sue over an off-label prescription is governed by medical malpractice and state medical practice statutes.<sup>168</sup> Off-label status alone does not show negligence or create liability<sup>169</sup> that would lead to a

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*Mifeprex (mifepristone) Information*, FOOD & DRUG ADMIN. (Feb. 5, 2018), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information> [<https://perma.cc/5FFA-VYT9>].

161. Okla. Coal. for Reprod. Just. v. Cline, 368 P.3d 1278, 1289 (2016).

162. Britton & Bryant, *supra* note 160, at 433.

163. Humble v. Planned Parenthood Ariz., Inc., 574 U.S. 1060 (2014) (denying cert); Cline v. Okla. Coal. for Reprod. Just., 571 U.S. 985 (2013) (dismissing cert on constitutional questions previously granted in Cline v. Okla. Coal. for Reprod. Just., 570 U.S. 930 (2013)).

164. See, e.g., *Cytotec (misoprostol)*, FOOD & DRUG ADMIN., [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2002/19268slr037.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf) (last visited Oct. 3, 2020) [<https://perma.cc/9QH6-NVP7>].

165. Areta Kupchyk, Paul W. Radensky & Michael W. Ryan, *Potential Liability for Drug Companies, Health Care Providers, and Insurers: Off-Label Prescribing and Internet Advertising*, in PHARMACEUTICAL AND MEDICAL DEVICE LAW REGULATION OF RESEARCH, DEVELOPMENT, AND MARKETING 1–2 (Bloomberg BNA, 2d ed.). See also *id.* at 10 (“Since 1982, the FDA has acknowledged that physicians may prescribe a drug to serve any legitimate medical purpose, regardless of whether the agency has approved the drug for that use”); Britton & Bryant, *supra* note 160, at 434 (“FDA has the authority to regulate the entry of prescription drugs into the market but the FDA cannot regulate the practice of medicine, which is how off-label drug prescribing is categorized.”); Benjamin A. Hooper, *The Negative Effects of Cumulative Abortion Regulations: Why the 5th Circuit Was Wrong in Upholding Regulations on Medication Abortions (Planned Parenthood of Greater Texas Surgical Health Services v. Abbott)*, 83 U. CIN. L. REV. 1489, 1495 (2015) (“Though the FDA approves only the on-label use of drugs, it is commonly expected that many drugs will be used off-label at the discretion of medical doctors”); *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULLETIN 4 (Apr. 1982); David Kessler, *Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug and Cosmetic Act*, 15 HARV. J. LEGIS. 693, 698 (1978); William S. Comanor & Jack Needleman, *The Law, Economics, and Medicine of Off-Label Prescribing*, 91 WASH. L. REV. 119 (2016).

166. See Areta Kupchyk et al., *supra* note 165, at 9.

167. Beck & Azari, *supra* note 154.

168. Areta Kupchyk et al., *supra* note 165, at 66 n.5.

169. See e.g., *Watson v. Gish*, 2011 U.S. Dist. LEXIS 58317, at \*6–7 (N.D. Cal. May 31, 2011) (“Novartis argues that “[a]n off label use allegation does not provide a basis for a medical

malpractice claim. Courts use a reasonable physician standard to determine negligence,<sup>170</sup> and a plaintiff must establish “that a physician’s off-label prescription deviated from an acceptable and prevailing standard of practice.”<sup>171</sup>

In assessing the reasonableness of the provider’s prescription of an off-label use, a court will look to the doctor’s medical judgment, scientific literature, and common medical practice.<sup>172</sup> This negligence assessment drives at whether the provider met the standard of care.<sup>173</sup> “Whether a given off-label prescription meets the standard of care will depend on the level of evidence available to support the use and how the clinician used the available evidence. In general, the more scientific evidence there is to support a given off-label use, the more likely that use is to meet the standard of care.”<sup>174</sup> If a provider is aware of danger or risk associated with an off-label use, they could be liable, as was the case in *Watson v. Gish* where a physician prescribed an off-label use of Zometa despite knowing warnings that it could lead to osteonecrosis.<sup>175</sup>

Because MR is relatively unusual right now, the standard of care<sup>176</sup> against which to compare providers’ treatment may be unclear. Standards of care are established by statute,<sup>177</sup> common practice, or medical research.<sup>178</sup> While MR may not be common practice in the United States, its use, efficacy, and safety are documented in scientific literature and thus a provider would be able to point to

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malpractice claims because a drug can be prescribed non-negligently for off label indications.’ Def.’s Opp’n at 10 (citing Compl. ¶ 52). The flaw in this contention is that Plaintiff’s malpractice claim is not limited to the act of prescribing medication for off label use. Rather, the Complaint also alleges that despite Novartis’ warnings to physicians regarding the risk of osteonecrosis resulting from the use of Zometa, the Healthcare Defendants nonetheless prescribed and administered the medication to Plaintiff, who then suffered osteonecrosis as a result... Dr. Gish’s decision to prescribe Zometa, notwithstanding his alleged awareness of its dangers, potentially could give rise to a claim for medical negligence.”)

170. See, e.g., *Mero v. Sadoff*, 31 Cal. App. 4th 1466 (1995); *Avivi v. Centro Medico Urgente Med. Ctr.*, 159 Cal. App. 4th 463 (2008); *Huffman v. Lindquist*, 37 Cal. 2d 465 (1951).
171. James B. Riley, Jr. & P. Aaron Basilius, *Physicians’ Liability for Off-Label Prescriptions*, HEMATOLOGY & ONCOLOGY NEWS & ISSUES 24, 27 (May/June 2007), [https://www.mcguirewoods.com/news-resources/publications/health\\_care/off\\_label.pdf](https://www.mcguirewoods.com/news-resources/publications/health_care/off_label.pdf) [<https://perma.cc/U4P7-NFTE>].
172. *Id.*
173. *Flowers v. Torrance Mem’l Hosp. Med. Ctr.*, 8 Cal. 4th 992, 997 (1994) (holding that negligence is conduct that falls below the standard of care).
174. *Liability and Off-Label Prescriptions*, 6 PSYCHIATRY (EDGMONT) 43 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2719453/> [<https://perma.cc/NM32-AF2R>].
175. *Watson v. Gish*, 2011 U.S. Dist. LEXIS 58317, at \*6–7 (N.D. Cal. May 31, 2011). See also *Crone v. Pfizer, Inc.*, WL 1946386, at \*5 (N.D. Cal. Sept. 1, 2004) (holding that a physician was not fraudulently joined in suit against pharmaceutical company for prescribing an off-label use despite his awareness it was “risky”).
176. Judicial Council of California Civil Jury Instructions (CACI) No. 501. *Standard of Care for Health Care Professionals* (2017).
177. See, e.g., *Galvez v. Fields*, 88 Cal. App. 4th 1410, 1413–15 (2001) (using a civil statute requiring physicians to advise women on prenatal testing for birth defects as the standard of care to evaluate the possible negligence per se of a physician). If the standard of care is not set by statute or regulation, a court will refer to instructions on negligence per se. Judicial Council of California Civil Jury Instructions, CACI Nos. 418–421 (2017).
178. Eleanor D. Kinney, *The Brave New World of Medical Standards of Care*, 29 J.L. MED. & ETHICS 323, 325 (stating that courts look to expert testimony on community standards and professional literature to determine the standard of care).



such studies in liability suits. Prior emphasis on local standards of care have largely given way to a more global understanding of medical practice. Thus, international studies could provide further support for establishing a standard of care. The ability to look to international research is important in the case of MR as most studies come from other countries, such as Bangladesh, where the practice is current.

Providers will be held liable for an off-label prescription that results in adverse effects if they are indeed negligent, fail to meet the standard of care, ignore warnings, or pursue an unestablished or risky therapy. However, the low rate of complications from misoprostol for MR suggests that rampant negligence claims are unlikely. Providers reasonably prescribing an off-label use that is backed up by their judgment of the patient's situation and medical practice are also not more liable for an adverse outcome simply because the use is off-label.<sup>179</sup> As long as physicians are not negligent in their prescription of off-label uses, there is no heightened malpractice liability.

Another important factor for providers offering MR to consider is informed consent.<sup>180</sup> In the case of MR as an off-label therapy, it is worth noting that the standard for informed consent is not heightened simply by the regulatory status of being "off-label."<sup>181</sup> Common law informed consent focuses on health benefits, serious risks, nature of the treatment, and the condition the treatment seeks to remedy.<sup>182</sup> The California jury instruction, for example, details that informed consent requires the physician to explain the treatment, serious risks, and other information a skilled provider would convey in a way the patient understands.<sup>183</sup> Courts have rejected arguments that off-label status requires more detailed informed consent and have refused to require physicians to relay to patients the regulatory and legal implications of an FDA-approved medication they have judged is a safe treatment option in its off-label use.<sup>184</sup> In a recent study, researchers provided a detailed description of MR that explained, "The pills would be offered instead of a pregnancy test and would serve to bring on bleeding similar to your period. If you were pregnant, they would terminate the pregnancy in almost

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179. *See, e.g., Carson v. Depuy Spine, Inc.*, 365 Fed. Appx. 812 (9th Cir. 2010) (no liability for physician who prescribed off-label use of spine device where there was no evidence of causation). Note this decision is unpublished.

180. Riley & Basilius, *supra* note 171, at 26–27.

181. *Id.* at 27.

182. Beck & Azari, *supra* note 154, at 86.

183. Judicial Council of California Civil Jury Instructions (CACI) No. 532. Informed Consent—Definition (2017).

184. *See, e.g., Klein v. Biscup*, 673 N.E.2d 225, 231 (1996) (“[T]he off-label use of a medical device is also a matter of medical judgment, and, as such, subjects a physician to professional liability for exercising professional medical judgment. Off-label use of a medical device is not a material risk inherently involved in a proposed therapy which a physician should have disclosed to a patient prior to the therapy [citation omitted]. Therefore, since Biscup engaged in off-label use of this medical device he could be subject to professional liability for medical negligence, but in this case those claims have been litigated and are not before us. Accordingly, we conclude failure to disclose FDA status does not raise a material issue of fact as to informed consent.”).

all women.”<sup>185</sup> Informed consent for MR, as illustrated by this example, would need to be clear about the possibility of terminating pregnancy in the case that the user is pregnant.

In the case that MR is classified as an abortion, the FDA and malpractice issues raised above would still apply, as well as abortion-specific regulations. For example, MR could only be carried out by an “authorized provider,” which in California includes physicians and surgeons<sup>186</sup> as well as Advanced Practice Clinicians for medical and aspiration abortion in the first trimester.<sup>187</sup> If MR is categorized as abortion, a non-authorized provider providing MR would face criminal liability. Providers would also need to follow state restrictions requiring, for example, ultrasounds, parental consent, or waiting periods.<sup>188</sup> Because abortion regulations require a confirmed pregnancy, providers would seemingly bypass these statutes in carrying out MR (which does not confirm pregnancy). Even if abortion laws do apply, difficulty in proving that they apply, due to lack of intent where pregnancy is unconfirmed, to a given MR procedure would be a barrier to enforcement.<sup>189</sup> This dissonance further underlines how MR does not fit well within the abortion regulatory framework, and thus should not be categorized as such.

### CONCLUSION

MR has the potential to be a valuable addition to the spectrum of fertility control methods in the United States. Imagine a range of options including: “plan A (contraception), plan B (the morning-after pill), plan C (misoprostol to bring down a missed period), and access to safe abortion.”<sup>190</sup> As a third point of intervention, MR could increase access and choice, offering an additional simple, safe, and early option to ensure non-pregnancy. Through telemedicine, now more

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185. Sheldon et al., *supra* note 7, at 2 (“Suppose there were “missed period pills” that could be taken if you had missed your period and did not want to know if you were actually pregnant. The pills would be offered instead of a pregnancy test and would serve to bring on bleeding similar to your period. If you were pregnant, they would terminate the pregnancy in almost all women. The pills would be safe to take but could cause side effects such as bleeding, cramping, shivering and nausea. The side effects would be similar to those experienced by many women during menstruation.”).

186. 1 CAL. FORMS OF PLEADING AND PRACTICE—ANNOTATED § 4.12 (2018); CAL. HEALTH & SAFETY CODE § 123405; CAL. BUS. & PROF. CODE § 2253(b)(1) (Deering 2018). *See also* *People v. Barksdale*, 8 Cal. 3d 320, 338 (1972) (finding it is constitutional to limit authority to perform abortions to physicians and surgeons).

187. Nurse practitioners (NPs), certified nurse-midwives (CNMs), and physician assistants (PAs) are authorized to perform “nonsurgical abortion,” including the “termination of pregnancy through the use of pharmacological agents” (medication abortion). CAL. BUS. & PROF. CODE § 2253(b)(2), (c) (West 2012); CAL. BUS. & PROF. CODE § 2052 (Deering 2018). Section 3.b goes into more detail on the role and authority of APCs in abortion provision in California.

188. *An Overview of Abortion Laws*, GUTTMACHER INST. (Oct. 1, 2020), <https://www.guttmacher.org/state-policy/explore/overview-abortion-laws> [<https://perma.cc/R5TM-YGF6>].

189. Lee & Paxman, *supra* note 32, at 196–97 (“[I]f the same rules are applied to menstrual regulation that are applied to abortion, i.e., that pre-existing pregnancy must be shown, it will be virtually impossible for the prosecutor to prove the illegality of the procedure.”).

190. Coeytaux & Nichols, *supra* note 6.

common and accepted in light of the COVID-19 pandemic, it could be particularly transformative for rural women. In an increasingly restrictive environment, MR could provide even more critical benefits, especially for poor women and women of color who are disproportionately burdened by barriers to reproductive health care access. MR would be a safe alternative to other self-help methods women may try to disrupt a pregnancy.

Were MR to be reintroduced in the United States, it would not fit neatly within the current regulatory dichotomy of contraception and abortion. While a third category may be most appropriate, at the very least it is clear the abortion category is not appropriate because MR lacks the basic elements of intent to abort and the underlying fact of confirmed pregnancy. The legal implications depend largely on this categorization. So long as MR is not categorized as an abortion, implications for patients and providers would be largely the same as for any medical therapy. If MR is classified as an abortion, there would be more complex implications, but even so, users would likely be relatively shielded from sanctions. A third, stand-alone category may be most appropriate for MR, but whether drawing additional, hard to define lines governing women's reproductive health and autonomy is wise is another question. This analysis of how MR would be regulated shows the limits of the law and its struggle to adapt to grey spaces and suggests that reproductive health would be better left to people who can become pregnant and the medical field, rather than lawmakers and courts.

A strong starting point to create a supportive legal framework would be to develop a standard of care that distinguishes MR from abortion. This would not only clarify to providers how to best offer MR, but would also provide protection against litigation that attempts to criminalize MR. More broadly, advocates should keep an eye on ensuring women are not prosecuted for self-induced MR. Challenging fetal disposal and other statutes that can be creatively stretched to punish women for self-induced abortion or MR would also create a more supportive context. Finally, advocates should work to protect provider autonomy to recommend the best options for their patients and challenge statutes that mandate on-label prescriptions.

This Paper is a preliminary wide-lens analysis of how MR would be received in the current reproductive health legal regime. Further research is needed to understand how MR would interact with abortion and contraception jurisprudence, particularly at the state level. Reactive legislation to limit MR in states hostile to reproductive rights should be expected, and additional analysis is warranted to prepare counter arguments to restricting MR access.

MR reveals the grey space in both the personal experience and legal framework of fertility control. Adding another point along the fertility control spectrum could be a real resource to women and other people who can become pregnant, while challenging the rigid reproductive health framework of contraception and abortion to better reflect the lived reality of fertility experiences and choices. Reproductive health advocates and medical providers should continue to debate the potential benefits and drawbacks of reviving MR in light of

the diverse and contingent legal implications.