The Promise of Abortion Pills: Evidence on the Safety and Effectiveness of Self-Managed Medication Abortion and Opportunities to Expand Access

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THE PROMISE OF ABORTION PILLS: EVIDENCE ON THE SAFETY AND EFFECTIVENESS OF SELF-MANAGED MEDICATION ABORTION AND OPPORTUNITIES TO EXPAND ACCESS

Dana M. Johnson, PhD*

ABSTRACT

Since the Dobbs v. Jackson Whole Women’s Health Organization ruling, medication abortion pills have received an enormous amount of attention. The two medication abortion pill regimens, mifepristone used with misoprostol, or misoprostol used by itself, have been the subject of extensive public health research. Less discussed in the legal scholarship are the differences between the two regimens and their uses for self-managed medication abortion. In the United States, when people refer to medication abortion pills, they are often referencing mifepristone used with misoprostol. But in other parts of the world, when people refer to medication abortion pills, they often mean misoprostol alone. Public health researchers have examined the safety, effectiveness, and acceptability of self-managed abortion using both medication abortion regimens. This Article draws on this evidence base and provides opportunities for expanding access to medication abortion pills. This is especially important now that some states have legal climates similar to countries where abortion has long been restricted and researchers anticipate that people will increasingly seek access to medication abortion pills and turn to self-managed medication abortion.

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I. INTRODUCTION: THE PROMISE OF ABORTION PILLS

Since the Dobbs v. Jackson Women's Health Organization1 ruling, medication abortion pills have received an enormous amount of attention.2 The two medication abortion pill regimens, mifepristone used with misoprostol, or misoprostol used by itself, have been the subject of extensive public health research.3 Less discussed in the legal scholarship are the differences between the two regimens, and the different contexts surrounding them. In the United States, when people refer to

1. 142 S. Ct. 2228 (2022).
medication abortion pills, they are often referencing mifepristone used with misoprostol.4 But in other parts of the world, when people refer to medication abortion pills, they mean simply misoprostol used alone.5 These regimens differ in terms of safety and effectiveness,6 and different federal and state policies contextualize access to them.

Following the Dobbs decision, abortion access has become severely limited or outright banned in at least fourteen states.7 The legality of abortion is now a moving target that depends on one’s location. Some states have moved to ban abortion, and others have expanded access.8 With nationwide access to clinical abortion care significantly reduced, some people may acquire medication abortion pills without clinical supervision.9 This process, referred to as self-managed abortion (SMA), includes practices such as obtaining medication abortion pills and managing one’s own abortion outside of the formal health care setting.10 There are a range of methods people may use, some safe and effective, others not;11 however, in recent years self-managed abortion using abortion pills has become increasingly common through online sources.12

Many might assume that any abortion occurring outside of the clinic setting is unsafe. However, self-managed abortion through the use of abortion pills has proven to be a safe practice around the world, especially in countries where abortion is illegal or highly restricted.13 In the


6. See Ferid A. Abubeker, Antonella Lavelanet, Maria I. Rodriguez & Caron Kim, Medical Termination for Pregnancy in Early First Trimester (=63 days) Using Combination of Mifepristone and Misoprostol or Misoprostol Alone: A Systematic Review 20 BMC Women’s Health 142 (2020); Nguyen Thi Nhu Ngo et al., Comparing Two Early Medical Abortion Regimes: Mifepristone+Misoprostol vs. Misoprostol Alone, 83 Contraception 410, 415 (2011).


8. See id.


13. See Singh et al., supra note 5, at 5–6, 27.
United States, state-level abortion bans have severely limited access to abortion clinics, and as a result, people have had to self-manage their abortions with medication abortion pills ordered from the internet.\textsuperscript{14} Now that some states have legal climates similar to countries where abortion has long been illegal,\textsuperscript{15} researchers anticipate that this practice will continue, and demand for medication abortion pills will grow.\textsuperscript{16} To this end, public health researchers have examined the safety, effectiveness, and acceptability of self-managed medication abortion.\textsuperscript{17}

Mifepristone used with misoprostol is the standard medication abortion regimen in the United States,\textsuperscript{18} but worldwide, misoprostol alone is the most common option.\textsuperscript{19} In the United States, access to the combined mifepristone and misoprostol regimen has been restricted by the Food and Drug Administration’s (FDA) Risk Evaluation and Mitigation Strategies (REMS) classification, a federal policy that limits who dispenses mifepristone and how patients acquire it.\textsuperscript{20} Misoprostol, on the other hand, is not restricted by a REMS classification, and because of its wide range of uses, it is regularly stocked in U.S. pharmacies.\textsuperscript{21} Both regimens have been used for safe self-managed abortion.\textsuperscript{22} In this Article, I will focus on the legal context that creates differential access to both regimens, the current literature on their safety and effectiveness, and opportunities for expanding access to safe self-managed abortion in the United States.


\textsuperscript{18} Jessica Beaman, Christine Prifti, Eleanor Bimla Schwarz & Mindy Sobota, \textit{Medication to Manage Abortion and Miscarriage}, 35 J. GEN. INTERNAL MED. 2398, 2398 (2020).


\textsuperscript{22} See IBIS REPROD. HEALTH, supra note 19.
This Article begins with the origins of medication abortion pills and the different scientific advancements and laws that have shaped their use. Second, I discuss the use of medication abortion pills, particularly in the United States, including the evolving policies now limiting their availability and the shifts in their provision following the COVID-19 pandemic. Third, I introduce self-managed medication abortion. I discuss current data on the safety and effectiveness of self-managed medication abortion with a focus on the two regimens of mifepristone and misoprostol, and misoprostol alone. Fourth, I discuss current research on the self-managed medication abortion conducted by Aid Access, a non-profit organization shipping pills to the United States. Fifth, I discuss issues of equity and the criminalization of self-managed medication abortion. To conclude, given the clinical abortion access landscape following the Dobbs decision, I revisit opportunities for expanding access to medication abortion pills in the United States.

II. MEDICATION ABORTION

Since the late 1980s, there have been two widely recognized medication abortion regimens. The first, mifepristone used in combination with misoprostol, can be used for early pregnancy termination. Mifepristone blocks the hormone progesterone, which is necessary to carry a pregnancy to term. By blocking progesterone during a pregnancy, mifepristone “alters the lining of the uterus and causes disruption to the decidua (which later becomes the placenta).” The drug causes the gestational sac to detach from the uterus by causing the uterine lining to thin and it “can also cause the cervix to soften and dilate, assisting with the expulsion of pregnancy.” Mifepristone’s companion drug misoprostol then generates contractions to expel the pregnancy. The World Health Organization (WHO) guidelines for the combined mifepristone and misoprostol regimen recommends 200mg of mifepristone administered orally, followed by 800mg of misoprostol administered vaginally, sublingually (dissolved under the tongue), or buccally (held in the cheek), twenty-four to forty-eight hours later. The second regimen, misoprostol used without mifepristone, can also terminate a pregnancy. When using misoprostol alone, WHO recommends 800µg of misoprostol administered

24. See id. at S5.
27. Donley, supra note 25, at 633.
28. Id.
29. WORLD HEALTH ORG., ABORTION CARE GUIDELINES 68 (2022).
30. Id. at 62.
vaginally, sublingually, or buccally. Misoprostol is effective when used without mifepristone, but mifepristone is not usually sufficient to end a pregnancy on its own.

A. The History of Mifepristone and Misoprostol

It is crucial to recognize the origins of these drugs to understand the stark political and legal differences surrounding them. Unlike misoprostol, mifepristone is specifically FDA approved as an abortifacient. Since its introduction to the public, mifepristone “has encountered . . . resistance from moralists who fear[ed] it w[ould] trivialize sex” and make light of pregnancy termination. Misoprostol, however, was originally approved to prevent and treat stomach ulcers. It is used off-label for other obstetric uses, including to induce labor or evacuate a pregnancy after an incomplete or missed miscarriage. Misoprostol has flown somewhat under the radar in the United States because of its variety of other uses. As such, it has not been scrutinized in the same way mifepristone has, and it is available at most pharmacies with a prescription.

Mifepristone was created by French scientists Etienne-Emile Baulieu, Georges Teutsch, and Alain Belanger. Baulieu in particular received extensive attention as the “father of the pill,” winning multiple awards and honors for his involvement in discovering the drug. The original name, RU-486, comes from the French pharmaceutical company, Roussel-Uclaf. To be highly effective, mifepristone must be used in combination with a prostaglandin, a medication that mimics the function of

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31. Id. at 68.
38. See Belluck, supra note 21.
39. See id.
41. Id.
42. Charo, supra note 34, at 75.
hormones and causes uterine contractions.\textsuperscript{44} In Europe, clinicians administered mifepristone with the prostaglandin sulprostone, an effective but clinically onerous treatment that had to be administered by injection twenty-four hours later.\textsuperscript{45}

Misoprostol as an abortion-inducing drug was first discovered by feminist activists in Brazil.\textsuperscript{46} Abortion in Brazil had long been criminalized and only permitted to save a woman’s life (now the law has only slightly expanded to include cases of rape).\textsuperscript{47} Despite this legally restrictive environment, the ingenuity and creativity of Brazilian women led to the discovery of a critical companion to the mifepristone pill.\textsuperscript{48} Misoprostol was approved in Brazil for the prevention and treatment of gastric and duodenal ulcers.\textsuperscript{49} It was sold in pharmacies and drug stores under the commercial name “Cytotec” and could be purchased without a prescription.\textsuperscript{50} Women in Brazil noticed a warning on the label that cautioned against using the drug while pregnant, presenting its potential as an abortion inducing drug.\textsuperscript{51} Misoprostol was safer and more effective than alternative methods, and women began to share this information.\textsuperscript{52} Researchers and doctors took note, and soon studies on the efficacy, sales volume, and gynecological applications of the drug followed.\textsuperscript{53} An analysis of the sales

\textsuperscript{44} See Remi Peyron et al., \textit{Early Termination of Pregnancy with Mifepristone (RU 486) and the Orally Active Prostaglandin Misoprostol}, 328 \textit{NEW ENG. J. MED.} 1509, 1509 (1993).


\textsuperscript{47} Nolen, supra note 46; Costa, supra note 46, at S132 (1998); \textit{The World’s Abortion Laws}, supra note 46.


\textsuperscript{49} Costa, supra note 46, at S132.


\textsuperscript{52} See id. at 2–3; Costa, supra note 46, at S133; Löwy & Corrêa, supra note 48, at 678–79.

\textsuperscript{53} See Assis & Erdman, supra note 51, at 2; Costa, supra note 46, at S133–36.
volume demonstrated a sharp increase in the late 1980s, supporting anecdotal reports that Brazilian women were rapidly sharing information about this new option for pregnancy termination. By the early 1990s, Brazilian researchers were among the first scientists in the world to document its off-label use. The abortifacient properties were publicized, and coverage in Brazilian news outlets generated controversy and spurred regulatory controls. Even with new restrictions in place, sales increased. Information about misoprostol’s low cost, convenient use, private access, and success in reducing abortion complications had already spread, and further studies began.

Misoprostol’s increased regulation was starkly incongruent with the science coming out of the country at the time. Doctors in Brazil reported fewer incidents of severe abortion-related complications, and the international scientific community began to take note. Later, Baulieu discussed using misoprostol in combination with mifepristone, citing this regimen as less painful and possibly even safer than previous mifepristone regimens. However, policy stalled the widespread research and application of a dual mifepristone and misoprostol regimen. Misoprostol’s manufacturer warned about the dangers of off-label use, and misoprostol con-

55. Id. at 238; Michael Klitsch, Antiprogestins and the Abortion Controversy: A Progress Report, 23 FAM. PLAN. PERSP. 275, 278 (1991).
56. See, e.g., Helena Lutícia Coelho et al., Misoprostol: The Experience of Women in Fortaleza, Brazil, 49 CONTRACEPTION 101 (1994); Barbosa & Arilha, supra note 54, at 238; Klitsch, supra note 55, at 278, 282; Adams, supra note 45.
58. Asis & Erdman supra note 51, at 4. But see Barbosa & Arilha, supra note 54, at 237 (“An analysis of Cytotec sales, using data furnished by the manufacturer, shows an increasing trend beginning in January 1989, with sales reaching more than 50,000 units per month during some months. This trend was maintained until July 1991, when the Ministry of Health imposed sales restrictions.”).
59. Barbosa & Arilha, supra note 54, at 238–239.
61. See Asis & Erdman supra note 51, at 12–13; see also Sarah H. Costa & Martin P. Vessey, Misoprostol and Illegal Abortion in Rio de Janeiro, Brazil, 341 LANCET 1258 (1993); Barbosa & Arilha, supra note 54.
62. See Asis & Erdman supra note 51, at 11–16; Zordo, supra note 60, at 22.
64. See Asis & Erdman supra note 51, at 11–15; Charo, supra note 34, at 54–58.
continued to be over-monitored and regulated. Fortunately, the media, activists, pharmacists, and researchers continued to advocate for the drug’s utility as an inexpensive abortion care option that was registered for use in over eighty countries. Today, low-cost “generic misoprostol products are . . . ubiquitous and informal supply channels continue to grow, including . . . online services, feminist initiatives, and community-based networks.” Its use as an abortifacient has spread throughout Latin America, the Caribbean, South Asia, and Sub-Saharan Africa. Based on extensive research and knowledge from widespread use of the drug, misoprostol’s gynecological applications have been expanded and refined, and it is one of WHO’s essential medicines.

B. THE DIFFERENT CULTURAL CONTEXTS OF MIFEPRISTONE AND MISOPROSTOL

In addition to different historical origins and policy contexts, there are distinct cultural contexts surrounding mifepristone and misoprostol. Mifepristone was a drug researched and manufactured by a French pharmaceutical company. Its scientific discovery garnered the prestige of western medical technology and academic science. Misoprostol, however, has not been academically celebrated in the same way. As sociologist Siri Suh writes, “Although misoprostol has been widely recognized as an essential obstetric medication, its application remains highly contested precisely because it disrupts medical and legal authority over pregnancy, delivery, and abortion.” To this day, the Brazilian women who pioneered misoprostol’s off-label use remain unnamed, and their discovery came from experiential evidence (instead of formal pharmaceutical research) that has not been academically recognized the way mifepristone


67. Assis & Erdman, supra note 51, at 3; see also Angel M. Foster, Grady Arnott & Margaret Hobstetter, Community-Based Distribution of Misoprostol for Early Abortion: Evaluation of a Program Along the Thailand-Burma Border, 96 CONTRACEPTION 242, 245 (2017); Chloe Murtagh, Elisa Wells, Elizabeth G. Raymond, Francine Coeytaux & Beverly Winikoff, Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet, 97 CONTRACEPTION 287, 287 (2018).

68. J. Sherris, A. Bingham, M.A. Burns, S. Girvin, E. Westley & P.I. Gomez, Misoprostol Use in Developing Countries: Results from a Multicountry Study, 88 INT’L. J. GYNECOLOGY & OBSTETRICS 76, 77 (2005).


71. See Löwy & Corrêa, supra note 48, at 683 n.7.
The contexts surrounding these drugs hold specific legitimacies and power. They are indicative of a long history of the medicalization of reproductive technologies. This has influenced current understandings of the medication abortion regimens and the reality that, despite much of the world’s misoprostol alone regimen, some consider the regimen to be undesirable.

Furthermore, the practice of self-sourcing and managing one’s own abortion outside the formal health care setting is deeply embedded in these different histories. Brazil is credited as the origin of self-managed abortion with misoprostol, a practice now used worldwide. Alternatively, the French pharmaceutical company Roussel-Uclaf sought to profit from the creation and implementation of mifepristone. It is no coincidence that international self-managed abortion protocols are informed by decades of experiential knowledge, information that fundamentally challenges the for-profit, medicalized model of drug research, manufacturing, and use.

III. MEDICATION ABORTION PILLS IN THE UNITED STATES

After a long-fought political battle in 2000, mifepristone was finally approved in the United States for pregnancy termination. Misoprostol had already been approved for use in the United States as an ulcer treatment. Today, the FDA has approved the combined mifepristone and misoprostol regimen for use up to the first seventy days (or ten weeks) of pregnancy. The WHO recommends a slightly longer period for use, up to twelve weeks of pregnancy.

Medication abortion is the most common form of abortion care (over surgical abortion) and as of 2021, 53% of abortions in the formal health
care setting were medication abortions.\textsuperscript{81}

It is extremely safe, and mifepristone and misoprostol administered in the clinic setting “successfully terminates pregnancy 99.6\% of the time, with a 0.4\% risk of major complications and an associated mortality rate of less than 0.001\%.”\textsuperscript{82} This is especially striking considering the risk of death associated with childbirth is fourteen times higher than that with abortion,\textsuperscript{83} and recent estimates find that a nationwide ban would lead to a 21\% rise in pregnancy-related deaths.\textsuperscript{84} Despite this safety profile, medication abortion is burdened by FDA restrictions, state bans on telehealth provision, state bans on abortion, and an increasingly creative strategy of anti-abortion policymaking.

A. \textbf{The Food and Drug Administration’s Risk Evaluation and Mitigation Strategy Label}

The FDA imposes REMS “to ensure that the benefits of a drug outweigh [possible] risks.”\textsuperscript{85} This label is “intended for drugs that are known or suspected to cause serious adverse effects that cannot be mitigated simply by label instructions.”\textsuperscript{86} Researchers, clinicians, and legal scholars have argued that, given the very low rates of adverse events associated with mifepristone, the REMS classification is unnecessary, unscientific, and only adds further burdens to medication abortion access.\textsuperscript{87}

The original REMS guidelines determined,

First, the drug may be dispensed to patients only in clinics, medical offices, and hospitals by or under the supervision of a certified prescriber; it may not be sold in retail pharmacies. Second, to prescribe the drug, a health care provider must become ‘certified’ by completing and sending a form to the drug distributor attesting that he or she can assess pregnancy duration, diagnose ectopic pregnancy, and provide surgical intervention if needed, either personally or by referral.

\textsuperscript{81} Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin & Marielle Kirstein, \textit{Medication Abortion Now Accounts for More Than Half of All US Abortions}, GUTTMACHER INST., guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions [https://perma.cc/N8CK-3NTV].


\textsuperscript{83} Raymond & Grimes, supra note 82, at 216.


\textsuperscript{86} Id.

\textsuperscript{87} See id. at 791–92; Editorial, \textit{Contraception Special Issue on the Mifepristone Risk Evaluation Mitigation Strategy (REMS)}, 104 CONTRACEPTION 1, 1–2 (2021); Donley, supra note 25.
Third, each woman taking mifepristone must be given an FDA-approved medication guide and sign an FDA-approved patient agreement that summarizes the use instructions specified in the label and the potential risk of the drug.88

In contrast to these FDA requirements, misoprostol is legally and commonly used off-label in gynecological settings and has no REMS restrictions.89

The onset of the COVID-19 pandemic strained access to abortion clinics,90 and policymakers and clinicians advocated suspending the REMS’s in-person dispensing requirement so that medication abortion could be dispensed by clinics using telehealth.91 In April 2021, the FDA temporarily paused the requirement,92 and following the order, abortion care in the United States changed dramatically.93 Virtual clinics launched and telehealth companies and non-profit organizations expanded.94 Patients experienced firsthand that telehealth provision is convenient and private.95 Data from various U.S. studies showed that when the in-person dispensing requirement was temporarily suspended by a court order, people still had safe, effective, and positive abortion experiences.96 On December 16, 2021, the FDA officially removed the in-person dispensing requirement, solidifying these changes as permanent.97 This decision was directly in response to political organizing and overwhelming evidence that medication abortion can be safely and effectively prescribed without an in-person visit.98

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88. Mifeprex REMS Study Grp., supra note 85, at 790.
89. See id. at 790–91.
92. Belluck, supra note 91.
98. See id.
Lifting the in-person dispensing requirement fundamentally changed abortion in states that did not have laws requiring in-person dispensation of mifepristone. The FDA still imposes a certification requirement for pharmacies, and this poses several challenges. First, pharmacists might be concerned about anti-abortion groups targeting them for supplying mifepristone. There is a long history of anti-abortion movements committing violent acts against health care providers, and by choosing to provide mifepristone, they may experience vandalism or threats. Second, many physicians and pharmacies lack the infrastructure to sell and dispense mifepristone, even if they are in compliance with the REMS certification requirements. Misoprostol is already stocked in most pharmacies and, as discussed throughout this Article, is less scrutinized than mifepristone, allowing it to be stocked covertly. It is also a cheaper medication, posing fewer financial risks to physicians who might have to buy the medication themselves and run the risk of absorbing extra costs if drugs are not used. Finally, it is important to note the remaining elements of the REMS that experts continue to advocate to remove.

In addition to REMS, there are state laws that restrict the provision of medication abortion pills mifepristone and misoprostol through telehealth. Six states ban the use of telehealth for abortion, and thirteen states require the physician prescribing mifepristone and misoprostol to be physically present when it is dispensed. Furthermore, the Dobbs decision has created an overarching legal framework where clinical abortion care, from medication to surgical, is extremely restricted in certain parts of the country. The legality of abortion will continue to

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100. See id.
101. Id.
103. See Donley, supra note 25, at 645.
105. See generally, Donley, supra note 25; David S. Cohen & Carole Joffe, Obstacle Course: The Everyday Struggle to Get an Abortion in America (2020).
vary state by state, and these restrictions will intersect with existing laws limiting medication abortion provision. This means that access in these places is not only severely restricted, but clinicians must also navigate a complicated web of laws and potential criminalization, which creates an overall culture of stress and fear around abortion care.

B. ADVANCEMENTS IN TELEHEALTH provision of medication abortion

State bans on medication abortion and its provision through telehealth, as well as the remaining REMS classifications of mifepristone and ongoing strategies to revoke its FDA approval, are incongruent with the evidence of the safety and effectiveness of medication abortion. With new evidence from care provided during the COVID-19 pandemic, medical protocols have advanced to include the safety of clinic-facilitated, no-test telehealth medication abortion.\(^{109}\) No-test medication abortion is the process of offering medication abortion to patients without ultrasound or in-person tests.\(^{110}\) In asynchronous care models, abortion care providers communicate with patients entirely through secure messaging; in synchronous care models, providers communicate using live phone or video technology.\(^{111}\) Both models are safe and effective.\(^{112}\) Prior to COVID-19 shifts in care provision, individuals visited abortion clinics, and clinicians performed ultrasounds, pelvic exams, or blood tests to evaluate eligibility.\(^{113}\) “Many abortion providers require[d] a follow-up ultrasound or blood test after treatment to confirm abortion completion.”\(^{114}\) However, landmark research has recently demonstrated that these tests are not necessary and medication abortion can be safely provided to a patient without them.\(^{115}\)


\(^{113}\) Raymond et al., supra note 109, at 361.

\(^{114}\) *Id.*

New protocols by Elizabeth Raymond and colleagues provide guidance for abortion clinics to implement these no-test models, and results from ongoing studies of no-test medication abortion continue to underscore that these direct-to-patient, clinic-facilitated telehealth models are safe and effective. They offer patients the convenience and privacy of staying at home, expand geographic access to care, and have the potential to address structural inequities in abortion care. States where abortion remains legal have already received an influx of patients from states where abortion is now banned. The availability of telehealth in states where abortion is legal could reduce the pressure on some clinics, especially in Minnesota, New Mexico, Colorado, and Illinois, which border states where abortion is now banned or restricted. But the legal ability to travel to these states and receive telehealth medication abortion is much trickier. Patients may avoid onerous travel by having abortion pills mailed to a Post Office Box across the border in a nearby legal state or use a mail forwarding service to arrange delivery to their home. These care models are evolving, and patients, providers, and advocates are all navigating the new legal landscape surrounding telehealth provision of medication abortion.


118. Courtney Kerestes et al., “It was Close Enough, but It Wasn’t Close Enough”: A Qualitative Exploration of the Impact of Direct-to-Patient Telemedicine Abortion on Access to Abortion Care, 104 CONTRACEPTION 67, 69 (2021); Ruggiero et al., supra note 117.

119. See Seymour et al., supra note 117.


121. See SOC’y OF FAM. PLAN., #WeCount REPORT 3, 7 (2022), https://doi.org/10.46621/UKA16324 [https://perma.cc/XT8L-U9MA].


123. See id. at 17.
IV. SELF-MANAGED ABORTION USING MEDICATION ABORTION PILLS

While the application of no-test medication in the United States signals a major shift in the provision of abortion care, the concept of no-test medication abortion is not new.124 International organizations have long provided medication abortion by mail and determined eligibility by screening patients with a health history questionnaire.125 Researchers examining the organization Women on Web have studied this model extensively.126 Founded in 2005 by Dr. Rebecca Gomperts, Women on Web created a website where people living in countries where abortion was illegal or restricted could have an online consultation with a physician.127 If eligible for treatment, physicians mailed them medication abortion pills with email instructions for self-managed medication abortion.128 Women on Web has provided pills to “more than 100,000 people . . . around the world,”129 and their services have been evaluated throughout the world, including in the Republic of Ireland, Northern Ireland, Latin America,130 Great Britain,131 and among U.S. service members stationed overseas.133

The scientific advances that have confirmed the safety of no-test medication abortion also support the safety of Women on Web’s original model of self-managed medication abortion, or medication abortion provided outside of the formal health care setting.134 In general, there are a variety of methods people may use to induce an abortion, including

127. See id.
128. See id.
129. See id.
131. Abigail R.A. Aiken, James G. Scott, Rebecca Gomperts, James Trussell, Marc Worrell & Catherine E. Aiken, Requests for Abortion in Latin America Related to Concern about Zika Virus Exposure, 375 NEW ENGL. J. MED. 396, 396 (2016).
132. Abigail R.A. Aiken, Katherine A. Guthrie, Marlies Schellekens, James Trussell & Rebecca Gomperts, Barriers to Accessing Abortion Services and Perspectives on Using Mifepristone and Misoprostol at Home in Great Britain, 97 CONTRACEPTION 177, 178 (2018).
134. See Raymond et al., supra note 115, at 192.
herbs, teas, vitamins, medications, noxious substances, or self-harm.\textsuperscript{135} An abundance of information on the internet regarding these techniques has resulted in “considerable demand” for medication abortion pills from online sources in the United States.\textsuperscript{136} Since the \textit{Dobbs} decision, interest in this model has already increased, and demand for self-managed medication abortion will likely continue to grow.\textsuperscript{137}

In the United States, there are many online sources for medication abortion pills, some of which are legitimate sources of authentic medication, and others that are completely unregulated.\textsuperscript{138} The organization Plan C Pills has monitored and tested some of these sources for self-managed medication abortion.\textsuperscript{139} Their “report card” details the variety of online sources and prices, the authenticity of medication, and the legal context in which they are being provided.\textsuperscript{140} This report card is widely shared and is frequently updated with the most current sources and state policy contexts.\textsuperscript{141} Plan C, along with other online and community-driven sources, have been incredible resources for people looking to obtain medication abortion online.\textsuperscript{142} But in the nineteen states where it is illegal to provide medication abortion through telehealth, even Plan C yields limited options.\textsuperscript{143} Dr. Rebecca Gomperts and her team saw this as a major gap in the United States, and in 2018, they launched Aid Access, the first online telemedicine organization to offer a low-cost option for self-managed medication abortion in all fifty states.\textsuperscript{144} It is important to note that Aid Access is an Austria-based non-profit organization that operates outside of the United States’ legal framework and does not observe state abortion bans, restrictions, or FDA policies.\textsuperscript{145} In its first two years of
operation, Aid Access received 57,506 requests for medication,146 and demand for this service continues to surge as state abortion restrictions have been enacted.147 Research on this demand for services and individual motivations and experiences with Aid Access will be discussed in Part VI of this Article.

V. SAFE AND EFFECTIVE: CURRENT DATA ON SELF-MANAGED ABORTION

Self-managed medication abortion provided through online telemedicine can be highly effective and has low rates of complication or serious adverse events. In this Part, I will discuss current data on the Aid Access model, as well as some of the international literature on misoprostol alone used for self-managed abortion.

A. SELF-MANAGED ABORTION USING MIFEPRISTONE AND MISOPROSTOL

Abigail Aiken and colleagues have conducted a retrospective record review of outcomes of abortions provided by Aid Access using the combined mifepristone and misoprostol regimen.148 In their study, “medications were mailed to 4,584 people and 3,186 (70%) provided follow-up information” on the outcome of their abortion.149 Individuals were prescribed “200mg of mifepristone to be taken orally and 800[μg] misoprostol to be taken sublingually, along with an additional 800[μg] of misoprostol for use if needed, according to the [WHO] recommended dosage regimen for medication abortion.”150 Overall, Aiken and colleagues found that 96.4% of people who used mifepristone and misoprostol “reported successfully ending their pregnancy without surgical intervention.”151 One percent “reported treatment for any serious adverse event,” 0.6% “reported receiving a blood transfusion, and 0.5% . . . reported receiving intravenous antibiotics.”152 “No deaths were reported to the service from family, friends, the authorities, or the media.”153 Overall, these are incredibly promising results, putting the com-

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149. See id. at 1.
150. Id. at 3.
151. Id. at 1.
152. Id.
153. Id.
bined mifepristone and misoprostol Aid Access regimen on par with clinically managed medication abortion. Like the studies of no-test medication abortion, study participants did not receive an ultrasound and they successfully self-dated their pregnancy duration.

B. SELF-MANAGED ABORTION USING MISOPROSTOL ALONE

Research also suggests that misoprostol alone regimens are safe and effective when used for self-managed abortion. A study by Heidi Moseson and colleagues at Ibis Reproductive Health found self-managed abortion with misoprostol and support from an accompaniment group to be “non-inferior to the effectiveness of clinician-managed medication abortion.” Accompaniment groups are feminist organizations or safe abortion hotlines that connect people self-managing an abortion to trained (usually volunteer) counselors. They provide “evidence-based counselling and person-centered support” to people via text, phone call, or in-person support. In this study of people in Argentina and Nigeria, 99% of 593 participants who self-managed their abortion with misoprostol alone, had successful abortions without surgical intervention.

In another study of self-managed abortion among 918 women living along the Thailand–Burma border, 96% were not pregnant one month after taking the misoprostol, and in a study of 120 women in Pakistan, “none of the women were pregnant” after a four-week follow-up period. A study in Lagos State, Nigeria, looked at 394 women who acquired misoprostol from drug sellers, and 95% had a complete abortion. Finally, in Bangladesh, in a study of pharmacy-distributed medication abortion pills, a subsample of twenty women acquired just misoprostol and 75% reported they were not pregnant at follow-up.

154. See id. at 6.
155. See id. at 4.
156. Heidi Moseson et al., Effectiveness of Self-Managed Medication Abortion with Accompaniment Support in Argentina and Nigeria (SAFE), 10 LANCET GLOB. HEALTH e105, e111 (2022).
157. Id.
158. See id. at e106.
160. Moseson et al., supra note 156, at e105.
161. Angel Foster, Grady Arnott & Margaret Hobstetter, Community-Based Distribution of Misoprostol for Early Abortion: Evaluation of a Program Along the Thailand–Burma Border, 96 CONTRACEPTION 242, 244 (2017).
163. Melissa Stillman et al., Women’s Self-Reported Experiences Using Misoprostol Obtained From Drug Sellers: A Prospective Cohort Study in Lagos State, Nigeria, 10 BMJ OPEN e034670, 6 (2020).
164. Katherine Footman et al., Feasibility of Assessing the Safety and Effectiveness of Menstrual Regulation Medications Purchased From Pharmacies in Bangladesh: A Prospective Cohort Study, 97 CONTRACEPTION 152, 156 (2018).
Taken together, these studies suggest that misoprostol alone medication abortion regimens are safe and effective. This evidence emphasizes the reality that, when people have accurate information, genuine medication, and support, self-managed abortion can be effective.

In the United States, my colleagues and I examined self-managed abortion with misoprostol from Aid Access. As implied in the safety data presented above, Aid Access typically offers the mifepristone and misoprostol regimen for medication abortion but pivoted to misoprostol alone due issues shipping mifepristone to the United States during COVID-19. Through a research partnership with Aid Access, we saw this as an opportunity to examine the outcomes of misoprostol alone in the United States. Misoprostol used for self-managed abortion had never been examined in the United States before.

Aid Access provided misoprostol to people up to ten weeks’ gestation at the time of their request. Individuals completed a consultation online, which physicians then checked for contraindications. Those eligible for treatment received a prescription for three doses of 800μg of misoprostol that was either mailed directly or picked up at a retail pharmacy. A $35 suggested donation was requested to support the service, and reduced donations were accepted. Aid Access emailed patients detailed instructions, directing them to take three doses of misoprostol sublingually every three hours. An additional dose of misoprostol was prescribed if expulsion did not occur after several days. Four weeks after patients used their prescribed misoprostol, Aid Access asked them to fill out an online form or send an email providing their outcomes and followed-up with those who did not.

Aid Access mailed misoprostol prescriptions and instructions to 1,016 people between June 1, 2020, and June 30, 2020. Among this group, 610 people (60%) confirmed that they had used the prescription, and the remaining 406 provided no follow-up information. Overall, 88% of people reported successfully ending a pregnancy without surgical intervention. These results compare favorably to results from clinical trials using misoprostol alone, but this is a conservative estimate—our analysis did not presume unknown abortion outcomes to be successful, though some of them may have been.

Considering these findings along with data from previous studies and the nature of misoprostol, this regimen may have merit for wider application. This treatment option is particularly valuable in the United States

165. This study is also detailed in an article published in the journal Perspectives on Sexual and Reproductive Health. The remainder of this Section draws on this study. Dana M. Johnson, Mira Michels-Gualtieri, Rebecca Gomperts & Abigail R.A. Aiken, Safety and Effectiveness of Self-Managed Abortion Using Misoprostol Alone Acquired from an Online Telemedicine Service in the United States, 55 PERSPS. ON SEXUAL & REPROD. HEALTH 4 (2023). https://onlinelibrary.wiley.com/doi/10.1363/psrh.12219 [https://perma.cc/FA48-TW47].

166. Id. at 6.

now that the constitutional right to abortion is lost. Mifepristone and misoprostol together have been the clinical default, but misoprostol is a safe option for those denied full access to clinical care.

These findings must also be contextualized with evidence from the millions of abortions that happen around the world. As abortion options dwindle in the United States, WHO guidelines now endorse self-managed medication abortion as an option within the range of safe and effective options for abortion care. We argue that misoprostol can help ensure reproductive autonomy in the United States—“especially for populations who have been systematically cut off from safe, affordable, and non-coercive reproductive health care services.”168

VI. DEMAND FOR AID ACCESS, AND EXPERIENCES USING THIS SERVICE

We know that self-managed abortion through Aid Access can be safe and effective, but what are the experiences of people who use these services? In this Part, I will discuss demand for the service, motivations for using the service, and experiences with this service.

A. DEMAND FOR AID ACCESS SERVICE

As discussed above, major policy changes have increased the demand for Aid Access. In 2021, when the Texas legislature passed an extreme early gestation abortion ban (Senate Bill 8), requests for Aid Access services from Texas tripled and “then leveled off to a more moderate but sustained increase over pre-SB 8 levels.”169 Abigail Aiken and colleagues compared the weekly rate of Aid Access’s medication requests across three time periods after Dobbs.170 The baseline time period started on September 1, 2021; the second time period started on May 1, 2022, when a draft of the Dobbs opinion was leaked to the press; and the third time period started on June 24, 2022, when the official opinion was announced.171 Between September 1, 2021, and August 31, 2022, Aid Access “received 42,259 requests from 30 states.”172 Compared to the baseline, “[e]very state, regardless of abortion policy, showed a higher rate of requests during the periods after the leak and after the formal decision.”173 States that implemented total bans saw the largest increased, and people “frequently cit[ed] these bans as their motivation for” seeking out Aid Access.174 Of note, increases in requests “were also observed in states where the legal status of abortion did not immediately

169. See Aiken et al., supra note 147.
170. Aiken et al., supra note 14, at 1768.
171. Id.
172. Id.
173. Id.
174. Id. at 1769.
change.” This could be because of “increased awareness of the service”—since Senate Bill 8 and the Dobbs decision, there has been widespread news coverage of Aid Access and Dr. Rebecca Gomperts—“disruption to in-clinic services following [an influx of] out-of-state patients” traveling for clinical care, or “confusion about state laws.” Overall, this study illustrates the immediate effect the Dobbs decision had on requests for self-managed medication abortion. These findings confirm that when in-clinic abortion is limited, people will search for options outside of the formal health care setting.

B. Motivations for Pursuing Aid Access

Prior to the Dobbs decision, my colleagues and I studied individual motivations for pursuing Aid Access. There are many reasons people seek out Aid Access services, but the primary motivators are lack of clinic access and economic hardship. “[I]ntersecting experiences of personal financial hardship and restrictive abortion policies” have created a landscape in which many people are left without any option for care. For people with children, we find that their financial decisions were further guided by the concerns of providing economic stability for their families. Although telemedicine through Aid Access is more affordable than paying out of pocket for clinical abortion care, even the suggested donation of $90 at the time of this study can pose a financial burden—“accessing pills at no cost or a reduced cost [is] necessary” for many users.

Advocates have been optimistic that self-managed medication abortion will increase access in the post-Dobbs legal context. But data on individual experiences with the services and the major financial constraints among users, “challenge the notion that [this model] will accomplish full accessibility among populations with low incomes.” Furthermore, Aid Access users struggle to sustain the burden of associated pregnancy costs such as ultrasound and follow-up care. This highlights a deeper flaw in the American health care system: “for those already struggling financially, unexpected health care expenses, even if significantly reduced from the typical price, are still too much.”

175. Id. The legal status of abortion has changed in many states since the Dobbs decision. In this study, the legal status assigned to each state was the projected legality of abortion in each state during the study period. If the legal status changed during the study period, the study authors used the legal status with the longest exposure.

176. Id.


178. Id. at 4.

179. See id. at 6.

180. See id. at 5.

181. Id. at 1.

182. Id.

183. See id. at 4.

184. Id. at 6.
C. EXPERIENCES WITH AID ACCESS

Among those who completed treatment through Aid Access, we found that people had both positive and negative experiences. Some viewed Aid Access as a “godsend.” When people first “decided to have an abortion, they turned to the internet for information.” After ruling clinics out due to “wait times, cost, logistical issues, and other barriers,” people learned of Aid Access from websites such as Reddit or Facebook. Some immediately trusted the service, but others did not: some study participants feared “scams, shipping delays of medication, and surveillance,” making the online ordering process a stressful experience. The “personal touch” Aid Access offered “calmed fears and fostered trust” in the service. People expressed a general worry about the “what ifs” of the process of self-managed abortion and felt unsure “what to expect physically and emotionally.” People also had concerns about the lack of medical supervision, the possibility of complications, and the authenticity of medication. Despite these concerns, most people said they would use Aid Access again. Overall, it met their acute need for access to safe and effective abortion care, offering “legitimate and trustworthy” care when people needed it most.

D. INNOVATIONS FOR A POST-ROE AMERICA

Several features of the Aid Access model aim to expand access to mifepristone and misoprostol. Aid Access uses a sliding scale model to ensure as many people as possible can financially afford its services. The suggested donation for Aid Access as of 2021 was $90 for mifepristone and misoprostol together and $35 for misoprostol alone. This fee includes a physician reviewed consultation form, access to a 24/7 help desk chat function, and shipping of medication abortion pills. People have relied on this sliding scale fee, paying half the amount or nothing at all. Aid Access has a policy that it will not turn anyone away from care.

186. Id.
187. Id.
188. See id. at 3–4.
189. Id. at 3.
190. Id.
191. Id. at 5.
192. Id.
193. Id. at 6.
194. Id. at 1.
195. See Johnson et al., Economic Context of Pursuing Online Medication Abortion, supra note 177, at 6.
196. See id.; Johnson et al., supra note 165, at 2.
197. Johnson et al., supra note 165, at 2.
198. Id.; Johnson et al., supra note 177, at 6.
199. See id. at 2.
Aid Access also provides advance prescriptions of abortion pills—pills to be kept on hand in case of a future unwanted pregnancy. There is not yet data on the demand for advance provision of abortion pills from Aid Access, but it is another tool to expand access to authentic medication for self-managed abortion.

To meet the increasing demand for its services, Aid Access also partners with U.S.-based doctors who prescribe medication abortion in the formal health care setting. In the twenty states where it is legally possible, individuals access the same Aid Access consultation form and fill out their gestation, health history, and any contraindications to medication abortion. Then they are contacted by a physician in the United States who prescribes medication abortion pills in the formal health care setting. Together with other reproductive health groups, this network of physicians now “mobilizes, trains, and supports clinicians” throughout the United States. They are also connected to the M+A Hotline, a confidential live hotline that provides support for self-managed abortion and miscarriage management.

VII. ACCESS DOES NOT MEAN EQUITY

Above, I have discussed two medication abortion regimens that can be used safely for self-managed abortion, as well as evolving evidence on expanding access to medication abortion. These are promising results, but to fully achieve reproductive autonomy for all, we must center equity in all strategies designed to expand access to care. Self-managed medication abortion is a critical opportunity to expand access and use of safe abortion pills, but it will not be the right option for all people. To truly meet the needs of all pregnancy-capable people, we must work for care models that are safe, effective, and meet a range of needs and desires.

It is a fundamental violation of human rights to be denied a wanted abortion. People who are unable to get a wanted abortion experience a much greater risk to their physical and emotional well-being. These harms disproportionately fall on poor people, people of color, people living in rural areas, and young people. When people are denied access to
desired care, their health and economic well-being are sacrificed.\textsuperscript{207}

Despite data demonstrating that self-managed medication abortion is safe and effective, the experience can be stressful. People have acute concerns about shipment delays, privacy, safety, and the threat of criminalization.\textsuperscript{208} Furthermore, these models are not logistically feasible, medically recommended, or preferable for all people, and it is important to be clear about this gap in accessibility. Self-managed medication abortion is an abortion care option, but it does not address the core problem: that the Dobbs decision has created a legal landscape that violates human rights and reproductive autonomy. Below, I discuss a few of the persistent inequities in self-managed abortion, including criminalization, access for pregnancies beyond twelve weeks, and access for minors.

A. Criminalization of Self-Managed Abortion

Given the United States’ history of surveillance and criminalization of reproductive behaviors,\textsuperscript{209} it is important to discuss the risks associated with self-managed abortion. These punitive policies and misapplication of laws have historically been aimed at communities of color, immigrant communities, communities with low incomes, and minors\textsuperscript{210}—the very same communities that weather the burden of today’s abortion bans. The organization If/When/How: Lawyering for Reproductive Justice has been compiling and tracking data on the criminalization of self-managed abortion.\textsuperscript{211} It found that between 2000 and 2020, police and prosecutors have arrested or investigated at least sixty-one people for suspected self-managed abortions.\textsuperscript{212} Among the cases, most were adults, but seven were minors.\textsuperscript{213} “[P]eople of color [were] disproportionately represented,” and most of the adult cases “involved people living in poverty.”\textsuperscript{214} The cases occurred in twenty-six states, most frequently “in Texas, followed by Ohio, Arkansas, South Carolina, and Virginia.”\textsuperscript{215}

The If/When/How study also found that other people are a threat to the privacy of people who might self-manage their abortion.\textsuperscript{216} Suspected cases were brought to law enforcement most frequently by health care professionals, as well as other people who abortion seekers reached out.
These findings highlight a fundamental breakdown in trust and ethics of the patient/provider relationship, as well as violations of privacy and human rights.

B. ACCESS FOR PREGNANCIES BEYOND TWELVE WEEKS

Up to this point, this Article has focused on circumstances and uses before the twelfth week of pregnancy, or when WHO guidelines recommend safe use of medication abortion. There will always be a need for abortion care at later gestations. Some may not know they are pregnant until after the twelfth week, others will need more time to acquire funds, find childcare, and travel, and there are any number of other circumstances that lead to later abortion care. Most people who have abortions are poor or low-income, and any additional financial barrier can be devastating, pushing abortion into the later trimesters. Additionally, people may prefer in-clinic surgical abortion care, or have medical circumstances that make them ineligible for medication abortion. These situations are not discussed in-depth in this Article, but it is crucial to note that, for this reason and others discussed in this piece, self-managed abortion will never be a replacement for clinical abortion care.

C. ACCESS FOR MINORS

Adolescents have long faced multiple barriers to obtaining clinical abortion care. Parental consent and notification laws, the high cost of abortion clinics, and the need to arrange and pay for long distance travel to clinics pose major challenges. With abortion illegal or restricted in half of the United States, an increasing number of young people will now need to travel long distances to out-of-state clinics, a major financial and logistical challenge. Self-managed medication abortion may be an option for some young people, but certainly not all. Aid Access provides medications to minors on a case-by-case basis, but other telemedicine organizations may be restricted to those eighteen and older or comply with state parental consent and notification laws. This poses a major gap in abortion access for young people.

217. Id. at 3.
221. See Assifi et al., supra note 220.
VIII. CONCLUSION

The discovery of medication abortion pills revolutionized safe abortion access for the world. These essential medicines—mifepristone and misoprostol—have helped people achieve reproductive autonomy by determining if, when, and how they build a family.

Since the Dobbs decision, access to abortion care in the United States has been decimated. In some states, people can safely and legally access clinical abortion care. In others, people no longer have that right. There are deep, long-term consequences associated with inequitable access to abortion care. These include increased morbidity and mortality from using unsafe abortion methods, forced childbearing, criminalization, and lasting economic, social, and psychological impacts. Multiple interconnected systems of oppression in the United States also dictate who has access to abortion. The long histories of racism, sexism, homophobia, ableism, colonialism, and gender inequality have created a system where historically marginalized communities cannot access the care they need.

Self-managed medication abortion can help with some of these burdens and offers an opportunity for safe and effective care. Despite occurring outside of the formal health care setting, this practice is still deeply shaped by the social, political, and legal histories of abortion pills. In this Article, I discuss the origins of mifepristone and misoprostol and the different scientific advancements and laws that have shaped them. I introduce their use in the United States and briefly examine the policies that limit access to pills as well as the evidence that reinforces their safety. Building on the evidence we have for safe medication abortion through telehealth, I discuss how people have further brought pills out of the formal health care setting and used them for self-managed medication abortion. Current evidence finds that the dual regimen of mifepristone used with misoprostol is the most effective medication abortion option, but now that medication abortion is extremely restricted in some states and banned in others, access to this regimen may be impossible for some. I argue that misoprostol’s history and its straightforward use make it an ideal option for supported self-managed abortion, especially in restrictive environments.


settings. The features of misoprostol, the effectiveness data of previous studies, and the results of our U.S. study signal that a wider application of this method should be considered.

Time and time again, the U.S. legal framework has put up roadblocks to medication abortion access, and despite major scientific advancements in the reproductive technologies of abortion pills and the rigorous research around their safe use, current laws prevent the widespread accessibility of medication abortion. I argue that it is our job to address this injustice by sharing the research we have on safe and effective abortion methods. Overall, following the *Dobbs* decision, barriers to clinical care will continue, and self-managed medication abortion remains an essential, lifesaving option. But it cannot be the only route to safe abortion care, and it is certainly not a silver bullet for the United States’ current crisis. The true focus of our research and advocacy efforts must remain on the unjust laws that keep people from accessing the abortion they desire.