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ARTICLE

Remote Reproductive Rights

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Abstract

In July 2020, a federal district court lifted the U.S. Food & Drug Administration's ("FDA") restriction requiring patients to pick up the first drug of a medication abortion—mifepristone—at a healthcare facility. Soon after, an ongoing experiment with remote care for abortion expanded, as telemedicine did in other areas, and virtual clinics began offering no-touch abortions. Growth of virtual care stalled in January 2021 when the Supreme Court stayed a district court's order pending the appeals process. But in April 2022, persuaded by the evidence of remote abortion's safety and efficacy, the FDA suspended enforcement of the in-person rule for the course of the pandemic. On December 16, 2021, the FDA lifted the requirement that patients pick up mifepristone at a healthcare facility, clearing the way for supervised mail delivery and pharmacy dispensation.

The expansion of virtual clinics, however, is not without significant limitations. First, questions remain about how to implement the new FDA regulation, specifically regarding certified pharmacies, and several FDA restrictions on mifepristone remain in place. Second, about half the country prohibits telehealth for abortion by either banning all abortion or by requiring the physical presence of a healthcare professional. Third, participation in telemedicine depends on various forms of privilege. Patients must have a stable internet connection or smartphone as well as an uncomplicated pregnancy, which, in part because of U.S. health disparities, is more likely for wealthier and white people. Even with the expansion of remote care, the need for clinical spaces will not disappear; in fact, it will come under increasing pressure.

This Article maps the emergence of virtual abortion care and analyzes the potential trajectory of medication abortion access, given that the Supreme Court has overturned constitutional protections for abortion. It considers the limits of telehealth for abortion—who telehealth can reach and who it cannot. Those living in states that permit abortion will have new options for ending early pregnancies. Those residing in states hostile to abortion will have to seek cross-border care, carry pregnancies to term, or find other avenues to end pregnancies. But the portability of abortion pills, when mailed by prescribers or dispensed by certified pharmacies, will test how closely states officials (or anyone else) can police or impede access to medication abortion.

Introduction

In December 2021, the FDA permanently lifted the requirement that patients collect mifepristone, the first drug in a medication abortion, at a health care facility.[1] Moving forward, certified providers can prescribe medication abortion after an online consultation, then mail pills to patients, as they had been permitted to do for most of the COVID-19 pandemic. In addition, certified pharmacies will be able to dispense medication abortion pills in the near future. Though the process of certification for pharmacies is not yet clear, the FDA's decision could make a critical difference to people's ability to gain access to medication abortion. In June 2022, the Supreme Court issued its ruling in *Dobbs v. Jackson Women's*

[1] *See infra* Parts II.B, C.

Health Organization, overturning *Roe v. Wade* and clearing the way for states to enact abortion bans from the earliest stages of pregnancy.[2]

A medication abortion involves taking two types of drugs within twenty-four to forty-eight hours to end pregnancies, as approved by the FDA, through ten weeks of gestation. The first drug, mifepristone, is subject to a safety protocol that the FDA applies to medicines deemed risky and in need of monitoring.[3] However, the consensus, even at the FDA, is that mifepristone is not risky and is in fact exceedingly safe. Among various requirements, the FDA, until recently, mandated that patients pick up the drug at a health care facility. The effect of this rule was to prohibit dispensation of mifepristone through the mail or at a pharmacy. The burdens this restriction imposed on patients became clear during the COVID-19 pandemic. In July 2020, a federal district court suspended the in-person collection requirement to allow patients to receive medication abortion services through telehealth.[4] As was true across many healthcare sectors, telehealth became a means by which patients could minimize provider and clinic contact and receive online oversight of their care.

Telehealth for medication abortion has proved to be an effective and safe means to end a pregnancy. After the federal district court enjoined the in-person collection requirement, virtual clinics launched to counsel patients online, deliver medication abortions through a mail order service, and monitor patient health through text, smartphone apps, and helplines.[5] Research on "no-touch" abortions revealed that patient satisfaction with remote care is high and the incidence of adverse effects is very low.[6]

Virtual abortion care is cheaper, costing hundreds of dollars less than brick-and-mortar procedures, and less cumbersome for many: picking up the two-drug regimen at a pharmacy or receiving it in the mail reduces the costs and delay of travel.

Telehealth for abortion, however, faces significant limitations. At the time of writing, fourteen states ban abortion from the early stages of pregnancy.[7] In addition to these states, eight states have statutes that require the in-person delivery of care, effectively banning an entirely virtual process for abortion.[8] Patients in these places will need to travel to states with permissive policies or find other means of gaining access to abortion pills.

Moreover, telehealth only works for people with internet connectivity, smartphones, digital literacy, and other resources that are often marked by racial, income, and geographic disparities. The expansion of telemedicine could consequentially fail to reach many low-income people who compromise three-fourths of abortion patients.[9] And only patients who have uncomplicated pregnancies, such as those with a low risk of an ectopic pregnancy, are candidates for teleabortion. Finally, medication abortion cannot serve those needing care after the first trimester or those who cannot gain access to telehealth for whatever reason; people will continue to need services at brick-and-mortar clinics.

[2]Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228 (2022).

[3]*See infra* Part II.A.

[4]Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., No. TDC-20-1320, 2020 WL 8167535, at *1 (D. Md. Aug. 19, 2020).

[5]*See infra* Part III.

[6]*See* Erica Chong et al., *Expansion of a Direct-To-Patient Telemedicine Abortion Service in the United States and Experience during the COVID-19 Pandemic*, 104 Contraception 43, 46-48 (2021); *see infra* Parts II.C, III.

[7]Thirteen states ban abortion throughout pregnancy and Georgia bans abortion after six weeks of pregnancy. Arizona and Florida ban abortion after fifteen weeks, and Utah after eighteen weeks. *Tracking States Where Abortion is Now Banned*, N.Y. Times (Oct. 13, 2022), https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html [https://perma.cc/M7MG-FDVK].

[8]*See infra* Part IV.A. Whether states can restrict mifepristone beyond FDA requirements presents a question of federal preemption and was at the heart of a lawsuit withdrawn by the petitioner, the generic drug manufacturer of mifepristone. Brief of Plaintiffs GenBioPro at 27, GenBioPro Inc. v. Dobbs, No. 3:20-cv-00652-HTW-LGI, (S.D. Miss. Oct. 9, 2020). On FDA preemption of state medication abortion bans, *see* David Cohen, Greer Donley, & Rachel Rebouché, *The New Abortion Battleground*, 123 Colum. L. Rev. __, Part III.A (forthcoming 2023).

[9]*See infra* Part IV.A.

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The barriers to telehealth for abortion should not be understated, but they are not insurmountable. Providers, researchers, advocates, and lawyers who made the case for changing federal restrictions on medication abortion have introduced new ways of reaching medication abortion care.[10]

This Article proceeds in three parts. Part II describes the federal restrictions on medication abortion that have curtailed introduction of remote care before turning to the litigation and policy developments that have ushered in telehealth for abortion. Specifically, this Part explains the court decision that suspended FDA regulations during the pandemic and the review of those regulations by the FDA. Part III maps where telehealth for abortion is available and the process for obtaining care through virtual clinics. Part IV assesses the limitations of teleabortion: state bans, disparities in who can gain access to telehealth, and consequences for brick-and-mortar clinics. This Article concludes by briefly assessing the road ahead for mailed medication abortion.

Telehealth for medication abortion

Although there had been investigations of telehealth for medication abortion over the last decade, the onset of the pandemic was the catalyst for the expansion of "teleabortion" as well as several other applications of telemedicine.[11] The wider introduction of remote abortion care, however, is a result of a court decision suspending the FDA rule governing how the drug regimen is collected by patients—a restriction the FDA subsequently lifted. This Part reviews the FDA's regulation of mifepristone and the litigation over and changes to that policy.

FDA regulation of medication abortion

A medication abortion is accomplished by taking two drugs. Mifepristone is the first drug ingested and it blocks the hormone progesterone, which is necessary for a pregnancy to continue.[12] The second drug, misoprostol, is taken twenty-four to forty-eight hours after mifepristone and causes uterine contractions that expel the pregnancy.[13] The FDA approves medication abortion through ten weeks of gestation.[14]

A drug safety program—a Risk Evaluation and Mitigation Strategy ("REMS")—applies to mifepristone (and not to misoprostol).[15] In 2007, the Food and Drug Administration Amendments Act created the REMS program for drugs with "serious safety concerns."[16] The FDA issues a REMS if it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug."[17] As part of a REMS, the FDA can adopt "elements to assure safe use" ("ETASU"), which can limit distribution and set the terms of who can prescribe a drug and under what conditions.[18]

[10]As this Article notes, providers have set up mobile clinics that park on borders between states that permit and prohibit abortion, serving patients in the permissive state. And self-managed medication abortion is available through a website operated by the non-profit organization, AidAccess.

[11]Gynuity, a research non-profit organization that conducted an investigational drug study, noted in Part III, used the term "TelAbortion." See *Gynuity's TelAbortion Study Has Completed Enrollment,* Gynuity Health Projects, https://telabortion.org/ [https://perma.cc/R7Y7-SJ9T].

[12]*Mifeprex (mifepristone) Information*, U.S. Food & Drug Admin. (Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/Y83U-YSK8].

[13]Almost all medication abortions are completed through a mifepristone-misoprostol regimen. Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, 2014, 49 Persp. Sexual & Reprod. Health 17, 22 (2017).

[14]*Mifeprex (mifepristone) Information*, *supra* note 13.

[15]NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg: Risk Evaluation & Mitigation Strategy (REMS), U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2011-06-08_Full.pdf [https://perma.cc/UXS9-Z37Q]. Mifepristone and misoprostol are delivered together even though the same FDA restrictions do not apply to misoprostol. Maya Manian, *The Consequences of Abortion Restrictions for Women's Healthcare*, 71 Wash. Lee L. Rev. 1317, 1331 (2014).

[16]21 U.S.C. § 355-1.

[17]*Id.* § 355-1(a)(1).

[18]*Id.* § 355- 1(f)(3).

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There are several parts to mifepristone's ETASU. Providers must be certified to dispense the drug. Certification entails submitting a form to the drug sponsor attesting to abilities to "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," and "provide surgical intervention" or "plans to provide such care through others."[19] Patients must receive a Medication Guide and sign a Patient Agreement Form; providers agree to report any adverse events.[20] And, as noted, patients were required to pick up mifepristone at a healthcare facility—a hospital, clinic, or medical office—precluding dispensation through the mail or by a pharmacy.[21]

In 2016, the FDA reviewed and revised some of the restrictions on mifepristone.[22] For example, the FDA approved use of mifepristone from up to forty-nine days to up to seventy days from the first day of the last menstrual period, lowered the dose regimen, permitted non-physician providers to apply for certification to prescribe mifepristone, and allowed patients to take mifepristone outside a healthcare facility.[23] The FDA did not revise the in-person dispensation requirement (or other aspects of the REMS). At the time, mifepristone was the only FDA-regulated drug that had to be collected at a healthcare facility but could be taken anywhere without healthcare provider supervision.[24]

REMS litigation

In 2020, the American College of Obstetricians and Gynecologists ("ACOG") brought suit with four other parties to enjoin the in-person dispensation ETASU during the pandemic.[25] ACOG argued that applying the in-person requirement contradicted substantial evidence of the drug's safety and was ineffectual in protecting patients. Any adverse event, which is very rare, would occur where the patient takes the medicine, which is typically the patient's home.[26] Further, requiring patients to come to a healthcare facility heightened the risk of COVID-19 contraction,[27] which was the reason the FDA had suspended the in-person ETASU for far riskier drugs, like certain opioids, during the pandemic.[28]

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[19]*Questions and Answers on Mifeprex*, U.S. Food & Drug Admin. (Apr. 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex [https://perma.cc/AGQ5-AALM].

[20]Government Accountability Off., Food & Drug Admin.: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts, 7-8 (2018); Alexandra Thompson et al., *The Disproportionate Burdens of the Mifepristone REMS*, 20 Contraception 1, 2 (2021). After the district court's opinion in *ACOG v. FDA*, patients were permitted to electronically sign the Patient Agreement form during a telehealth appointment and return the form electronically or by mail; alternatively, a patient could give verbal consent to the terms of the form during a telehealth session. Order Clarifying July 13 Memorandum Op., Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., No. TDC-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

[21]The non-profit organization, Plan C, argued that in-person collection was not required because the FDA REMS did not specify how mifepristone should be dispensed. *Abortion Pill FAQ*, Plan C, https://www.plancpills.org/guide-how-to-get-abortion-pills#faq [https://perma.cc/444W-VG8R].

[22]The FDA first approved mifepristone (or, as known then, RU-486) in 2000. Before and after its approval, FDA decision-making has been embroiled in controversy. Greer Donley shows that the FDA decisions around mifepristone often have been motivated by partisan politics and are distinct as compared to drugs with similar risk profiles. Greer Donley, *Medication Abortion Exceptionalism*, 107 Cornell L. Rev. 627, 667 (2021).

[23]*Mifeprex (mifepristone) Information*, *supra* note 13.

[24]Of the 17 drugs with the same ETASU, only mifepristone could be taken at home but must have been picked up at a healthcare facility. Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., No. TDC-20-1320, 2020 WL 8167535, at *1-2 (D. Md. Aug. 19, 2020).

[25]The other plaintiffs were the Council of University Chairs of Obstetrics and Gynecology, the New York State Academy of Family Physicians, SisterSong Women of Color Reproductive Justice Collective, and Dr. Honor Macnaughton. *See id.*

[26]Between 2000 and 2017, over 3 million people terminated pregnancies with medication abortion and only 4,200 adverse events occurred; of those, only 0.01% – 0.7% required hospitalization. Government Accountability Off., *supra* note 21.

[27]Plaintiffs' Amended and Corrected Memorandum of Law in Support of Motion for Preliminary Injunction at 4-10, Am. Coll. of Obstetricians & Gynecologists v. FDA, 506 F. Supp. 3d 328 (D. Md. 2020) (No. 20-1320), 2020 WL 5700818.

[28]The district court detailed the FDA's pandemic-based approach on remote drug delivery. Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 194 (D. Md. 2020); *see also* Dept. Health & Hum. Servs., Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID–19 (Mar. 17, 2020).

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In July 2020, the U.S. District Court for the District of Maryland enjoined the in-person requirement for the course of the public health emergency.[29] The district court held that the relevant part of the ETASU imposed an undue burden on the right to an abortion because requiring collection at a healthcare facility for a medicine that need not be taken there offers no medical benefit. Any possible benefit was outweighed by the burdens that the ETASU imposed.[30] The district court found that the practical and economic strains of the pandemic caused clinics to scale back operating hours or close altogether, creating long wait lists to collect medication abortion.[31] The court asserted that "abortion patients generally face more significant health risks arising from traveling to a medical facility during the pandemic … 60 percent of women who have abortions are people of color, and 75 percent are poor or low-income," and those populations are more likely to have preexisting medical conditions.[32] Such populations also are less likely to have access to medical care, which would have left a significant number of abortion patients at higher risk of illness and death if infected with COVID-19.[33]

In addition to health risks, the pandemic made arranging childcare, housing, transport, and time off work all the more difficult. The district court's decision highlighted how people seeking abortions—again, primarily low-income patients and people of color—shoulder these hardships disproportionately under the FDA's rules.[34] Taking the example of travel, the court cited providers' testimony that many patients do not own a car or cannot afford private transportation. The resulting logistical hurdles can delay individuals from obtaining a medication abortion, "which can either increase the health risk to them or, in light of the ten-week limit, prevent them from receiving a medication abortion at all."[35]

The district court's order was in effect for six months until the Supreme Court granted the FDA's petition to stay the district court's order in January 2021.[36] The litigation became moot in April 2021 because the FDA suspended enforcement of the in-person REMS for the duration of the pandemic and, soon after, announced that it would reconsider aspects of the REMS based on existing evidence.[37] The FDA could have decided to keep the restrictions in place, drop them altogether, or waive some existing rules while maintaining others. The FDA took the third road. The next Section assesses the FDA's decision and what may lie ahead for the FDA's regulation of medication abortion.

Reviewing remote care

The FDA's REMS review adheres to the process authorized by Congress as part of the Federal Food, Drug and Cosmetic Act. Under that Act, the FDA must balance the risks and benefits of a drug, based on the most current evidence, without overly burdening health care delivery.[38] Evidence submitted by drug sponsors must establish an "adequate rationale" for modification, including the reasons why modification is necessary.[39]

[29] Am. Coll. of Obstetricians & Gynecologists v. Food & Drug Admin., 472 F. Supp. 3d 183, 210-11 (D. Md. 2020).

[30] *Id.*

[31] *Id.* at 214.

[32] *Id.* at 214-15.

[33] *Id.* at 215.

[34] *Id.*

[35] *Id.*

[36] Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021). Justice Sotomayor's dissent called the Court's reinstatement of the FDA rule "callous" given the lived effects of the restriction: "patients' health vulnerabilities, public transportation risks, susceptible older family members at home, and clinic closures and reduced services pose substantial, sometimes insurmountable, obstacles for women seeking medication abortions during the COVID-19 pandemic." *Id.* at 579, 583 (Sotomayor, J., dissenting).

[37] The FDA indicated that it would rely on "information submitted by the sponsors of the new drug application and the abbreviated new drug application, as well as information from other sources, including published literature." Joint Motion to Stay Case Pending Agency Review at 2, Chelius v. Wright, No. 17-cv-493 (D. Haw. May 7, 2021), ECF No. 148.

[38] 21 U.S.C. §§ 355-1 (2007).

[39] Risk Evaluation and Mitigation Strategies: Modifications and Revisions, Guidance for Industry, Food & Drug Admin. 12 (June 2020).

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Much like the changes made to the REMS and labeling in 2016, the FDA considered "safety data" and "information about current clinical practice" in its review.[40] The FDA's website noted the safety of mifepristone: "[a]s of December 31, 2018, there were reports of 24 deaths of women associated with Mifeprex since the product was approved in September 2000" compared to 3.7 million women who had taken the drug.[41] Even those "adverse events cannot with certainty be causally attributed to mifepristone."[42]

Since then, numerous studies have demonstrated not only the safety of mifepristone but also the efficacy of the drug when taken without in-person oversight.[43] Research resulting from an investigational drug study of "TelAbortion," for example, demonstrated that of over 1300 patients, only two participants reported serious adverse events, and "neither event would have been averted had the abortion medications been provided in person."[44] U.S.-based research has been supported by experimentation with telehealth for medication abortion abroad. A U.K. study of teleabortion during the pandemic, for instance, saw no increase in complications from medication abortions as compared to before COVID-19 when a physician's office visit was required.[45] Of almost 30,000 at-home abortions between January and June of 2020, seven people needed hospitalization, as compared to eight people (in a comparison group) who picked up pills from a physician.[46]

In sum, substantial evidence suggests that in-person dispensation of medication abortion does not protect patient health and "no-touch" abortions are safe. But it took years for the FDA to reach that conclusion, and mifepristone remains one of the safest yet most restricted drugs on the market.[47] In lifting in-person dispensation but keeping the other restrictions, the FDA maintains the pattern of treating medication abortion differently than other drugs with similar safety profiles.

An additional avenue to retrieve medication abortion, however, will soon be available—dispensation by a certified pharmacy.[48] The FDA will define pharmacy certification after reviewing the suggested protocols put forward by mifepristone's manufacturers.[49] In comparing pharmacy certification requirements for other drugs, a range of possibilities emerge for how the FDA could proceed.[50] Pharmacies may

[40]*See* Food & Drug Admin., Ctr. For Drug Evaluation & Research., Application No.: 020687Orig1s020, Risk Assessment and Risk Mitigation Review(s) 30 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf [https://perma.cc/8A2D-FJ5C].

[41]Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018, https://www.fda.gov/media/112118/download [https://perma.cc/A9ZG-V533] (last visited April 13, 2022).

[42]*Questions and Answers on Mifeprex*, Food & Drug Admin. (Apr. 12, 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex [https://perma.cc/3H8T-GGSQ].

[43]*See* Hillary Bracken et al., *Alternatives to Routine Ultrasound for Eligibility Assessment Prior to Early Termination of Pregnancy with Mifepristone-Misoprostol*, 118 BJOG 17, 21-22 (2011). No-touch protocols have a 98% accuracy in identifying patients within the eligible gestational limits for medication abortion. Ushma D. Upadhyay & Daniel Grossman, *Telemedicine for Medication Abortion*, 100 Contraception 351, 352 (2019).

[44]Elizabeth Raymond et al., *TelAbortion: Evaluation of a Direct to Patient Telemedicine Abortion Service in the United States*, 100 Contraception 173, 174-76 (2019).

[45]Abigail Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG 1464, 1471 (2021).

[46]*Id.*

[47]*See generally* Donley, *supra* note 23 (detailing the exceptional treatment by the FDA of reproductive health issues that primarily affect women).

[48]Per the FDCA, the FDA must consider, and accept or reject, possible ETASU, one of which includes the requirement that pharmacies are specially certified. *See* 21 U.S.C. § 355-1(f)(3)(B) (2007).

[49]"In April 2022, the manufacturers will submit proposed protocols to the FDA. After the FDA accepts the submissions, it has 180 days to review or modify the proposed protocols. Pharmacies may be able to sign up for certification to dispense mifepristone by late 2022." Laurie Sobel et al., *The Intersection of State and Federal Policies on Access to Medication Abortion via Telehealth*, KFF Women's Health Pol'y (Feb. 7, 2022), https://www.kff.org/womens-health-policy/issue-brief/the-intersection-of-state-and-federal-policies-on-access-to-medication-abortion-via-telehealth/ [https://perma.cc/2DN2-JPSQ].

[50]Medicines like Pomalyst that can cause birth defects are subject to pharmacy certification under a REMS, and those requirements vary in what additional dispensation and administrative restrictions they impose. Food & Drug Admin., REMS Dispenser Certification Requirements (June 1, 2013), https://www.fda.gov/files/about%20fda/published/REMS-Dispenser-Certification-Requirements.pdf [https://perma.cc/7BPM-XNGM].

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have to attest to compliance with safety standards by submitting a Pharmacy Enrollment Form to the drug sponsors, the FDA, or both. But the new REMS also could require a pharmacy, to be certified, to utilize an authorization number that marks the prescription valid for a period of time—that is, requiring dispensation within twenty-four or forty-eight hours, for example.

The FDA can mandate that certified pharmacies maintain a system that documents compliance with FDA rules and engage in ongoing education and training for pharmacists as well as counseling for patients. Education or training might entail materials on the risks and benefits of the drug. Counseling for patients could include information about the drug's risks, in addition to instructions on administration, as well as a warning not to share mifepristone with anyone else. Certification is a crucial component of mifepristone's broader distribution: the certification will either incentivize or disincentive larger pharmacies to dispense medication abortion pills.[51]

In addition to the future of pharmacy certification, it bears repeating that other aspects of the mifepristone REMS have not changed. The FDA still mandates that only certified providers, who must register with the drug manufacturer, may prescribe the drug, which is an unnecessary administrative burden.[52] The Patient Agreement Form, an additional informed consent requirement that patients sign before a medication abortion, remains a requirement despite repeating what providers communicate to patients.

The removal in-person dispensation of mifepristone, however, may not result in distribution at your neighborhood pharmacy or through your primary care provider, though both scenarios are more likely than ever before. In the wake of events described in this Part, abortion providers have refashioned and reimagined their practices to serve patients online. The rise of telehealth for abortion has revealed what is possible for early abortion care.

Telehealth and the virtual clinic

As court decisions and new policies changed the regulation of mifepristone, providers changed their practices. Healthcare providers formed to provide medication abortion virtually in 2020. But well before then, an on-going national study of "TelAbortion" demonstrated the effectiveness and safety of remote care.[53]

In 2016, Gynuity Health Projects ("Gynuity") received an Investigational New Drug Approval to deliver medication abortion without the in-person collection requirement.[54] Providers counseled patients through videoconferencing and patients confirmed gestational age with blood tests and ultrasounds at a location of their choosing.[55] Potentially because of the ultrasound requirement, which kept the project from being entirely virtual, only a few hundred people participated the first few years of the study.[56] During the pandemic, however, study participants who were at low risk of complications did not have to undergo an ultrasound or have a blood test; rather, gestational age was assessed by home pregnancy tests and questions about the date of the patient's last menstrual period.[57] Gynuity mailed the

[51]David Cohen, Greer Donley, & Rachel Rebouché, *Abortion Pills* (Sept. 20, 2022) (on file with the author).

[52]Donley, *supra* note 23, at 643-47 (showing how certification could disincentive physicians from providing medication abortions).

[53]Gynuity's TelAbortion project completed enrollment on September 30, 2021 after five years of study. *See Gynuity's TelAbortion Study Has Completed Enrollment*, *supra* note 11. Note that the Gynuity project is not the first telehealth abortion project: "The first telemedicine abortion program began in Iowa in 2008 … The patient took the first pill, mifepristone, in front of the provider via videoconference, and the second pill at home. Within two weeks, the patient returned to the clinic for a follow-up to ensure the abortion was complete." *Evaluation of Telemedicine in Iowa*, Advancing Standards in Reproductive Health, U.C.S.F., https://www.ansirh.org/research/ongoing/evaluation-telemedicine-iowa [https://perma.cc/HQG2-XA6Z] (last visited April 8. 2022).

[54]Raymond et al., *supra* note 45, at 174.

[55]*Id.*

[56]*Id.*

[57]*See* Chong et al., *supra* note 6 at 44.

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medication abortion regimen directly to the patient and requested to meet the patient online seven to fourteen days after. Other REMS requirements, such as receipt of a Medication Guide, also occurred virtually.[58]

Following in Gynuity's footsteps, virtual clinics have worked with online pharmacies to mail medication abortion as prescribed by certified providers.[59] Take the example of Choix, which operates in California, Colorado, Maine, New Mexico, and Illinois.[60] Two nurse practitioners, partnered with a physician certified in family medicine and with a practice at a family health clinic, launched a virtual clinic in the summer of 2020, shortly after the district court's ruling in ACOG. Choix prescribes medication abortion up through eleven weeks of pregnancy.[61]

Clear advantages of virtual care are its speed and affordability. The founders describe how Choix's asynchronous telehealth platform works:

> Patients first sign up on our website and fill out an initial questionnaire, then we review their history and follow up via text with any questions. Once patients are approved to proceed, they're able to complete the consent online. We send our video and educational handouts electronically and make them available via our patient portal. We're always accessible via phone for patients.[62]

The asynchronous intake is completed within one business day, and Choix partners with an online pharmacy, which mails pills to patients one to four business days after the intake process.[63] Patients have check-in visits via text once the first drug is ingested and then a 72-hour follow-up, also by text, after the second drug (misoprostol) is taken.[64] The cost is $289, with a consultation fee of $20 applied toward the total, which is around $300 less than medication abortions offered by a clinic.[65] From October 2020 to January 2022, Choix served over 2,200 people.[66]

A constellation of clinics, some with physical spaces and some without, offer telehealth services in twenty-four states and Washington, DC.[67] Providers offering remote care operate in states that have not banned abortion or in states that do not require in-person dispensation of the pills.[68]

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[58]The Gynuity study offered teleabortion services in 13 states and Washington, D.C. Those states were Colorado, D.C., Georgia, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, Montana, New Mexico, New York, Oregon, and Washington. *Id.* at 44. Gynuity partnered with carafem, which operates a telehealth program for abortion as well as health centers in several states. CARAFEM, ANNUAL REPORT 3 (2020), https://carafem.org/wp-content/uploads/2020/08/2020-Annual-Report.pdf [https://perma.cc/ZS4G-Z85E].

[59]*See* Carrie N. Baker, *How Telemedicine Startups are Revolutionizing Abortion Health Care in the U.S.,* MS. MAG. (Nov. 16, 2020), https://msmagazine.com/2020/11/16/just-the-pill-choix-carafem-honeybee-health-how-telemedicine-startups-are-revolutionizing-abortion-health-care-in-the-u-s/ [https://perma.cc/C3E2-KQ2N].

[60]This example also is offered in Greer Donley & Rachel Rebouché, *The Promise of Telehealth for Abortion, in* DIGITAL HEALTH CARE OUTSIDE OF TRADITIONAL CLINICAL SETTINGS: ETHICAL, LEGAL AND REGULATORY CHALLENGES AND OPPORTUNITIES (I. Glenn Cohen et al. eds., forthcoming 2023).

[61]Choix imposes age thresholds in compliance with parental involvement laws. *Medication Abortion (Abortion Pills)*, CHOIX, https://www.mychoix.co/abortion-care [https://perma.cc/D2HF-WYQ7].

[62]Carrie N. Baker, *Online Abortion Providers Cindy Adam and Lauren Dubey of Choix: "We're Really Excited about the Future of Abortion Care,"* MS. MAG. (Jan. 14, 2022), https://msmagazine.com/2022/01/14/abortion-pills-california-colorado-illinois-online-abortion-cindy-adam-lauren-dubey-choix/ [https://perma.cc/9VMM-XK7C].

[63]*Id.*

[64]*Id.*

[65]*Id.*

[66]*Id.*

[67]Abortion on Demand, for example, offers telehealth services in 22 states. *Abortion on Demand,* ABORTION ON DEMAND, https://abortionondemand.org/ [https://perma.cc/Z3D5-SYL7]; Carrie N. Baker, *People are Getting Creative Obtaining Abortion Pills Online,* MS. MAG. (Feb. 7, 2022), https://msmagazine.com/2022/02/07/how-to-get-abortion-pills-online-telemedicine-abortion/ [https://perma.cc/258C-RZZU]; *see also* Rachel Rebouché, *The Public Health Turn in Reproductive Rights*, 78 WASH. & LEE L. REV. 1355, 1416-28 (2021) (describing states that have telehealth services for abortion as of 2021).

[68]Baker, *supra* note 6.

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Plan C is a non-profit organization that endeavors to open access to medication abortion for people across the country, even in the states that ban abortion. Carrie Baker reports:

> Many people are getting abortion pills from outside of the U.S. by ordering them directly from online pharmacies. Researchers at Plan C have vetted many of these online pharmacies by ordering abortion pills from them and testing the pills for quality. On their website, Plan C lists websites that send quality medication, along with cost and shipping time, …[from] pharmacies that do not require a prescription to obtain abortion pills.[69]

Another organization, AidAccess, works with European-based physicians, who review the consultation forms and prescribe the pills for patients in states with abortion bans, which are delivered by an India-based pharmacy within one to three weeks for $105.[70]

In addition to state prohibitions, on-the-ground realities about how telemedicine is delivered obstruct gaining access to remote care. The next section covers legislative barriers to medication abortion, the limited reach of telehealth for certain populations, and the continued need for brick-and-mortar clinics before concluding with thoughts about the future of remote abortion access.

The limits and future of remote care

The landscape of abortion provision—early terminations without a visit to a physical clinic—has shifted in ways that many thought unimaginable ten years before.[71] And patient satisfaction surveys suggest that the value of remote abortion care is what one could have predicted: effective care with privacy, convenience, and reduced delay and cost.[72] However, many states have banned or erected roadblocks to teleabortion.[73] At the same time, barriers to telemedicine, generally, and the continuing need for clinical spaces may shorten the reach of teleabortion.

The limits of telehealth

Laws in about half of the country limit, explicitly or indirectly, telehealth for abortion.[74] As noted, fourteen states ban almost all abortion within their borders, and an additional eight states require a physician to be present upon delivery of medication abortion.[75] State legislation that requires in-person visits for counseling or ultrasounds also influences whether telehealth for abortion is feasible.[76]

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[69]*Id.*; *Abortion Pill FAQ*, *supra* note 22.

[70]*Id.* AidAccess offers U.S.-based telehealth services in Alaska, California, Colorado, Connecticut, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, New York, New Jersey, New Hampshire, New Mexico, Nevada, Oregon, Rhode Island, Vermont, Virginia and Washington. Shipping takes two to five days and the cost for U.S.-based services is $150. AidAccess, Consultation, https://aidaccess.org/en/i-need-an-abortion.

[71]*See* Rachel Rebouché & Ushma Upadhyay, *Online Clinics Show Abortion Access Can Survive State Restrictions and Roe v. Wade Threat*, USA Today, Apr. 12, 2021, https://www.usatoday.com/story/opinion/2021/04/12/medication-abortion-rights-protected-online-clinics-column/7106777002/ [https://perma.cc/6YLX-YBHG].

[72]Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Through Telemedicine Compared with In Person*, 130 Obstetrics & Gynecology 778, 778 (2017).

[73]Jareb A. Gleckel & Sheryl L. Wulkan, *Abortion and Telemedicine: Looking Beyond COVID-19 and the Shadow Docket*, 54 U.C. Davis L. Rev. Online 105, 112 (2021); Katherine Fang & Rachel Perler, *Abortion in the Time of COVID-19: Telemedicine Restrictions and the Undue Burden Test*, 32 Yale J.L. & Feminism 134, 135 (2021).

[74]Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists, 141 S.Ct. 578, 580 (2021).

[75]*Medication Abortion Requirement,* Pol'y Surveillance Program (Dec. 2021), http://lawatlas.org/datasets/medication-abortion-requirements [https://perma.cc/Y46L-XT7V].

[76]*See* Planned Parenthood of the Heartland v. Iowa Bd. of Med., 865 N.W.2d 252, 269 (Iowa 2015); Carrie N. Baker, *Advocates Cheer FDA Review of Abortion Pill Restrictions*, Ms. Mag. (May 11, 2021), https://msmagazine.com/2021/05/11/fda-review-abortion-pill-restrictions-mifepristone-biden/ [https://perma.cc/35RV-C3PY] (describing the Ohio law and state court injunction); Iris Samuels, *Montana Governor Signs Three Bills Restricting Abortion Access*, Associated Press, Apr. 26, 2021; Dan

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Some state legislation has targeted telehealth for abortion. Before *Dobbs,* for example, Indiana passed a law requiring in-person provision of medication abortion and banning the use of telehealth.[77] In addition to states that ban all abortion, bans on teleabortion have passed in Arizona, Iowa, Ohio,[78] and legislators in Maryland and Minnesota are considering similar restrictions.[79] A Montana law, temporarily enjoined by a state court, bans distribution of "abortion-inducing medication by mail;" it is one of six similar laws passed last year.[80] As in Montana, some courts (federal and state) have enjoined these legislative efforts.[81] And now that the FDA expressly permits mailed and pharmacy-dispensed medication abortion, state laws contradicting FDA rules could be subject to preemption.[82]

State law, however, is not the only obstacle to remote care: there is also the unequal access to telehealth, mirroring broader health disparities.[83] Patients often need access to a telehealth-capable device, high-speed data transmission, and digital literacy. Consider, for instance, the availability of broadband internet service.[84] The "digital divide" disproportionately affects the marginalized populations that live in places that lack the infrastructure necessary for telehealth delivery.[85]

Finally, remote care cannot assist those who need or want in-person care, which currently accounts for forty-six percent of the country's abortions—a percentage that may decrease as teleabortion expands.[86] As the use of medication abortion increases, particularly as an online service at lower cost, financial sustainability of brick-and-mortar clinics will be under threat.[87] Many facilities operate at a loss, due in no small part to the costs of complying with state restrictions.[88] As clinics shut down, either because of abortion bans or because of the costs of staying in business, patients who need abortions past ten weeks of gestation or patients who are not candidates for medication abortion—patients with health

Whitcomb, *Judge Issues Last-minute Delay to Montana Abortion Laws Hours after Taking Case*, Reuters (Oct. 1, 2021), https://www.reuters.com/world/us/judge-issues-last-minute-delay-montana-abortion-laws-hours-after-taking-case-2021-10-01/ [https://perma.cc/9W8C-DQ5N].

[77]State Legislation Tracker, Guttmacher Inst. (Dec. 15, 2021), https://www.guttmacher.org/state-policy [https://perma.cc/3BVV-EKNG].

[78]The states with teleabortion bans or bans on mailing medication abortion, before *Dobbs*, included Arizona, Arkansas, Iowa, Alabama, Montana, Ohio, Oklahoma, South Dakota, Wyoming, and West Virginia.

[79]Alice Miranda Ollstein, *New Attention on Abortion Pill Dispensing Amid Challenge to* Roe v. Wade, Politico (May 31, 2021) https://www.politico.com/news/2021/05/31/supreme-court-abortion-fda-491375 [https://perma.cc/FCS7-KAB7].

[80]Sobel et al., *supra* note 52, at 5.

[81]Courts in Oklahoma, Iowa, South Dakota, Ohio, and Montana have blocked telemedicine bans. *Id.* These decisions may be moot in places like Oklahoma and South Dakota where almost all abortion is banned after *Dobbs.*

[82]Greer Donley, Rachel Rebouché & David Cohen, *Existing Federal Laws Could Protect Abortion Rights Even if* Roe *Is Overturned*, TIME (Jan. 24, 2022), https://time.com/6141517/abortion-federal-law-preemption-roe-v-wade/ [https://perma.cc/2XXR-M5FN].

[83]Cason D. Schmit et al., *Telehealth in the COVID-19 Pandemic*, in Assessing Legal Responses to COVID-19 123, 123 (Scott Burris et al. eds., 2020), https://debeaumont.org/wp-content/uploads/2020/08/Assessing-Legal-Responses-to-COVID-19-APHA-de-Beaumont.pdf [https://perma.cc/KE4Z-NKNQ].

[84]*See* Betsy Lawton, *COVID-19 Illustrates Need to Close the Digital Divide*, *in* Assessing Legal Responses to COVID-19 222 (Scott Burris et al. eds., 2020).

[85]Thompson et al., *supra* note 21, at 17. Non-English speakers have additional barriers for navigating telehealth services, and people with cognitive impairment also may have trouble interacting with video. Jorge A. Rodriguez et al., *Disparities in Telehealth Use Among California Patients with Limited English Proficiency*, 40 Health Affairs 487, 487 (2021), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00823 [https://perma.cc/A39B-SP6B].

[86]Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, Guttmacher Inst. (Feb. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions (reporting that 54 percent of the nation's abortions in 2017 were medication abortions).

[87]AOD contributes 60 percent of all profits to the Save Our Clinics fund of the Abortion Care Network. Carrie N. Baker, *Abortion on Demand Offers Telemedicine Abortion in 20+ States and Counting: "I Didn't Know I Could Do This!",* Ms. Mag. (June 7, 2021), https://msmagazine.com/2021/06/07/abortion-on-demand-telemedicine-abortion-fda-rems-abortion-at-home/ [https://perma.cc/WSK6-PUEX].

[88]Michelle L. McGowan et al., *Care Churn—Why Keeping Clinic Doors Open Isn't Enough to Ensure Access to Abortion*, 383 New Eng. J. Med. 508, 509 (2020).

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complications, for example—will have limited options.[89] As smaller providers are driven out of business, only large clinical centers will exist in states with permissive abortion laws. Future access to abortion clinics will require travel, sometimes extensive or cost-prohibitive travel, meaning that those with resources will be able to reach care while those without may self-manage their abortions or carry pregnancies to term.

In the light of these obstacles, the next section asks what the future of abortion access looks like in a country where many people will travel or pursue terminations in defiance of state law.

Remote reproductive rights

With increased regional disparities for abortion law and care, workarounds to state laws will emerge, as they have already. In states where abortion services are non-existent or scarce, studies demonstrate that people self-manage their abortions by ordering medications online.[90]

The portability of medication abortion opens avenues that test the bounds of legality and networks of advocates for abortion care have mobilized to make pills available to people across the country.[91] One can envision various means for obtaining mailed abortion pills:

> For practical purposes … it is not clear how (or why) an abortion clinic would ensure that patients attend their telemedicine appointments from the state in which they purport to be. Then, as long as a patient has friends or family (or someone they could pay) in a state where abortion is legal, the clinic could mail the pills to that address. At that point, the patient could drive to pick up the pills at her convenience, such as over a weekend when she does not have to work. Alternatively, friends or family could drive the pills to a half-way point, deliver them on a visit, or even risk mailing the pills.[92]

Providers of virtual services, however, warn against trying to circumvent state laws through virtual private networks or mail forwarding.[93] Abortion on Demand, for example, tracks IP addresses to confirm location at patient intake.[94] Extralegal strategies could have serious consequences and costs, particularly for those already vulnerable to state surveillance and punishment. And attempts to bypass state laws might backfire for providers, who are subject to professional, civil, and criminal penalties, as well as those who assist providers and patients.

That said, there are a number of measures that could expand telehealth for abortion. First, the federal government can play a role in improving access to telehealth for abortion.[95] The FDA could remove the remaining elements of the mifepristone REMS, such as requiring that only certified providers prescribe the medication. And the agency could ensure that the yet-to-be-determined pharmacy certification process reflects mifepristone's excellent safety record and imposes minimal requirements. Second, state

[89] *See* Ruqaiijah Yearby, *Breaking the Cycle of "Unequal Treatment" with Health Care Reform: Acknowledging and Addressing the Continuation of Racial Bias*, 44 Conn. L. Rev. 1281, 1305-06 (2012).

[90] Chloe Murtagh et al., *Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet*, 97 Contraception 287, 289 (2018).

[91] Having done this for some time, Plan C, a non-profit organization disseminating information about medication abortion, has been a hub for information about virtual clinics as well as self-managed care. Patrick Adams, *Amid Covid-19, a Call for M.D. s to Mail the Abortion Pill*, N.Y. Times (May 12, 2020), https://www.nytimes.com/2020/05/12/opinion/covid-abortion-pill.html [https://perma.cc/7THA-T4J3].

[92] Gleckel & Wulkan, *supra* note 76, at 120.

[93] *Frequently Asked Questions,* Abortion on Demand, https://abortionondemand.org/faq/ [https://perma.cc/V259-R8K3] ("Our software will confirm you are physically in the state you selected at the time of your scheduled video appointment. This state needs to match the state selected for your medication abortion packet sent in the mail. We cannot provide care outside of the specific states we are licensed to practice. We cannot ship to P.O. boxes, UPS boxes or FedEx shipment centers.") (last visited Mar. 29, 2022).

[94] *Id.*

[95] *See* Cohen, Donley, & Rebouché, *The New Abortion Battleground*, *supra* note 8.

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policy in jurisdictions supportive of abortion rights can invest in telehealth generally to reduce disparities and continue to loosen restrictions on telehealth (such as permitting telephonic appointments), which many states have done in response to the pandemic. Third, practical solutions to the legal barriers to teleabortion are already underway. Providers are setting up mobile clinics with telehealth stations at state borders with restrictive laws and advocates are increasing logistical and funding support for interstate travel.

These potential strategies for protecting medication abortion access will no doubt result in litigation and carry their own risks. What will undoubtedly remain in the midst of legal and practical uncertainty is the problem of resources. How will advocates, researchers and lawyers work together to redistribute resources to enable low-income people in hostile states to access abortion care? Answering that question depends on political mobilization, money, and state as well as federal commitment to protecting abortion rights in different ways.

Conclusion

An uncertain future is in store for reproductive rights. On the one hand, the Supreme Court reversed constitutional protection for abortion, allowing states to ban abortion early in pregnancy. On the other hand, the federal government, through the FDA, has taken steps to make medication abortion more accessible. What seems clear, in a moment in which there is much change, is that abortion access does not solely depend on courts' articulation of abortion rights. Rather, executive action, agency decisions, and protective state legislation are legal inventions that will shape abortion's availability in a post-*Dobbs* country.

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