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History and Politics of Medication Abortion in the United States and the Rise of Telemedicine and Self-Managed Abortion

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Abstract This article examines the decades-long campaign to increase access to abortion pills in the United States, including advocates' work to win US Food and Drug Administration approval of mifepristone and misoprostol for abortion, the continuing restrictions on mifepristone, and the multiple strategies advocates have pursued to challenge these restrictions, including lobbying the FDA to remove the restrictions, obtaining a limited research exemption from FDA restrictions, and suing the FDA during the COVID-19 pandemic. The article pays particular attention to the influence of research conducted on the safety and efficacy of medication abortion as well as research on the impact of increased availability of abortion pills through telemedicine during the pandemic. The article also addresses self-managed abortion, wherein people obtain and use mifepristone and/or misoprostol outside the formal health care system, and it documents the growing network of organizations providing logistical, medical, and legal support to people self-managing abortion. The article concludes with reflections on the role abortion pills might play in the post-*Roe* era amid increasingly divergent abortion access trends across different regions of the United States.

Keywords medication abortion, abortion pills, COVID-19, US Food and Drug Administration, mifepristone

Seven years after the US Supreme Court legalized abortion in *Roe v. Wade* in 1973, scientists patented the abortion pill mifepristone, which interrupts the flow of the hormone progesterone, which sustains a pregnancy (Haussman 2013). Mifepristone is used in combination with the synthetic prostaglandin misoprostol, which causes contractions to expel the contents of the uterus. This combination of pills is a safe and effective

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method of abortion in early pregnancy (Upadhyay et al. 2015). Medication abortion has a success rate of more than 95% and is very safe, with less than one third of 1% (0.31%) of medication abortions resulting in serious adverse events (Upadhyay et al. 2015). In 2000, the US Food and Drug Administration (FDA) approved mifepristone for abortion during the first seven weeks of pregnancy. But as a result of antiabortion political pressure, and despite mifepristone's strong safety record, the FDA tightly controlled the medication by placing it under several restrictions. The FDA allowed only doctors registered with the drug manufacturer to distribute the drug and required them to stock the medication themselves and distribute it in person to patients. In 2011, the FDA placed mifepristone in a drug safety program called the Risk Evaluation and Mitigation Strategy (REMS) that continued these restrictions (Haussman 2013). In 2016, the FDA modified the REMS, recommending the use of mifepristone through 10 weeks of pregnancy and at a lower dosage better tolerated by users (FDA 2021).

During the COVID-19 pandemic, the FDA loosened these restrictions. When the pandemic hit in March 2020, many health care services became available via telemedicine, delivered remotely by videoconference, by telephone, or online asynchronously. Under the Trump administration, the FDA lifted in-person distribution requirements on most drugs to increase telemedicine access, but they kept the REMS restriction on mifepristone in place. Health care providers, medical researchers, and reproductive rights advocates pressed the FDA to lift this restriction to make telemedicine abortion available (Baker 2020). Advocates filed lawsuits and lobbied the FDA to remove the REMS restriction, and multiple researchers submitted new evidence on the safety and efficacy of telemedicine abortion (cited in Cavazzoni 2021a). In July 2020, a federal district court in Maryland ordered the FDA to lift the in-person distribution requirement for the duration of the pandemic. Then in December 2021, under the Biden administration, the FDA permanently lifted the in-person distribution requirement, allowing telemedicine abortion by certified prescribers, and permitting certified pharmacies to distribute mifepristone for the first time (FDA 2021). As a result, telemedicine abortion services proliferated across the country and eventually became available in about half of the states, but 19 states still had laws prohibiting telemedicine abortion, in direct contradiction to the FDA rule (interview with Elisa Wells and Francine Coeytaux, January 27, 2022).

This article examines the history of the development of mifepristone and the decades-long political fight to increase access to the medication. It focuses on the politics that have kept mifepristone highly restricted and

the multiple strategies advocates have pursued to challenge the REMS restrictions, including suing the FDA in court, lobbying the FDA to remove the restrictions, reinterpreting the REMS restrictions to allow telemedicine abortion, expanding a research exemption to the REMS restriction, and supporting self-managed abortion, where people obtain and safely use abortion pills outside the formal health care system. The article pays particular attention to research conducted on the safety and efficacy of prescribing mifepristone by telemedicine, and how advocates used this research in their campaigns for removal of these restrictions. This article also addresses the growing network of organizations supporting people who choose to self-manage abortion, which proliferated across the United States in response to the Supreme Court's increasing threat to overturn constitutional abortion rights established in *Roe v. Wade*.

After the Court overturned *Roe* in *Dobbs v. Jackson Women's Health Organization* in June 2022, many states banned abortion, while others strengthened abortion rights (Guttmacher Institute 2023a); but across all states, medication abortion and telemedicine abortion played an increasingly important role in enhancing abortion access. Understanding the history of abortion medications as well as the ongoing political and legal battles over access to abortion pills is important for imagining a future with increased abortion access in the United States.

Mifepristone Development, FDA Restrictions, and Campaigns to Expand Access

The French company Roussel Uclaf patented mifepristone, known as RU-486, in 1980 (Haussman 2013). Chemist Georges Teutsch first synthesized mifepristone, and endocrinologist Étienne-Émile Baulieu arranged tests of its use for abortion. After extensive testing, the company applied for and obtained the French government's approval in 1988 for the drug to be used for abortion. A month later, antiabortion protests in France and pressure from its parent company Hoechst AG of Germany led Roussel Uclaf to withdraw mifepristone from the market. The French government responded by ordering Roussel Uclaf to resume selling the medication in the interest of public health. French Health Minister Claude Évin famously explained at the time, "I could not permit the abortion debate to deprive women of a product that represents medical progress. From the moment government approval for the drug was granted, RU-486 became the moral property of women, not just the property of a drug company" (Greenhouse 1989).

Because of antiabortion pressure in the United States led by the National Right to Life Committee, Roussel Uclaf declined to bring mifepristone to

the US market. The Feminist Majority Foundation, led by former National Organization for Women President Eleanor Smeal, organized a campaign to pressure Roussel Uclaf to introduce mifepristone in the United States. Over the next four years, FMF collected 700,000 signatures on a petition to Roussel Uclaf and its majority shareholder Hoechst AG demanding they market mifepristone in the United States. In 1990, they organized a delegation of feminist leaders, medical professionals, and prominent scientists to travel to the Paris headquarters of Roussel Uclaf and deliver the petition before visiting Hoechst AG's headquarters in Germany. They then made repeated visits over the next several years. Other organizations working to bring mifepristone to the United States included Lawrence Lader's Abortion Rights Mobilization and the Reproductive Health Technologies Project, a coalition of reproductive rights organizations. In 1995, as a result of these efforts, Roussel Uclaf donated all rights for medical uses of mifepristone in the United States to the nonprofit organization Population Council, which then tried to find a large drug company willing to develop the drug for the US market. After threatened boycotts from antiabortion groups, large drug companies declined the offer, so the Population Council worked with a small private company named Danco Laboratories formed specifically for the purpose of conducting the necessary research and applying for FDA approval (Hausmann 2013; Jackman 2002).

After a long fight by antiabortion activists to block the drug from the US market, the Clinton administration's FDA finally approved mifepristone for use within the United States in 2000, but the FDA placed the drug under several restrictions; in 2011, the FDA placed it in the REMS drug safety program. Under the REMS, the FDA prohibited retail pharmacies from stocking and distributing mifepristone, instead requiring mifepristone to be dispensed in an office, clinic, or hospital by a physician registered with the drug manufacturer. The FDA allowed use of mifepristone only in the first seven weeks (49 days) after a patient's last menstrual period, required patients to sign a consent form, and required the patient to make three office visits. The FDA's medication abortion protocol required a 600-mcg dose of mifepristone dispensed to patients in-clinic, then a 400 mcg oral dose of misoprostol administered in clinic 48 hours later, and finally, a follow-up in-clinic appointment to confirm that the pregnancy had successfully ended (Haussman 2013). When the FDA approved the drug in 2000, the agency refused to reveal the names of the manufacturer or the FDA employees involved in approving the drug, citing fear of antiabortion violence. The threats were so serious the agency had to increase security at its offices (CBS News 2000).

The pro-choice medical and political communities hoped this new technology would address the chronic shortage of providers in many places (Joffe and Yanow 2004). They hoped that primary care doctors would offer medication abortion integrated into their office practices so that abortion opponents would not be able to target and protest this service (Talbot 1999). However, because the FDA required providers to be certified and to stock and distribute the medication themselves, most medication abortions came to be offered in the same places as procedural abortions (Talbot 1999).

Subsequent research revealed that a lower dosage of mifepristone was effective and had fewer side effects, so many health care providers began offering mifepristone at the lower dosage along with a higher dose of misoprostol—an acceptable off-label practice (Jones and Boonstra 2016). In response, some antiabortion states, such as Ohio, passed laws requiring abortion providers to use the FDA protocol for medication abortion, which resulted in a higher number of medical interventions to complete abortions, more side effects, higher costs for abortion, and an 80% decline in medication abortion in Ohio between 2010 and 2014 (Upadhyay et al. 2016). Research revealed that the Ohio law disproportionately kept historically marginalized groups from obtaining medication abortion care (Upadhyay et al. 2018).

As a result of the safety and efficacy of mifepristone used at the lower dose and taken later in pregnancy (Jones and Boonstra 2016), advocates and medical professionals repeatedly called on the FDA to remove the REMS on mifepristone. The Expanding Medication Abortion Access Project and others worked to inform the FDA about the latest medical and scientific evidence relating to mifepristone and the REMS (interview with Kirsten Moore, May 10, 2021). In 2016, during the final days of the Obama administration, the FDA finally modified the medical protocol for mifepristone provision to 200 mcg of mifepristone followed 24–48 hours later with 800 mcg of misoprostol taken buccally (in the cheek pouch). The FDA also replaced the term "physician" with "health care provider," opening the door for nurses, nurse midwives, and physician assistants to dispense the medication. Finally, the FDA extended the period for use of the medications to 10 weeks (70 days after the last menstrual period) and updated the label to clarify that a remote follow-up visit was acceptable, reducing the number of required in-person visits from three to one (FDA 2021). Also in 2016, the FDA granted a research exception to the REMS for Gynuity Health Projects to study telemedicine abortion. Under this study, called TelAbortion, the FDA required an in-person ultrasound

but allowed clinicians to provide medication abortion care by videoconference and mail the pills to patients (Raymond et al. 2019).

Despite the ongoing FDA restrictions on mifepristone, the use of medication abortion increased steadily over time. In 2017, mifepristone accounted for 39% of all recorded abortions. By 2020, the percentage of medication abortions overall had risen to 54% of all recorded abortions (Jones et al. 2022). In addition to approving mifepristone for abortion, the FDA has approved the drug to treat some forms of cancer and Cushing's syndrome (Baker 2021a). The medication may also be effective for treating fibroids (Shaikh et al. 2021), endometriosis, and depression, but the REMS has restricted research on its usefulness for treating these conditions (Baker 2021a).

After the 2016 modification, reproductive health advocates continued to press the FDA to remove the REMS restrictions by challenging them in court, lobbying the FDA to remove them, and reinterpreting the REMS to allow the mailing of abortion pills (Baker 2020). In 2017, the American Civil Liberties Union (ACLU) sued the FDA, seeking removal of the REMS restrictions on mifepristone in the case of *Chelius v. Azar*. In their complaint, the ACLU argued that the REMS violated women's rights to liberty, privacy, and equal protection as guaranteed by the US Constitution by imposing significant burdens on abortion access without proof of a valid medical justification (ACLU 2017). In addition, reproductive rights advocates directly pressured the FDA to release mifepristone from the REMS classification, arguing that the restrictions were medically unnecessary (interview with Kirsten Moore, May 10, 2021). On April 6, 2020, the National Women's Health Network (NWHN) sent a letter on behalf of 80 women's health organizations to FDA Commissioner Stephen Hahn demanding that the FDA remove the REMS restriction on mifepristone. The NWHN created a social media campaign called "Get the Pill Where You Take It—At Home!" with the hashtag #FreeTheAbortionPill (Baker 2020).

On April 27, NWHN's executive director, Cynthia Peterson, teamed up with a former FDA assistant commissioner for women's health, Susan Wood, to write an opinion piece published in *The Hill,* arguing that in light of the COVID-19 pandemic, the FDA "should allow pregnant people to get the pill where they take the pill—at home, and not require them to make an unnecessary and risky visit to a clinic" (Wood and Pearson 2020). Public officials joined advocates in demanding that the FDA remove the REMS restrictions. On March 30, 2020, 21 state attorneys general sent a letter to FDA Commissioner Hahn asking the FDA to lift the in-person distribution

requirement during the pandemic (Becerra 2020). On April 14, 2020, Senators Elizabeth Warren, Patty Murray, and Tammy Baldwin sent their own letter to the FDA making the same request (Warren, Murray, and Baldwin 2020).

Finally, some advocates reinterpreted the FDA's REMS to not require in-person distribution of mifepristone or ultrasounds. The general consensus was that the REMS restriction required medical providers to meet with their patients in person to dispense the abortion pills. But some medical providers and advocates began challenging this interpretation. The nonprofit abortion pill advocacy organization Plan C argued that the REMS did not require clinicians to hand the mifepristone to patients in person, and some medical providers began offering telemedicine abortion appointments and mailing abortion pills to their patients (Baker 2021b).

Meanwhile, Elizabeth Raymond from Gynuity and nine doctors and public health experts published a new "no-test" medication abortion protocol (Raymond et al. 2020). This protocol built on Raymond's original "simplified screening" research from the United States, Mexico, and Moldova (Raymond et al. 2018). The no-test protocol would enable clinicians to safely administer medication abortion to their patients without any preliminary tests or in-person encounters, thus enabling patients to fully access telemedicine abortion. This protocol challenged the longstanding standard medical protocol requiring two tests to determine eligibility for a medication abortion. The first required test was an ultrasound or pelvic exam to ensure the pregnancy was within the FDA's gestational limit of 70 days and was not ectopic. The second required test was a blood test to determine if a patient had Rh-negative blood, in which case they may receive counseling for possible RH factor incompatibility with future pregnancies. The protocol concluded that both of these tests were unnecessary because women could reliably report their last periods for dating pregnancy, and because abortion in early pregnancy does not create risk of an immune response in Rh-negative patients (Raymond et al. 2020). Medical research had for years demonstrated that patients could accurately determine the gestational age of their pregnancies (Bracken et al. 2011; Schonberg et al. 2014). Authors of the protocol noted that for 15 years international organizations had safely provided abortion pills by mail to tens of thousands of patients screened only by medical history (Raymond et al. 2020, citing four studies). The protocol also cited the TelAbortion research on medication abortion provided to 406 patients without a screening ultrasound or pelvic examination. No serious adverse events resulted

from the omission of the tests, and participants were highly satisfied (Raymond et al. 2019). In fact, medical standards in many European countries do not recommend blood tests for abortion or miscarriage in early pregnancy (Mark et al. 2019). In addition to the preliminary tests, standard medical protocol required a follow-up appointment to confirm the absence of a continuing pregnancy. The no-test protocol recommended that follow-up appointments be conducted by videoconference, telephone, or email, along with a urine pregnancy test the patient performs at home.

Meanwhile, the Gynuity Health Projects' TelAbortion study provided increasing evidence that telemedicine abortion was safe and effective. Conducted at brick-and-mortar clinics in the United States from 2016 to 2021, this study allowed health care professionals to offer medication abortion care by videoconference and mail, although the FDA still required patients to obtain ultrasounds. The study began in four states, later expanding to a total of 17 states and the District of Columbia. Gynuity published preliminary results of the study in 2019, showing that the direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory (Raymond et al. 2019). These research studies providing evidence of the safety and effectiveness of telemedicine abortion became critical once the COVID-19 pandemic hit, and demand for telemedicine abortion increased.

COVID-19 Spurs Telemedicine Abortion

Shortly after the World Health Organization (WHO) declared COVID-19 a pandemic in early March of 2020, demand for telemedicine services in the United States soared. Abortion health care was no exception (Jones et al. 2022). On March 30, 2020, the American College of Obstetricians and Gynecologists (ACOG) issued guidance stating that clinicians could perform assessment, counseling, and consent for medication abortion by video or telephone and that an ultrasound and blood test were not necessary in most cases (ACOG 2020). But the FDA REMS blocked telemedicine abortion. Because of the pandemic, the Trump administration lifted in-person distribution requirements on every medication except for one: mifepristone (interview with Kirsten Moore, May 10, 2021). In response, medical providers and reproductive rights advocates sued, challenging the FDA's refusal to lift the REMS on mifepristone and arguing the restrictions subjected patients to unnecessary risks of contracting COVID-19 as a condition of receiving the medication. In July 2020, a

Maryland federal court enjoined the FDA requirement that patients make in-person visits to medical providers to get abortion pills while also allowing doctors to mail mifepristone to patients. In *ACOG et al. v. FDA*, US District Court Judge Theodore Chuang ruled that the FDA requirement of in-person visits during the pandemic imposed a "substantial obstacle" to abortion health care that was likely unconstitutional (case 8:20-cv-01320-TDC, filed July 13, 2020).

In the following months, telemedicine abortion startups began opening up across the country. Two online clinics, Just the Pill and Choix, were among the earliest to offer telemedicine abortion. These virtual clinics screened patients remotely using the no-test medical protocol. They then mailed abortion pills to eligible patients at home through online pharmacies. The nonprofit Just The Pill opened for business on October 12, 2020, offering telemedicine abortion care to people in Minnesota (interview with Julie Amaon, January 26, 2022). Choix opened on October 28, 2020, offering abortion care to people aged 16 and older in California (interview with Cindy Adam and Lauren Dubey, December 30, 2021). Several TelAbortion sites, including carafem and Maine Family Planning, began offering telemedicine abortion care without requiring ultrasounds to people and offered this service in more states (interview with Melissa Grant, January 18, 2022; interview with Leah Coplon, January 13, 2021). Alternatively, other clinics offered curbside pickup of abortion medications after a telehealth consultation (Kaller et al. 2021; Upadhyaya, Raymond, and Koenig 2022).

A key development facilitating access to telemedicine abortion was the opening of the online pharmacy Honeybee Health in the fall of 2020. Honeybee, based in California, began selling generic versions of the abortion pills at steep discounts, without the need for insurance, to patients who received prescriptions from certified clinicians in Washington, New York, and New Jersey, and quickly expanded to other states. Honeybee offered low prices because they bought medications directly from FDA-approved US wholesale distributors and cut out the intermediaries, such as insurance companies and pharmacy benefit managers. As a result, they could sell generic medications for up to 80% less than what traditional pharmacies charged, a price that often was lower than the amount of a copayment or coinsurance. Later, American Mail Order Pharmacy in Michigan began mailing abortion pills to patients who obtained prescriptions via telehealth or in a clinic (interview with Elisa Wells, November 5, 2020). While some clinicians stocked the medications themselves and mailed the pills directly to their patients, the option to use mail-order pharmacies to distribute the

drug made it easier for health care providers to offer medication abortion services because they did not have to stock and distribute the drugs themselves. Mail-order pharmacies and the no-test protocol made it possible for family medicine providers who did not own expensive ultrasound machines and did not want to stock mifepristone to provide medication abortion services.

But the Trump administration appealed the Maryland court ruling allowing telemedicine abortion to the Supreme Court twice. The second time, on January 12, 2021, in *FDA v. ACOG*, six members of the Supreme Court granted a Trump administration request to reinstate the FDA rule requiring patients seeking medication abortion to make an in-person visit to their health care provider, despite strong evidence showing this served no medical purpose and in fact exposed patients to unnecessary medical risks during the COVID-19 pandemic (ACLU 2021). Many virtual clinics stopped mailing abortion pills. Some found other ways to get abortion pills to their patients. Just the Pill started using a Class B RV as a mobile clinic to deliver pills to their patients (interview with Julie Amaon, January 14, 2022). Others, however, insisted the REMS did not disallow mailing of abortion pills, such as two new virtual abortion clinics that launched in early 2021: Hey Jane in Washington and New York in January 2021 (later expanding to California), and Forward Midwifery in California in February 2021 (later expanding to Massachusetts, Oregon, and Colorado) (interview with Christie Pitney, January 17, 2022).

After President Joseph Biden took office, the FDA issued new guidance on April 12, 2021, lifting the in-person distribution requirement for mifepristone for the duration of the COVID-19 public health emergency. On May 7, the Biden administration announced that the FDA would undertake a review of the REMS restrictions on mifepristone. The announcement came as part of a joint legal filing in the ACLU lawsuit *Chelius v. Becerra*, challenging the REMS restrictions. As a result, more virtual telemedicine abortion clinics opened. Abortion on Demand launched in 20 states and Washington, DC, in April 2021, and Pills by Post launched in Colorado, Illinois, and Minnesota in fall 2021 (interview with Jamie Phifer, May 28, 2021; interview with Razel Ramen, February 22, 2022).

Virtual abortion clinics run by doctors, midwives, and nurses provided convenient services and charged much less than in-clinic medication abortion providers. At Just the Pill in Minnesota, patients filled out an online form and then had a follow-up phone call with a patient educator and a doctor, who then mailed the pills to eligible patients. The clinic made follow-up phone calls at seven days and four weeks. Just the Pill charged a

sliding scale fee of $0–$350. The difference between a partial fee and the full amount was made up by a Minnesota abortion fund called Our Justice (interview with Julie Amaon, January 14, 2022). At Choix, nurses communicated with patients asynchronously using online forms and encrypted text messages that were compliant with the Health Insurance Portability and Accountability Act (HIPAA). They charged $199 and worked with the digital mutual-aid abortion fund Reprocare, which supported a sliding-scale payment mechanism on the Choix website (interview with Cindy Adam and Lauren Dubey, December 30, 2021). Reprocare also offered peer-based support by telephone for people during a medication abortion. Abortion on Demand conducted appointments by videoconference, used express shipping for next-day arrival, and charged $239. After the patient consumed the pills, Abortion on Demand checked in with them by text and offered 24/7 support from a doctor (interview with Jamie Phifer, May 28, 2021). Hey Jane offered telemedicine abortion for $249 using Spruce, a HIPAA-compliant texting app, but allowed patients to request a videoconference or telephone call at any time (interview with Hanna Kim, March 16, 2022). Forward Midwifery offered telemedicine abortion by telephone for a sliding-scale $150 fee (interview with Christie Pitney, January 17, 2022). Pills By Post offered telemedicine abortion by phone consultation for a sliding-scale fee of $150 (interview with Razel Ramen, February 2, 2022).

More brick-and-mortar reproductive health clinics began offering telemedicine abortion as well, often charging more than virtual clinics but sometimes less than in-clinic medication abortion. Unlike many virtual clinics, brick-and-mortar practices usually accepted insurance. Bethesda, Maryland-based Metro Area Advanced Practice Healthcare began offering telemedicine abortion in the fall of 2021, serving people in Virginia, Maryland, and Maine for a sliding scale fee of $150 (interview with Robin Tucker, December 24, 2021). Brick-and-mortar reproductive health care provider carafem offered videoconferencing visits for medication abortion for $325–$375, depending on the medication selected, and included a follow-up check-in within 48 hours and confirmation of a negative pregnancy test at 30 days. carafem accepted insurance, including Medicaid in Illinois and Maryland (interview with Melissa Grant, January 18, 2022). A reproductive health care provider in Seattle began offering telemedicine abortion via videoconferencing in April 2020 as part of her reproductive health care practice. She accepted health insurance and charged $600 for cash-pay patients, which included a follow-up if they needed a procedural completion (interview with Deborah Oyer, December 29, 2021).

Family medicine doctors also began offering telemedicine abortion as part of their general practice or on the side. Dr. Michele Gomez, a family medicine doctor working for Family Care Associates in California, began offering telemedicine abortion by videoconference to her patients shortly after the pandemic started. She charged a self-pay price of $280 but also accepted insurance. Dr. Gomez cofounded the nonprofit MYA Network to encourage and support primary care clinicians to begin offering early abortion services, including telemedicine abortion (interview with Michele Gomez, January 26, 2022). A doctor based in Indiana and working at a federally qualified health center began offering telemedicine abortion part time in the fall of 2021 through Whole Woman's Health to people in New Mexico for $400. Half of her patients came from Texas, which banned abortion after six weeks in September 2021 (interview with Alison Case, February 2, 2022).

To help medical providers who wanted to offer telemedicine abortion, the organization Plan C, which advocates for increased access to medication abortion, teamed up with the University of Washington Department of Family Medicine to develop a provider tool kit for primary care clinicians, with step-by-step instructions on how to offer medication abortion services without a clinic visit (University of Washington and Plan C 2020). Plan C worked closely with many providers to help them through the process of registering with the drug manufacturers Danco or GenBioPro (which obtained FDA approval of a generic mifepristone on April 11, 2019), signing up with Honeybee Health or American Mail Order Service, and developing their telemedicine platforms. These new telehealth abortion providers made medication abortion more convenient, affordable, and accessible for many people, which was especially important for low-income people and those living in rural areas.

New Research Leads to FDA Policy Change While State Restrictions Fuel Self-Managed Abortion

Expanding telemedicine abortion services increased opportunities for research on the practice both in the United States and abroad. This research produced scientific evidence that the FDA later used in its consideration of whether to lift the REMS. Unlike the piecemeal implementation of telemedicine abortion during the COVID-19 pandemic in the United States, the United Kingdom implemented a nationwide telemedicine abortion policy early in the pandemic. In February 2021, research released on telemedicine abortion in the United Kingdom provided the first real-world evidence in a national population that no-test telemedicine abortion was just as safe and

effective as in-person abortion health care (Aiken et al. 2021). Researchers found that patients reliably reported their last menstrual period, with only 0.04% of pregnancies estimated to be more than 10 weeks gestation at the time of the abortion. Overall effectiveness was higher for telemedicine than for in-person care (99.2% vs. 98.1%), and in-clinic and telemedicine abortion were equally safe, with both types of care having very low rates of serious adverse events (0.02% vs. 0.04%). There were no cases of significant infection leading to hospital admission, major surgery, or death. Patients were also highly satisfied with telemedicine abortion (96%), and 80% reported a future preference for telemedicine abortion. In addition, telemedicine patients received treatment more quickly. Whereas wait times for in-clinic medication abortion averaged 10.7 days, wait times for patients using the new no-test telemedicine model averaged only 6.5 days. As a result, patients were able to receive care earlier in their pregnancy; only 25% of in-clinic medication abortions occurred at or before six weeks, but 40% of telemedicine abortions did. Researchers noted that earlier treatment decreased patients' experiences of nausea or other negative symptoms of early pregnancy.

Research on telemedicine abortion in the United States showed similar levels of safety and efficacy. Gynuity published a study in March 2021 showing that TelAbortion services with ultrasounds were just as safe and effective as in-clinic medication abortion (Anger et al. 2021; Chong et al. 2021). In August 2021, the first-ever study on the safety and effectiveness of new online clinics offering telemedicine abortion without ultrasounds was published. The research tracked the efficacy and safety of fully remote, asynchronous medication abortion care provided by the virtual clinic Choix to 141 patients between October 2020 and January 2021. Among the 110 patients reporting outcomes, 95% had a complete abortion without intervention, 5% required medical care to complete the abortion, and no patients reported any major adverse events. The study concluded that this "efficacy rate is similar to in-person provision, suggesting that abortion provided via telehealth is feasible and safe" (Upadhyay, Koenig, and Meckstroth 2021). In July 2021, the journal *Contraception* published a special issue on the mifepristone REMS (Cleland et al. 2021). Articles in the issue showed how the REMS imposed "needless and unlawful barriers to care," noting the disproportionate burdens of the REMS on vulnerable populations, and several authors advocated for removing the in-person dispensing requirement (Kaye, Reeves, and Chaiten 2021). Advocates submitted this new research to the FDA as it considered whether to remove the REMS on mifepristone (interview with Kirsten Moore, May 10, 2021).

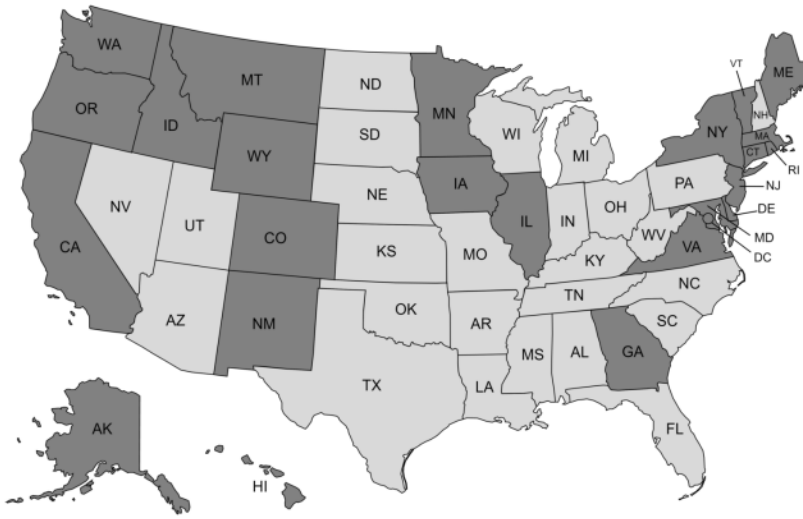

Figure 1 Telemedicine abortion availability in March 2022.

On December 16, 2021, the FDA partially lifted the REMS restriction by removing the long-standing rule that health care providers must distribute the abortion pill mifepristone to patients in person. The FDA also announced it would allow pharmacies to distribute the drug, but with the added requirement that pharmacies must be certified with the medication distributor. However, the FDA kept mifepristone within the REMS program, maintaining a requirement that health care providers must register with the drug manufacturer to become certified to prescribe mifepristone (Cavazzoni 2021b). The partial removal of the FDA REMS restriction opened the door to expanded telemedicine abortion access in many states. By March 2022, 24 states and the District of Columbia had telemedicine abortion access (fig. 1).

While the revised FDA REMS allowed qualified providers to mail the abortion pills to patients, 19 states had laws requiring clinicians providing medication abortion to be physically present with the patient when the medication is administered, thereby prohibiting telemedicine for abortion. Three states banned mailing abortion pills to patients, and mailing bans in another three states were blocked by courts (Guttmacher Institute 2022). Shortly after the FDA decision, antiabortion lawmakers introduced new restrictions on medication abortion. In the first three months of 2022,

lawmakers introduced 104 restrictions in 22 states, including eight measures that would ban medication abortion outright, nine measures that would prohibit the mailing of abortion pills, 11 measures that would restrict the administration of abortion pills to physicians, and five measures that would limit the provision of abortion pills to a specific point in pregnancy (Nash, Cross, and Dreweke 2022). The ACLU argued that these laws may be preempted by the December 2021 FDA decision (ACLU 2022). Meanwhile, new research with a sample of more than 4,000 patients from 14 clinics—the largest US-based study of the no-test approach to date—showed that medication abortion without an ultrasound or pelvic exam was just as safe as medication abortion that included those procedures (Upadhyay, Raymond, and Koenig 2022) and that medication abortion at 10 weeks was effective and safe, although slightly less effective than earlier in pregnancy (Aiken, Romanova et al. 2022). In 2022 the WHO endorsed the use of abortion pills through 12 weeks of pregnancy (WHO 2022).

In states expanding restrictions on abortion access, people increasingly turned to alternative ways of accessing abortion pills outside the formal medical system (interview with Rebecca Gomperts, February 11, 2022). Several organizations formed to help people self-manage their abortions, including SASS (Self-Managed Abortion, Safe and Supported), Plan C, HowToUseAbortionPill.org, Miscarriage and Abortion (M+A) Hotline, and Reprocare Healthline. They provided people with information about how to self-manage their abortions, including how to use abortion pills, where to purchase the pills online, and how to find medical supervision from clinicians inside and outside the country. SASS began providing information about abortion pills in 2019 and offered bilingual counselors to answer questions in English or Spanish through a secure portal. Plan C developed a guide to finding pills online, with a database of telemedicine abortion providers searchable by state with prices and delivery times. The M + A Hotline was formed in 2019 to offer free and confidential medical support to people self-managing their abortions. Reprocare offered a confidential peer-based health line to support people during a medication abortion (Baker 2020). Advocates also developed legal support resources. In April 2020 the organization If/When/How: Lawyering for Reproductive Justice launched the Repro Legal Helpline, a free, confidential hotline for callers to get legal information or advice about self-managed abortion (interview with Rafa Kidvai, June 14, 2021).

These advocates spread this information online and in person. For example, in the days before Texas enacted its six-week abortion ban on

September 1, 2021, Plan C and Progress Texas went to west Texas to educate people about how they could access abortion pills online. For three days, advocates drove a truck with illuminated billboards around the towns of Lubbock, Amarillo, Midland, and Odessa. The billboards read, "Missed period? There's a pill for that. PlanCPills.org. #TXDeservesBetter." The back of the truck read "Plan C. Convenience. Confidentiality. Control. PlanCPills.org." They drove to universities, past city halls, around the medical district, and in the evenings by bars and restaurants. The campaign sought to reach students in particular. The truck visited Texas Tech University in Lubbock and West Texas A&M near Amarillo, talking to students and handing out flyers. Many of the students they encountered had never heard of online access to abortion pills and expressed gratitude to Plan C advocates for sharing the information (interview with Elisa Wells, August 30, 2021). In April 2022, Plan C put up more than 250 posters sharing abortion pill information in English and Spanish throughout the New York City subway system (interview with Eliza Wells, April 13, 2021).

One option Plan C told people about was the international telemedicine provider Aid Access. Dutch physician Rebecca Gomperts founded Aid Access in Austria in 2018 to provide online telemedicine abortion to people in all 50 US states, including the 19 states that prohibited telemedicine abortion at that time. The service required an online consultation to determine eligibility for using abortion pills and provided information about how to use them. Patients in states allowing telemedicine abortion received care from US-based caregivers who shipped medications from Honeybee Health. For patients in states that blocked US providers from offering this service, Dr. Gomperts sent a prescription to a pharmacist in India, who shipped the medications directly to them. Patients received the medications in two to three weeks. Dr. Gomperts charged a sliding scale fee of up to $105 and offered advance provision abortion pills as well (interview with Rebecca Gomperts, February 11, 2022).

As abortion restrictions increased and clinics closed, people increasingly ordered abortion pills online and took them safely at home. Research found that Aid Access received tens of thousands of requests from people from all 50 US states between 2018 and 2020 (Aiken, Starling, and Gomperts 2021). Online demand for abortion pills surged when the pandemic hit in early 2020, especially in states that closed abortion clinics (Aiken et al. 2020). In the week after the Texas six-week abortion ban went into effect, Aid Access had a 1,180% increase in traffic on their website. In the following three weeks, demand remained 245% higher than before the ban, and demand remained 174% higher in the remaining months of 2021

(Aiken, Starling et al. 2022). Dr. Gomperts reported in February 2022 that Aid Access had mailed abortion pills to more than 30,000 people in all 50 states since they opened in 2018 (interview with Rebecca Gomperts, February 11, 2022). States with the most policy restrictions on in-clinic abortion had the highest rates of requests to Aid Access, such as Louisiana, Mississippi, Wyoming, and Alabama. The lowest rates of requests to Aid Access were in Vermont, Connecticut, Oregon, and California, where abortion was widely available (Aiken, Starling et al. 2022).

Research conducted with Aid Access patients revealed that they had highly positive experiences with the service and very low rates of complications. Between March 2018 and March 2019, Aid Access mailed abortion medications to 4,584 people. Of the 2,797 people who used the medications and responded to a follow-up survey, 96.4% reported successfully ending their pregnancy without further intervention, and only 1% reported any treatment for a serious adverse event, a rate only slightly higher than in clinical settings. No deaths were reported to the service by family, friends, the authorities, or the media (Aiken, Romanova et al. 2022). Respondents gave highly positive responses to questions about their experiences of using abortion medication through Aid Access: 98.4% were satisfied with their abortion experience; 95.5% said it was the right choice; 98.1% felt they had enough information on how to use the medications; and 93.4% felt they had enough information on what to expect from the process (Aiken, Romanova et al. 2022).

People reported various reasons for seeking abortion pills outside the formal US medical system. Research has found that the most common reasons people used the Aid Access services were their inability to afford in-clinic care (73.5%), a desire for privacy (49.3%), and clinic distance (40.4%). Other reasons given were that they were unable to take time away from work or school to go to a clinic (37.6%), they would be more comfortable self-managing their abortion at home (28.2%), and self-managed abortion would be more convenient (27%). About a quarter of respondents said they were self-managing their abortion because they did not want to deal with protesters outside clinics (Aiken, Starling, and Gomperts 2021).

In addition to telling people about Aid Access, Plan C informed people about other ways to access abortion pills, which became especially important as states began banning abortion. Researchers at Plan C vetted online pharmacies based outside the United States by ordering abortion pills and testing them for quality. On their website, Plan C lists online pharmacies that send high-quality medications, along with costs and shipping times. These pharmacies did not require a prescription to obtain abortion pills (interview with Elisa Wells and Francine Coeytaux. January 27, 2022).

Another option described by Plan C on their website was to use mail-forwarding services to access telemedicine abortion care from health care providers located in US states that allow it. To use this option, people rented a mailing address from mail-forwarding services such as Anytime Mailbox in states where telemedicine abortion was allowed, and they used the rented address for the telemedicine consultation. Then they asked the forwarding service to forward the pills to them in their home states. Another option was to use "general delivery" at a US post office near the state border, to reduce the distance they would have to travel. Plan C also informed people about providers offering abortion pills in advance of pregnancy. In December 2021, researchers at Advancing New Standards in Reproductive Health published an editorial extolling the safety of an advance provision model of medication abortion (Ehrenreich, Biggs, and Grossman 2021). Post-*Roe*, Plan C shared information about community support networks providing free abortion pills to people in states with abortion bans, such as Las Libres and Red State Access, and also shared information about Telefem Mexico delivering pills to people just over the Texas border in Mexico.

Finally, advocates shared information about misoprostol alone as a safe and effective way to end pregnancy (Raymond, Harrison, and Weaver 2019). Brazilian women in the 1980s first began using misoprostol for abortion after they noticed the drug's label warning against use while pregnant because it could cause a miscarriage. This practice, which has since spread across the globe, has greatly decreased death rates from illegal abortion in the last several decades (Löwy and Corrêa 2020). Misoprostol is available over the counter in many countries, including Mexico, where people living in Texas have traveled to obtain the medication (interview with Paula Rita Rivera, July 13, 2022).

If people self-manage abortions, however, they may be subject to investigations and possibly criminal prosecution. While the FDA still considers it illegal for overseas pharmacies to ship medications into the United States, this is done all the time, and the FDA has a policy of nonenforcement with regard to importation of medicines for limited personal use (up to a 90-day supply). South Carolina and Nevada had explicit criminal prohibitions against self-managed abortion, but most states did not. While 38 states had feticide laws that equated pregnancy termination with murder, most states explicitly *excluded* pregnant people from criminal penalties (If/When/How 2019). In February 2022, the American Bar Association adopted a resolution opposing the criminalization of self-managed abortion and pregnancy loss (Robert 2021).

Nevertheless, some antiabortion prosecutors across the country tried to investigate and criminally charge people for self-managing abortion.

Prosecutors used a range of laws against pregnant people, including laws against feticide, child neglect, practicing medicine without a license, and possession of a dangerous substance. There were 31 criminal prosecutions for alleged self-managed abortion between 2000 and 2020 (Huss, Diaz-Tello, and Samari 2022; If/When/How 2019; Paltrow 2013). Police obtained and used "mass extraction" technology that allowed them to download, organize, and archive a phone's contents (Glenza 2021). This digital evidence was used to identify search queries for abortion pills, including in the prosecution of Latice Fisher, a mother of three in Mississippi (Pregnancy Justice 2020). However, there were no successful prosecutions of people who self-managed an abortion using pills in early pregnancy (although there were some in later pregnancy, such as Purvi Patel) (Huss, Diaz-Tello, and Samari 2022). In response to concerns about criminal prosecutions, If/When/How launched a nationwide Repro Legal Defense Fund (RLDF), a first-of-its-kind resource to support people investigated, arrested, or prosecuted for self-managed abortion. RLDF provided money for bail and legal representation (interview with Rafa Kidvai, June 14, 2021).

Conclusion

Abortion pill access has resulted from the decades-long efforts of medical researchers, health care providers, and reproductive rights advocates here in the United States and abroad. From the development of mifepristone in France in 1980 to Brazilian women's discovery of the abortifacient effects of misoprostol, to the feminist campaign to bring mifepristone to the United States and win FDA approval for the medication in 2000, to the ongoing campaigns to remove medically unnecessary FDA restrictions on abortion pills, many people have fought long and hard to increase access to medication abortion (table 1). Today, more than half of abortions in the United States are performed using abortion pills (Jones et al. 2022). The antiabortion movement has fought this progress every step of the way. As abortion opponents have gained political power in recent years, overturned *Roe*, and banned abortion in many states (Guttmacher Institute 2023), the long-term campaign to loosen FDA restrictions on abortion pills has been spurred on by the increasing proliferation of telehealth during the COVID-19 pandemic.

These contradictory trends have made abortion access geographically more uneven across the nation, especially after *Roe.* Although many states now ban abortion, in states maintaining legal abortion access, abortion pills and telemedicine abortion promise to increase access to and affordability of abortion health care while also augmenting the procedure's

Table 1 Mifepristone Timeline

1980	Roussel Uclaf patents mifepristone.
1988	The French government approves use of mifepristone for abortion.
1994	Roussel Uclaf donates its US patent rights for mifepristone to the Population Council, which begins phase 3 clinical trials and subsequently licenses mifepristone to Danco Laboratories, a new single-product company formed to manufacture the medication.
2000	On September 28, the FDA approves 600 mcg of mifepristone and 400 mcg of misoprostol for use during the first 49 days of pregnancy, but it allows only certified physicians to dispense the medication to patients in person.
2011	The FDA places mifepristone in the REMS drug safety program, continuing the requirement that doctors must dispense the medication to patients in person.
2016	The FDA modifies the REMS to allow certified medical providers to prescribe 200 mcg of mifepristone and 800 mcg of misoprostol for use through 10 weeks of gestation, and it approves the TelAbortion research project.
2019	The FDA approves a generic form of mifepristone, produced by GenBioPro.
2020	Because of COVID-19 concerns, a Maryland federal court partially enjoins the REMS, allowing providers to mail abortion pills to patients. As a result, the online pharmacy Honeybee Health begins distributing mifepristone and is later joined by the American Mail Order Pharmacy.
2021	In January, the Supreme Court reverses the Maryland injunction and reinstates the REMS. In April, President Biden removes the in-person distribution requirement, and in May, he orders the FDA to review the REMS. In December, the FDA modifies the REMS, permanently removing the in-person distribution requirement and allowing health care providers to mail abortion pills. The FDA also permits certified pharmacies to distribute mifepristone for the first time.

Note: FDA = US Food and Drug Administration; REMS = Risk Evaluation and Mitigation Strategy.

convenience and privacy. But the battles continue. In November 2022, antiabortion groups filed a federal lawsuit in Amarillo, Texas, challenging the FDA approval of mifepristone and arguing that the 1873 Comstock Act prohibits mailing abortion pills. The plaintiffs asked the judge, who is an antiabortion Trump appointee, to remove mifepristone from the market nationwide (Baker 2022). Meanwhile, abortion rights supporters filed two lawsuits in North Carolina and Virginia challenging state restrictions on telemedicine abortion (Baker 2023b). They also worked to inform the public that mifepristone alone was a safe and effective alternative to the combination of mifepristone and misoprostol (Baker 2023e). In December

2022, the FDA issued procedures for pharmacies to become certified to dispense abortion pills, and several pharmacy chains, including CVS and Walgreens, pledged to do so, while antiabortion groups organized protests nationwide (Baker 2023c). Meanwhile, Biden's Department of Justice issued an opinion that mailing abortion pills does not violate the Comstock Act (Baker 2023a), and Democratic Senators urged the FDA to update the mifepristone label and add miscarriage use (Baker 2023d).

Post-*Roe* abortion pills offer a safer alternative than procedural abortion outside the medical system. Before *Roe*, when many women experienced severe health consequences from "illegal abortion," abortion pills did not exist, nor did the internet and social media, where people can now learn about abortion pills and order them online from inside or outside the country. A robust network of organizations, health care providers, medical researchers, and abortion rights advocates now exists to ensure that people know where to find abortion pills, how to use them safely, and how to find legal help if they are targeted by antiabortion prosecutors. However, unlike before *Roe*, the United States today has an extensive criminal justice system and increasingly sophisticated digital surveillance systems that may increase the likelihood of criminal prosecutions of those self-managing abortion. Nevertheless, abortion pills are here to stay, and they offer people a medically safe alternative to end a first-trimester pregnancy if clinical abortion is unavailable.

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