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Early Abortion Exceptionalism

Greer Donley*

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Abstract: Restrictive state abortion laws garner a large amount of attention in the national conversation and legal scholarship, but less known is a federal abortion policy that significantly curtails access to early abortion in all fifty states. The policy limits the distribution of mifepristone, the only drug approved to terminate a pregnancy so long as it is within the first ten weeks. Unlike most drugs, which can be prescribed by licensed healthcare providers and picked up at most pharmacies, the Food and Drug Administration only allows certified providers to prescribe mifepristone, and only allows those providers to distribute the drug to patients directly, in person, not through pharmacies. This policy segregates abortion care outside of the traditional healthcare setting and into abortion clinics, which provide ninety-five percent of abortions. As a result, women must often travel long distances to simply pick up a prescription at a clinic—an obstacle that disproportionately harms low-income women, women of color, and rural women. This paper is the first to examine the burdens, benefits, and impact of the mifepristone REMS. It argues that mifepristone fails to meet the statutory criteria for a REMS, and that the FDA’s improper regulation of mifepristone is a part of a larger history of the agency discounting women’s health. It concludes by exploring the future of early abortion care without the mifepristone REMS—a reality that may soon come to pass under the Biden administration. Without the REMS, women would be able to terminate an early pregnancy entirely through telemedicine, avoiding the logistical hurdles, lack of privacy, and harassment that occurs at clinics. These benefits will continue for women living in liberal states even if *Roe v. Wade* is limited or overturned, accelerating the disparity in abortion access across state lines and the trend toward self-managed abortion in states that have restricted abortion.

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INTRODUCTION

State abortion laws have received an enormous amount of attention in the national discourse and legal scholarship. But unknown to most is a federal policy that dramatically limits access to abortion care throughout the United States. The policy, created by the Food & Drug Administration (FDA), has burdened the medication used to induce abortion in the first ten weeks of pregnancy, mifepristone, through what is known as a Risk Evaluation and Mitigation Strategy (REMS).¹ A REMS subjects a drug to additional controls that theoretically improve the drug's safety profile at the expense of accessibility. The mifepristone REMS is quite stringent—it dramatically limits access to medication abortion and effectively isolates abortion care outside of traditional medical settings.² Though the FDA is only supposed to institute a REMS when it concludes that additional regulation is needed to ensure that a drug's health benefits outweigh its safety risks, every medical organization to consider mifepristone's risk profile has found that the REMS is unnecessary to protect patient safety.³

After the 2020 election, abortion rights activists have been concerned about the future of their mission. Justice Barrett was confirmed to fill Justice Ginsburg's seat only eight days before the election—a replacement that threatened most of the rights Justice Ginsburg had championed, perhaps most acutely, abortion rights. And though Democrats managed to narrowly win a majority of the Senate thanks to the special elections in Georgia and the Vice President's role as a tiebreaker, the margin is so thin that the passage of legislation expanding reproductive rights seems unlikely. Nevertheless, a Biden administration will likely be confronted with the opportunity to remove the mifepristone REMS and expand abortion access throughout much of the country. This Article explores the rationale for removing the mifepristone REMS and what impact that decision could have for abortion rights generally.

Most people take for granted the idea that abortion occurs outside of the traditional healthcare setting, typically at an abortion or family planning clinic. That is because 95% of abortions—including abortions that are completed with a simple medication regimen—are provided by those clinics.⁴ There is no reason, however, for medication

¹ *Risk Evaluation and Mitigation Strategy (REMS) Single Share System for Mifepristone 200MG*, FOOD & DRUG ADMIN., (last updated April 2019), https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2019_04_1_1_REMS_Document.pdf [Hereinafter REMS].

² See *infra* Section I.

³ See *infra* Section II.

⁴ Rachel K. Jones, Elizabeth Witwer & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2017*, GUTTMACHER INST. 16 (Sept. 2019),

abortion to be limited to any physical space. So long as a woman is within the first ten weeks of her pregnancy, she should simply be able to make an appointment with a general practitioner or OBGYN (in person or over telehealth), obtain a prescription for medication abortion, pick up the medications at her regular pharmacy, and end her pregnancy in the privacy of her own home. The primary reason this scenario cannot take place in the United States is the FDA’s REMS.

The mifepristone REMS created a few distribution limitations that have, in effect, isolated early abortion care to clinics. Most importantly, the REMS bars traditional pharmacies from distributing mifepristone and requires women⁵ to pick up the drug from a “certified provider” in a clinic, medical office, or hospital.⁶ So not only must providers opt into prescribing the drug, but patients must travel to pick up the drug from those who have done so. The logistical burdens associated with certification and distribution have ensured that abortion providers working at abortion and family planning clinics make up almost all certified providers.⁷ And given that clinics are few and far between in most southern and midwestern states, the REMS effectively requires women to travel far distances—sometimes hundreds of miles—to pick up a prescription. It also prevents women from obtaining the prescription through telehealth, which became an urgent necessity in the COVID-19 pandemic, but is also the most convenient way for most patients to obtain care regardless of the public health emergency. Quickly after taking office, the Biden administration used its discretion to suspend the in-person dispensing requirement associated with the mifepristone REMS⁸—an action the Trump administration refused to take and the Supreme Court affirmed.⁹

This Article starts with background on medication abortion, including the drug’s risks and benefits, the regulatory history of the REMS, and the significant negative impact the REMS has on abortion access. Section II then examines whether the burdens associated with the REMS are offset by any health benefit, as the statute requires. It concludes, as has every major medical organization to examine the issue, that there are no demonstrated medical benefits. Medication

https://www.guttmacher.org/sites/default/files/report_pdf/abortion-incidence-service-availability-us-2017.pdf.

⁵ Not every person capable of becoming pregnant identifies as a woman. Though I use the term ‘woman’ throughout this paper, the arguments apply with equal force to all people with uteruses, however they identify.

⁶ REMS, *supra* note 1.

⁷ *See infra* Section I.

⁸ Letter from FDA to Maureen G. Phipps and William Grobman (April 12, 2021), <https://www.aclu.org/letter/fda-response-acog-april-2021>.

⁹ ACOG v. FDA, 592 U. S. ____ (2021).

abortion is both safe and effective without limits on distribution. Though there are real risks to mifepristone—as there are for every drug—there is no reason that a physician or pharmacist could not ensure that patients are informed of the risks and what to do if they experience them. As a result, the section concludes that mifepristone failed to meet the statutory criteria for a REMS.

In Section III, the Article describes how the FDA’s mifepristone REMS is a part of a larger pattern of gender bias in the agency’s decision-making. The section traces a series of agency failures to protect women’s health, especially reproductive health, over the course of decades. This section concludes that the FDA has a history of placing political concerns over its scientific mission when it comes to issues concerning female sexuality and reproduction.

Finally, Section IV explores potential avenues for invalidating the REMS, some of which are ongoing in the courts. Though litigants are challenging the REMS on both constitutional and administrative law grounds, this Article argues a new FDA Commissioner under the Biden administration could and should order the agency to reconsider the REMS. Ultimately, the Article concludes that removing the FDA’s REMS could represent the largest expansion of abortion rights in decades, and explores how a removal of the REMS could reshape early abortion care in the United States. In states that lack their own limits on mifepristone, women will be able to obtain early abortion care entirely from the privacy of their own homes, saving them the harassment and barriers to access associated with clinic-based care.¹⁰ Untangling abortion from clinics could also reduce the threats and violence abortion providers experience by making early abortion more anonymous. Even if *Roe v. Wade* is limited or overturned, women living in liberal states will continue to experience these benefits. But given that nineteen states have their own laws limiting the distribution of mifepristone, and that those states might be allowed to ban abortion entirely in the near future, removing the mifepristone REMS will accelerate polarization in abortion access across state lines. Nevertheless, easing the restrictions on mifepristone will inevitably make medication abortion easier to access even in states where abortion is illegal or harshly regulated, allowing women to more safely and easily self-manage their abortions outside of the traditional healthcare setting.

¹⁰ See Yvonne Lindgren, *the Doctor Requirement: Griswold, Privacy, and At-Home Reproductive Care*, 32 CONSTITUTIONAL COMMENTARY 341, 358-64 (2017) (describing the privacy benefits associated with abortion at home); see also Section IV *infra* (describing how telehealth can improve abortion access and the abortion experience).

I. THE STIFLED PROMISE OF MEDICATION ABORTION

Mifepristone is a drug that when used in combination with misoprostol, terminates a pregnancy. Mifepristone was originally sold exclusively under the brand name Mifeprex, but the FDA approved a generic version of the drug in 2019.¹¹ Mifepristone works by blocking the hormone progesterone, which is necessary for a pregnancy to continue.¹² In particular, when progesterone is blocked during pregnancy, it alters the lining of the uterus and causes disruption to the decidua (which later becomes the placenta).¹³ By thinning the uterine lining, mifepristone detaches the gestational sac from the uterus and stops its growth.¹⁴ It can also cause the cervix to soften and dilate, which can help express the pregnancy.¹⁵

Mifepristone, however, is not always sufficient to end a pregnancy on its own, which is why it is used in combination with a second drug, misoprostol. Misoprostol causes contractions and helps to expel the pregnancy.¹⁶ It is typically taken within 48 hours after the patient takes mifepristone.¹⁷ Unlike mifepristone, which is the only drug approved as an abortifacient, misoprostol was originally approved to prevent stomach ulcers after the use of certain anti-inflammatory drugs.¹⁸ However, it has been used off label¹⁹ for a variety of obstetric uses—including to induce labor or evacuate a pregnancy after an

¹¹ This Article uses the term “mifepristone” to refer to both the generic and brand name drug. *Questions and Answers on Mifeprex*, FOOD & DRUG ADMIN., (April 12, 2019), <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex>. The agency consolidated both products under a single REMS, but otherwise made no substantive changes to the REMS protocol. *Id.*

¹² Wood Alastair, Irving Spitz & CW Bardin, *Drug Therapy: Mifepristone (RU 486) – A Modulator of Progestin and Glucocorticoid Action*, 329 NEW ENGLAND J. OF MEDICINE 404, 405 (1993).

¹³ *Id.*

¹⁴ *Medication Abortion*, MAYO CLINIC, (May 14, 2020), <https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687>.

¹⁵ Alastair, Spitz & Bardin, *supra* note X at 405.

¹⁶ *Medication Abortion*, *supra* note X.

¹⁷ *The Availability and Use of Medication Abortion*, KAISER FAMILY FOUND., (June 8, 2020), <https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/>.

¹⁸ Rebecca Allen & Barbara M. O'Brien, *Uses of Misoprostol in Obstetrics and Gynecology*, 2 REVIEWS IN OBSTETRICS & GYNECOLOGY 159, 159 (2009).

¹⁹ Off label use refers to when a physician prescribes medication for a use that was not approved by the FDA.

incomplete or missed miscarriage.²⁰ Perhaps due to its variety of other uses outside of the abortion context, misoprostol has not been subject to the same controversy or regulatory limitations on its distribution despite similar side-effects and risks. As a result, women can obtain misoprostol as any other drug, with a prescription from their pharmacy.²¹

Though there are other drug regimens that can effectively terminate a pregnancy, 97% of medication abortions in the United States use the FDA-approved combination of mifepristone and misoprostol.²² With nearly twenty years of safety data, there is ample evidence that mifepristone is both safe and effective. In 2015, the Government Accountability Office (GAO) published a report on mifepristone; it found that from September 2000 to June 2017, 3.2 million women have used mifepristone to end a pregnancy.²³ Of those women, only 4,200 reported adverse events, including twenty deaths.²⁴ The fatality rate was therefore 0.0006%.²⁵ “In contrast, the background risk of pregnancy-related death among pregnant women in the United States who do not have abortions and instead proceed to live birth is approximately 0.009%, which is 14 times higher.”²⁶ The rate of serious adverse events like infection requiring hospitalization are also low, ranging from 0.01 to 0.7%, and are almost always treatable without long-term issues.²⁷ As for efficacy, the GAO reviewed a large number of studies showing that the FDA-approved combination of mifepristone and misoprostol is over 90% effective at complete termination—many studies suggesting it is over 96% effective.²⁸ For

²⁰ Allen & O’Brien, *supra* note X, at 159, 164. Studies have recently shown that a combination of mifepristone and misoprostol would be more effective at treating an incomplete miscarriage, but the regulatory limits on the mifepristone have made that protocol more difficult to implement. Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEW ENGLAND J. MEDICINE 2161, 2161 (2018).

²¹ Pharmacists can, however, invoke conscience laws to avoid dispensing misoprostol.

²² Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, 2014, 49 PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 1, 6 (2017), https://www.guttmacher.org/sites/default/files/article_files/abortion-incidence-us.pdf.

²³ GOVERNMENT ACCOUNTABILITY OFFICE, GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION OF MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 21 (2018) <https://www.gao.gov/assets/700/690914.pdf> [Hereinafter GAO-18-292]

²⁴ *Id.*

²⁵ *Id.*

²⁶ REMS Study Group, *supra* note X, at 791.

²⁷ *Id.*

²⁸ GAO-18-292, *supra* note X, at 12-14.

the remaining cases, where the traditional regimen does not complete the termination, an additional dose of misoprostol will frequently expel the remaining tissue.²⁹ Otherwise, a surgical procedure is required.

When the possibility of abortion by medication became a reality, it created enormous controversy: “Almost no pharmaceutical product has captured the public imagination with the force of mifepristone.”³⁰

Initially, predictions were both dire and ecstatic: women would run rampant, having more abortions than ever, boyfriends would slip mifepristone into their girlfriends’ tea, abortion would become simple and easy, women would have access to abortion without any medical interface and the politics of abortion would soften. Little of this set of predictions has become reality.³¹

Just as none of the provocative predictions of mifepristone have come true, neither has its promise to dramatically increase the accessibility of abortion in the United States.³² Though roughly forty percent of U.S. abortions are now completed using mifepristone,³³ obtaining abortion medication is not easy.³⁴ Though some have decried that mifepristone is, and must remain, “the moral property of women,” the potential for any woman in America to access the medication at her local pharmacy with a prescription from her regular provider—as they do with other medications—is not yet a reality in the United States.³⁵ As explained below, this is largely due to an FDA policy that limits the distribution of mifepristone.

A. Creation of the Drug

The idea for mifepristone was conceived after various studies of hormone-based contraception. Once researchers understood the role that progesterone played in pregnancy—scientists began to theorize that anti-progestins could also interrupt the embryo’s

²⁹ *Id.*

³⁰ Beverly Winikoff & Carolyn Westhoff, *Fifteen Years: Looking Back and Looking Forward*, 92 *CONTRACEPTION* 177, 178 (2015).

³¹ *Id.*

³² *See the Availability and Use of Medication Abortion*, *supra* note X.

³³ *Id.*

³⁴ *See infra* Section I.C.

³⁵ Winikoff & Westhoff, *supra* note X, at 178 (quoting Claude Evin, the then French Minister of Health).

implantation in the uterus.³⁶ Dr. Etienne-Emile Baulieu played a pivotal role in the drug's discovery, working as part of a team at the pharmaceutical company, Roussel Uclaf, to research new methods of fertility control.³⁷ Baulieu's team eventually created mifepristone and named it RU-486.³⁸

In 1982, the first clinical trial for mifepristone began in Geneva.³⁹ Nine out of the eleven women who participated in the study successfully terminated their pregnancies.⁴⁰ Additional studies were conducted to expand this research, including the first U.S. study in 1983 involving 300 research subjects in California.⁴¹ In 1988, after many successful clinical trials in France,⁴² the French government approved mifepristone (still then known as RU-486) for use as an abortifacient.⁴³ The decision was highly controversial, and Roussel Uclaf even suspended its distribution after pro-life organizations threatened the company.⁴⁴ Nevertheless, the drug re-entered the market a few days later after the French government intervened.⁴⁵ China also approved mifepristone as an abortifacient in 1988.⁴⁶ Britain and Sweden followed within a few years,⁴⁷ and the entire EU had access by 1999.⁴⁸

³⁶ Randall K. O'Bannon, *The Introduction and Use of the Abortifacient Mifepristone (RU-486) in the United States*, 24 ASS'N FOR INTERDISC. RSCH. IN VALUES AND SOCIAL CHANGES: RSCH. BULLETIN (2012).

³⁷ THE CASE FOR ANTIPROGESTINS: A REPORT OF THE REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT, REPROD. HEALTH TECH. PROJECT (RHTP) 5-6 (1992).

³⁸ Carolina J. Abboud, *The Development of Mifepristone for Use in Medication Abortions* (Aug. 8, 2017), THE EMBRYO PROJECT <https://embryo.asu.edu/pages/development-mifepristone-use-medication-abortions>.

³⁹ ÉTIENNE-ÉMILE BAULIEU & MORT ROSENBLUM, THE "ABORTION PILL": RU-486: A WOMAN'S CHOICE 16-18 (1991).

⁴⁰ *Id.*

⁴¹ THE CASE FOR ANTIPROGESTINS, *supra* note X, at 5-6; Amy D. Porter, *International Reproductive Rights: The RU 486 Question*, 18 B.C. INT'L & COMP. L. REV. 179 n.4 (1995).

⁴² Rebecca K. Kramnick, *RU 486 and the Politics of Drug Regulation in the United States and France* 25 CORNELL INT'L L.J. 677, 686 (1992).

⁴³ THE CASE FOR ANTIPROGESTINS, *supra* note X, at 7.

⁴⁴ JUDITH A. JOHNSON, CONGRESSIONAL RESEARCH SERVICE (CRS), ABORTION: TERMINATION OF EARLY PREGNANCY WITH RU-486 (MIFEPRISTONE) 1 (2001).

⁴⁵ *Id.* at 2.

⁴⁶ Winikoff & Westhiff, *supra* note X, at 177.

⁴⁷ *Id.*

⁴⁸ *Id.*

Roussel-Uclaf was hesitant to apply for new drug approval in the United States, fearing boycotts and lawsuits.⁴⁹ The risks were especially undesirable in the Bush administration, which had already tried to ban the importation of mifepristone for personal use as described in Section III below.⁵⁰ But once President Clinton entered office, his administration took the unusual step of actively recruiting the company to seek FDA approval, even helping the reluctant sponsor to negotiate licenses so that its brand would not be affected in the United States.⁵¹ In 1994, “after lengthy negotiations” with the Clinton Administration,⁵² Roussel-Uclaf “donated the rights to sell mifepristone in the United States to the Population Council, a large nonprofit group in New York City that conducts international research on reproductive health.”⁵³ The Population Council searched for large pharmaceutical companies to develop the drug, but was unsuccessful; it eventually licensed the rights to produce and distribute mifepristone to Danco Laboratories, LLC (“Danco”) in 1997.⁵⁴

B. Federal Regulation in the United States

In the United States, drug regulation is largely governed by the Food & Drug Administration (FDA). Drugs cannot be sold or distributed through interstate commerce unless they receive new drug approval from the FDA.⁵⁵ In 1996, mifepristone’s sponsor, Danco, finally submitted a new drug application (NDA) for FDA approval.⁵⁶ Later that year, the FDA sent a letter to Danco indicating that although the available evidence from abroad suggested that the drug was safe and effective, it could not approve the drug until it had final data from

⁴⁹ Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 579 (2001).

⁵⁰ See Section III; IMPORT ALERT 66-47: AUTOMATIC DETENTION OF ABORTIFACIENT DRUGS, FOOD & DRUG ADMINISTRATION (FDA) (June 6, 1989).

⁵¹ Noah, *supra* note X, at 578-79.

⁵² *Id.* at 579.

⁵³ Melody Peterson, *Abortion Pill Distributor Energized by New Mission*, N.Y. TIMES (Sept. 30, 2020), <https://www.nytimes.com/2000/09/30/us/abortion-pill-distributor-energized-by-new-mission.html>.

⁵⁴ *Id.*

⁵⁵ Greer Donley, *Regulation of Encapsulated Placenta*, 86 TENN. L. R. 225, 242 (2019).

⁵⁶ The original NDA was submitted by the Population Council; but Danco took over during the NDA process, and for ease of reference, this Article refers to Danco as the sponsor. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-08-751, APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 4 n.12 (2008), <https://www.gao.gov/assets/280/279424.pdf> [Hereinafter GAO-08-751].

a clinical trial in the United States.⁵⁷ The FDA also requested that the sponsor submit a plan on how to restrict the drug's distribution.⁵⁸

Three years later, in 1999, Danco responded to the FDA's letter and included data from a U.S. clinical trial showing that the drug was safe and effective.⁵⁹ By this time, the Clinton administration's previous enthusiasm to approve mifepristone had faded as President Clinton sought to rehabilitate his image after the scandal involving Monica Lewinsky.⁶⁰ And as Republicans now had control of the Senate, they were able to hold up the confirmation of a new FDA Commissioner for two years, only confirming Jane Henney "after receiving assurances that Dr. Henney would not actively facilitate final approval of mifepristone."⁶¹ Nevertheless, after reviewing the new information Danco had submitted, the FDA agreed that the drug was safe and effective, but "suggested a variety of unusual distribution restrictions such as making the drug available only through physicians who performed surgical abortions [who] would agree to register with the manufacturer."⁶² The FDA finally approved mifepristone in 2000 after reaching an agreement with the sponsor on the limited distribution plan, labeling, and manufacturing processes.⁶³

The FDA's initial approval of mifepristone was through the first 49 days of pregnancy.⁶⁴ It restricted mifepristone's distribution, which the agency grounded in its Subpart H authority; Subpart H allows distribution restrictions for drugs treating serious or life-threatening illnesses.⁶⁵ The sponsor objected to this classification, but "FDA concluded that termination of an unwanted pregnancy is a serious condition and that the drug can allow patients to avoid a surgical procedure."⁶⁶ The Government Accountability Office (GAO) reviewed this determination in 2008 and found it appropriate.⁶⁷ The

⁵⁷ *Id.* at 5.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Noah, *supra* note X, at 583.

⁶¹ *Id.*

⁶² *Id.* at 584; GAO-08-751, *supra* note X, at 5.

⁶³ GAO-08-751, *supra* note X, at 5.

⁶⁴ Memorandum entitled NDA 20-687 Mifeprex (mifepristone) Population Council (Sept. 28, 2000), <http://wayback.archive-it.org/7993/20170113112743/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf> [Hereinafter Mifepristone Memorandum].

⁶⁵ *Id.* at 6, 8.

⁶⁶ GAO-08-751, *supra* note X, at 6.

⁶⁷ *Id.* at 25-28.

FDA’s primary restriction was to prohibit pharmacies from distributing the drug—only qualified doctors could do so.⁶⁸ A physician was qualified only if she could “assess the duration of a pregnancy accurately,” “diagnose ectopic pregnancies,” “provide surgical intervention” or had “plans to provide such care through other qualified physicians” in the case of complications.”⁶⁹

Qualified physicians were also required to “read and underst[an]d the prescribing information of [mifepristone],” fully explain the procedure to each patient, provide them with a Patient Agreement Form and Medication Guide, ensure the patient signed the Patient Agreement Form, and agree to report any adverse events.⁷⁰ The Patient Agreement Form spelled out the risks and benefits of the drug,⁷¹ and the Medication Guide highlighted the need to follow-up with a provider to ensure complete expulsion of the pregnancy.⁷² The FDA’s original approval of mifepristone also required manufacturing and shipping controls on the drug⁷³ and the sponsor’s agreement to conduct additional studies to ensure that providers without surgical skills would have similar patient safety outcomes as those with surgical skills.⁷⁴

At the time, doctors could only distribute mifepristone in person and were required to supervise the administration of the drug—i.e., the patient was not allowed to take the drug at home.⁷⁵ Patients were also required to return to the office a few days later to take the second drug in the regimen, misoprostol, in person.⁷⁶ Finally, the drug also was given a black box warning—the most aggressive warning the FDA can require.⁷⁷ Black box warnings are typically reserved for drugs that can cause serious injury or death.⁷⁸

⁶⁸ Mifepristone Memorandum, *supra* note X, at 6, 8.

⁶⁹ *Id.* at 5-6.

⁷⁰ *Id.* at 6.

⁷¹ *Id.* at 3-4.

⁷² *Id.* at 4.

⁷³ *Id.* at 6.

⁷⁴ *Id.* at 7.

⁷⁵ *Id.* at 8.

⁷⁶ *Id.* at 2-3.

⁷⁷ 21 C.F.R. 314.

⁷⁸ The current black box warning notes, among other things, that “Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions.” *Highlights of Prescribing Information*, FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

The FDA's distribution restrictions were seen as problematic from the outset. In 2001, FDA law scholar, Lars Noah, wrote:

This degree of oversight resembles some of the restrictions imposed on Schedule II controlled substances such as methadone, but no one has suggested that mifepristone qualifies as a narcotic subject to the Controlled Substances Act, and nothing in the FDA's enabling statute explicitly authorized the imposition of such controls on access to the drug.⁷⁹

In the initial few years that mifepristone was on the market, the FDA received adverse event reports suggesting that the drug may have caused ruptured ectopic pregnancies, serious bacterial infections, and heart attacks—some of which had been fatal.⁸⁰ Adverse event reports are not conclusive evidence of cause, but can be an early sign of safety risks. As a result, the FDA sent “Dear Doctor Letters” to alert physicians of the possible risks and remind them to screen for ectopic pregnancy, among other things.⁸¹ After conducting investigations, the FDA determined that there was no causal connection between the FDA-approved use of mifepristone and fatal infections.⁸²

In 2007, Congress passed the Food and Drug Administration Amendments Act, which created the REMS program⁸³--“a drug safety program that the [FDA] can require for certain medications with serious safety concerns.”⁸⁴ The statute requires the FDA to issue a REMS if it “determines that a [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug.”⁸⁵ The statute also allows the FDA to use its deeming authority to institute a REMS for a previously approved drug if the drug was already on the market with

⁷⁹ Noah, *supra* note X, at 584.

⁸⁰ *Mifepristone Questions and Answers*, FOOD & DRUG ADMIN (last updated Apr. 17, 2002), <https://web.archive.org/web/20090720052929/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111354.htm#9>.

⁸¹ *Id.*; Letter from Danco Laboratories, LLC to Health Care Professionals Regarding Safety Information of Mifeprex (Apr. 19, 2002), https://web.archive.org/web/20050301171535/http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.PDF.

⁸² GAO-08-751, *supra* note X, at 7, 40-41.

⁸³ FDA's REMS authority was a part of the Food and Drug Administration Amendments Act, which was passed in 2007. 21 U.S.C. § 355-1.

⁸⁴ *Risk Evaluation and Mitigation Strategies*, FOOD & DRUG ADMIN., (last updated Aug. 8, 2019), <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>.

⁸⁵ 21 U.S.C. § 355-1(a)(1).

distribution limitations.⁸⁶ Given the restrictions that the FDA had already placed on mifepristone, the FDA used its deeming authority to require a REMS on the drug in 2008.⁸⁷ In response, Danco submitted a supplemental new drug application (sNDA)⁸⁸ proposing a REMS that would satisfy the agency, which the FDA accepted.⁸⁹

A REMS does not always create limitations on drug distribution; it could simply involve a communication plan, including a medication guide or required risk disclosures from the manufacturer to the provider.⁹⁰ When the FDA concludes that those basic REMS requirements are insufficient to protect patient safety, it can issue what is known as Elements to Assure Safe Use (ETASU)—a more stringent REMS that often includes limits on distribution, including restrictions on who can prescribe the drug and under what conditions.⁹¹ The FDA’s mifepristone REMS includes ETASU. Though there are only 58 REMS programs covering only 5% of all FDA-approved drugs,⁹² the vast majority (86%) also include ETASU.⁹³

⁸⁶ *Id.* at § 909(b)(1); *Questions and Answers on the Federal Register Notice on Drugs and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies*, FOOD & DRUG ADMIN. (last updated March 27, 2008), <https://www.fda.gov/regulatory-information/food-and-drug-administration-amendments-act-fdaaa-2007/questions-and-answers-federal-register-notice-drugs-and-biological-products-deemed-have-risk>.

⁸⁷ 73 Fed. Reg. 16313 (Mar. 27, 2008), <https://www.federalregister.gov/documents/2008/03/27/E8-6201/identification-of-drug-and-biological-products-deemed-to-have-risk-evaluation-and-mitigation>.

⁸⁸ To make a change to an approved drug, including the drug’s labeling, dose, or manufacturing, a manufacturer must submit a sNDA. *Drugs@FDA Glossary of Terms*, FOOD & DRUG ADMIN., (last updated Nov. 14, 2017), <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>.

⁸⁹ Letter from Dep’t of Health & Human Servs. to Danco Laboratories, LLC (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf.

⁹⁰ *What’s in a REMS*, FOOD & DRUG ADMIN. (last updated Jan. 26, 2018), <https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems>.

⁹¹ *The Availability and Use of Medication Abortion*, *supra* note X.

⁹² Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENGLAND J. MEDICINE 790, 790 (2017).

⁹³ *Approved Risk Evaluation and Mitigation Strategies (REMS)*, FOOD & DRUG ADMIN. (last visited July 7, 2020), <https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page>.

In May 2015, mifepristone’s sponsor submitted another sNDA, which proposed several changes to the administration of the drug.⁹⁴ These proposals included, among other things, “changing the dosing regimen, increasing the gestational age limit up to which [mifepristone] can be taken, and eliminating the requirement that the dose of misoprostol be administered in a medical facility.”⁹⁵ In the course of its review, the FDA also received multiple letters from academics and professional organizations requesting that the REMS be modified or eliminated.⁹⁶ In its review of the sNDA, the FDA concluded that “no new safety concerns have arisen in recent years and that the known serious risks occur rarely;” it also found that “[g]iven that the numbers of . . . adverse events appear to be stable or decreasing over time, it is likely that . . . serious adverse events will remain acceptably low.”⁹⁷

As a result, in 2016, the agency approved the sNDA. The modified approval updated the drug’s labeling and REMS in the following ways:

- It extended the gestational age for which the medication was approved for use (from 49 days to 70 days since a woman’s last missed period);
- It modified the dose regimen for mifepristone and misoprostol based on research showing improved safety and efficacy with an altered dose;
- It allowed providers who are not physicians to become certified to prescribe mifepristone; and
- It removed language requiring the drug to be taken (not just dispensed) in a healthcare facility.⁹⁸ The last requirement allowed women to only travel to a clinic once, where they could pick up the entire medication regimen and take it at home, instead of traveling to the clinic multiple times and taking the drugs at the facility.⁹⁹

Nevertheless, mifepristone is still approved under a REMS with an ETASU. The current REMS requires that (1) only certified healthcare providers¹⁰⁰ can prescribe the drug, (2) the drug can only be dispensed

⁹⁴ GAO-18-292, *supra* note X, at 2.

⁹⁵ *Id.*

⁹⁶ Joint Stipulation of Facts, *Chelius v. Azar*, No. 1:17-cv-00493-JAO-RT 11-12 (Nov. 27, 2019).

⁹⁷ *Id.*

⁹⁸ GAO-18-292, *supra* note X, at 7-8.

⁹⁹ *Id.*

¹⁰⁰ Only providers that can (a) “assess the duration of pregnancy accurately” (b) “diagnose ectopic pregnancies” and (c) “provide surgical intervention” or “have

in certain healthcare settings, and (3) patients must receive additional counseling and sign a Patient Agreement Form.¹⁰¹

The following section describes how the first and second of these requirements—the ETASU—significantly reduce access to mifepristone. The first limits the providers who can prescribe the drug. Physicians must affirmatively seek out the ability to prescribe this medication, which means that a patient cannot simply ask her regular PCP or OBGYN for a prescription, as the vast majority are not certified.¹⁰² The second requirement of the REMS—that the mifepristone can only be dispensed in certain healthcare settings—prohibits the distribution of mifepristone by mail, at a regular pharmacy, or through telehealth.¹⁰³ Rather, providers must have the drug in stock for patients and distribute it to them in person, which causes serious logistical hurdles that further disincentivize regular providers from becoming certified to prescribe the drug.¹⁰⁴ In effect, women can only access the drug by picking it up at an abortion or family planning clinic, the healthcare settings that regularly keep mifepristone in stock.

C. How These Regulations Affect Abortion Access

The mifepristone REMS has serious implications for abortion access. First, it helped prevent abortion care from entering the general practice of medicine—within the purview of any PCP or OBGYN—and has instead kept it segregated to abortion and family planning clinics. Isolating abortion care to clinics creates unnecessary stigma and logistical barriers; in many states, clinics are few and far between, making it more difficult for women to obtain care. Second, the REMS has prevented a pure model of telemedicine abortion from coming to fruition. Telemedicine has become increasingly important during the COVID-19 pandemic, but the REMS ensures that abortion access cannot adapt to the new circumstances.¹⁰⁵ I discuss both concerns

made plans to provide such care through others” are eligible for certification. REMS, *supra* note X.

¹⁰¹ *Id.*

¹⁰² REMS Study Group, *supra* note X, at 792.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ The FDA refused to suspend the mifepristone REMS during the pandemic, as it has done for other medications. *See* POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, FOOD & DRUG ADMIN. 7 n.13 (March 2020), <https://www.fda.gov/media/136317/download> (suspending multiple REMS for public health reasons, but leaving in-person dispensing requirements in place); *ACOG v. FDA*, 592 U. S. ____ (2021) (Sotomayor, J.,

below. Though the mifepristone REMS is not the only factor that has led to these outcomes—abortion stigma and antiabortion activism also play a large role—it is a necessary condition that must be addressed in order to see significant change in early abortion access.

The REMS keeps abortion separate from traditional healthcare by making it difficult or impossible for women to obtain mifepristone through their regular pharmacy after an appointment with their regular provider.¹⁰⁶ It is true that most OBGYNs and PCPs could apply for certification to dispense mifepristone,¹⁰⁷ but the practical barriers may be as effective as a prohibition.¹⁰⁸ Unlike most drugs, where physicians are granted the power to prescribe non-controlled substances through their medical license, doctors must affirmatively seek certification to prescribe mifepristone, a non-controlled substance.¹⁰⁹ Research from other settings confirms the psychological reality that simply requiring an affirmative opt-in can discourage behavior.¹¹⁰ But opting into prescribing mifepristone can also come with serious risks to the provider. Doctors reasonably worry that their certification as a mifepristone distributor could get leaked, subjecting them to harassment or violence.¹¹¹ Some doctors might be willing to provide abortions, but are hesitant to affirmatively identify as an abortion provider given the risks that come with that designation. For this reason, becoming certified to prescribe mifepristone is categorically different than seeking certification to prescribe, for instance, thalidomide—a drug used to treat multiple myeloma and leprosy that causes serious birth defects—which also requires certification under its REMS.¹¹² There is no stigma or threat of violence associated with

dissenting) (noting that mifepristone was subject to disparate treatment by the agency).

¹⁰⁶ See REMS, *supra* note X.

¹⁰⁷ Almost all physicians are qualified to seek certification. See *id.*

¹⁰⁸ See Jones & Jerman, *supra* note X, at 4 (noting the lack of physician offices that provide abortion care).

¹⁰⁹ See REMS, *supra* note X; *Controlled Substances*, DRUG ENFORCEMENT ADMIN., https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

¹¹⁰ *The Opt-Out Option*, ASSN. PSYCHOLOGICAL SCIENCE (Sept. 13, 2013), <https://www.psychologicalscience.org/news/minds-business/the-opt-out-option.html>; *Opt-in vs. Opt-out Psychology*, MEDIUM (Apr. 25, 2019), <https://medium.com/@alphaspath/opt-in-vs-opt-out-psychology-61b974e39ee2>

¹¹¹ REMS Study Group, *supra* note X, at 792 (“the expense and hassle of maintaining drug inventories as well as reluctance to be included on a list of certified abortion providers — understandable, given the long history of harassment and violence— may discourage some otherwise willing clinicians from offering medical abortion at all.”).

¹¹² *Thalomid REMS*, FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/rem/Thalomid_2017-06-27_REMS_Document.pdf.

treating those conditions. Thus, the certification requirement is less discouraging.

But much more importantly, the requirement that physicians also dispense the drug themselves creates additional reasons for doctors to avoid opting-in:

Physicians lack the setup, time and training to manage drug inventory, including maintaining stock and ensuring that expired medicines are not released. Few doctors are likely to be willing to stock this expensive medication, reported by the manufacturer to cost \$300 per dose. Physicians' offices are not usually engaged in retail sales and may not have the infrastructure to sell a medication, if sales are needed to dispense it.¹¹³

In other words, most physicians don't have the capability or infrastructure to sell and dispense medication. This is generally the purview of pharmacies.¹¹⁴ And even though the cost of mifepristone decreased after the introduction of a generic, physicians also risk losing money if they buy mifepristone that expires before a woman requests it.¹¹⁵ It would be entirely reasonable for doctors to decide they either do not want, or cannot handle, this extra responsibility.¹¹⁶ Studies show that more physicians would be willing to become certified to prescribe mifepristone if the drug could be distributed as almost all other drugs—through a pharmacy.¹¹⁷

The result is that as of 2017, it was estimated that only 261 physician offices in the United States offered abortion services (providing only 1% of abortions¹¹⁸), while 95% of abortions are provided by abortion and family planning clinics.¹¹⁹ The remainder of abortions occur in hospitals.¹²⁰ With a few exceptions, it seems like the only providers willing to become certified to prescribe mifepristone are those that already have an abortion care practice

¹¹³ Wendy V. Norman & Judith A. Soon, *Requiring Physicians to Dispense Mifepristone: an Unnecessary Limit on Safety and Access to Medical Abortion*, 188 CANADIAN MEDICAL ASS'N J. E429, E429 (2016).

¹¹⁴ *Id.*

¹¹⁵ DAVID S. COHEN & CAROLE JOFFE, OBSTACLE COURSE 223 (2020).

¹¹⁶ By simply allowing mifepristone to be distributed by a pharmacy, it is estimated that “the number of medication abortion providers among ob-gyns in the United States would likely increase from less than one-quarter of these physicians to 31 percent.” *Id.*

¹¹⁷ *Id.*

¹¹⁸ Jones, Witwer & Jerman, *supra* note X, at 16.

¹¹⁹ *Id.* at 9.

¹²⁰ *Id.* at 16.

through clinics.¹²¹ The REMS is not the only barrier that might prevent interested providers from prescribing mifepristone. Physicians would also need to become acquainted with the state laws governing abortion, which apply to medication abortion, to ensure that they do not unintentionally violate the law by, for instance, not abiding by the required waiting period or not disclosing certain state-mandated information before prescribing mifepristone.¹²² These barriers, however, can be fixed with physician outreach and education, while the REMS and similar state laws impose logistical challenges that are much more difficult to combat.

Why does it so negatively impact abortion access to create rules that disincentivize providers from prescribing mifepristone? For a few reasons. First, there are fewer providers to provide abortion care. Thus, it can be more difficult for women to find a provider and more difficult for the small number of providers to meet the demand.¹²³ Second, by isolating abortion care at abortion and family planning clinics, and preventing women from obtaining the drug at a pharmacy or through the mail, women must travel the often far distances to pick up their prescription.¹²⁴ Given that some states have only a handful of clinics left—and six states only have one—the long travel requires women to pay extra travel costs, find child care, and miss work, in addition to facing harassment from protesters.¹²⁵ This physical separation from the rest of the healthcare system not only isolates and stigmatizes abortion care,¹²⁶ but makes abortion much more difficult to obtain. I explore these issues in more detail in Section II.

Another significant barrier associated with the mifepristone REMS is that it has prevented a pure model of telemedicine from

¹²¹ See Jones & Jerman, *supra* note X, at 6.

¹²² See generally, *An Overview of Abortion Laws*, GUTTMACHER INST. (July 1, 2020) https://www.guttmacher.org/state-policy/explore/overview-abortion-laws?gclid=EAIaIQobChMIvY6L66u-6gIVIfC1Ch06UAHoEAAAYASAAEgJ6UPD_BwE# (giving an overview of abortion laws).

¹²³ See DAVID S. COHEN & KRISTEN CONNOR, *LIVING IN THE CROSSHAIRS: THE UNTOLD STORIES OF ANTI-ABORTION TERRORISM* ix-x (2015) (noting that “partly because abortion providers are not safe, there are very few abortion providers in the United States”).

¹²⁴ REMS, *supra* note X.

¹²⁵ Elizabeth Raymond et al., *TelAbortion: Evaluation of a Direct to Patient Telemedicine Abortion Service in the United States*, 100 *CONTRACEPTION* 173, 174 (2019).

¹²⁶ CAROL SANGER, *ABOUT ABORTION* 23 (2017) (“A network of rules whose purpose is to persuade pregnant women that what they are doing is wrong can make securing an abortion feel shady and crime-like. Clinics are isolated from the regular medical facilities that provide most other forms of health care”).

coming to fruition.¹²⁷ Though the REMS allowed abortion providers to use a limited telemedicine model, where patients who are physically present at a clinic can visit with a doctor who is not physically present via videoconference, the REMS still requires women to obtain mifepristone on site.¹²⁸ Even this limited telemedicine model has “increased patient choice,” “resulted in patients being seen sooner and closer to home,” and “improved access to medication abortion [] particularly for patients who lived more than 50 miles from the nearest clinic offering surgical abortion.”¹²⁹ These benefits are achieved because abortion providers, who typically live and work in larger cities, can provide care virtually without having to travel to smaller clinics in more rural areas. But imagine how much more accessible abortion could become if a woman could meet with a provider remotely from home and then have the medication either sent to her by mail or called into her local pharmacy so she would never need to travel to a family planning clinic in the first place.¹³⁰ This model is being tested with great success in thirteen states under an Investigational New Drug Application, whereby the FDA grants limited permission to use a drug off-label for the purpose of research.¹³¹

Over the course of the COVID-19 pandemic, telemedicine for abortion care quickly changed from a future dream to an urgent necessity.¹³² Not only might women delay an abortion to avoid an infection risk in a clinic, but for a while, some women were entirely unable to access a clinic.¹³³ The pandemic made travel much more difficult, especially those dependent on public transportation or those

¹²⁷ Megan K. Donovan, *Improving Access To Abortion Via Telehealth*, 22 GUTTMACHER POLICY REV. 23, 26 (2019).

¹²⁸ Julia E. Kohn et al., *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 143 OBSTETRICS & GYNECOLOGY 343, 344 (2019); Donovan, *supra* note X, at 24 (noting that this model exists in 10 states).

¹²⁹ Donovan, *supra* note X, at 24.

¹³⁰ COHEN & JOFFE, *supra* note X, at 222.

¹³¹ Pam Belluck, *Abortion by Telemedicine: A Growing Option as Access to Clinics Wanes*, N.Y. TIMES (Apr. 28, 2020), <https://www.nytimes.com/2020/04/28/health/telabortion-abortion-telemedicine.html?action=click&module=News&pgtype=Homepage>

¹³² See Laurie Sobel et al., *State Action to Limit Abortion Access During the COVID-19 Pandemic*, KAISER FAMILY FOUND. (Jun 25, 2020), <https://www.kff.org/coronavirus-covid-19/issue-brief/state-action-to-limit-abortion-access-during-the-covid-19-pandemic/> (“access is further challenged by difficulties traveling when a stay at home order is in effect, additional costs related to waiting periods and other delays, the loss of jobs, the risk of exposure to the coronavirus, and the uncertain future of the COVID-19 outbreak.”)

¹³³ *Id.*

who must travel long distances to the nearest clinic.¹³⁴ Many clinics also closed temporarily, either due to state orders or because providers could not come in; others dramatically reduced capacity to try to reduce infection risk, leading to long wait times that caused women to pass the 10-week mark entirely.¹³⁵ Women of color, rural women, and low-income women are always disproportionately harmed by disruptions to abortion care.¹³⁶ “[T]hree-quarters of abortion patients have low incomes, making them more likely to rely on public transportation to get to a clinic to pick up their medication. Such patients must bear further risk of exposure while they travel, sometimes for several hours each way, to clinics often located far from their home.”¹³⁷

Without the state and federal regulations requiring a physical presence in the office, women eligible for medication abortion could obtain an abortion through telemedicine without any infection risk for them or their provider. For these reasons, the U.K. has started allowing the remote administration of abortion medication during the pandemic, as was done in other countries, like Australia, even before the pandemic began.¹³⁸ Moreover, the FDA suspended the in-person requirements of other medications, including opioids, for public health reasons during the pandemic, but under the Trump administration, it refused to provide that same treatment to mifepristone.¹³⁹ As described in Section IV below, this led to litigation attempting to temporarily suspend the in-person dispensing requirements of the mifepristone REMS during the pandemic. After initial success at the district and appellate courts, the Supreme Court reinstated the in-person requirements pending litigation.¹⁴⁰ The Biden administration recently suspended them again throughout the duration of the public health emergency.¹⁴¹ As explored in more depth in Section IV.B, the temporary relaxation of the mifepristone REMS has already catalyzed

¹³⁴ Greer Donley, Beatrice A. Chen & Sonya Borrero, *The Legal and Medical Necessity of Abortion Care Amid the COVID-19 Pandemic*, J.L. & BIOSCIENCES (forthcoming 2020).

¹³⁵ *Id.*; Mem. Supporting Order for Preliminary Injunction, *Am. College of Obstetrics & Gynecologists v. FDA*, No. 8:20-cv-01320-TDC 13-15 (D. Md. Jul. 13, 2020).

¹³⁶ Donley, Chen & Borrero, *supra* note X; Mem. Supporting Order for Preliminary Injunction, *supra* note X, at 14-15.

¹³⁷ *ACOG v. FDA*, 592 U. S. ____ (2021) (Sotomayor, J., dissenting).

¹³⁸ Donley, Chen & Borrero, *supra* note X.

¹³⁹ See POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, *supra* note X, at 7 n.13; *ACOG v. FDA*, 592 U. S. ____ (2021) (Sotomayor, J., dissenting) (noting that mifepristone was subject to disparate treatment by the agency).

¹⁴⁰ *ACOG v. FDA*, 592 U. S. ____ (2021).

¹⁴¹ Letter from FDA to Maureen G. Phipps and William Grobman, *supra* note X.

seismic shifts in abortion care through telemedicine, which will only continue if the REMS is permanently modified or removed.

The imposition of a REMS is a dramatic tool to ensure risky drugs are prescribed and dispensed in the safest manner possible. The next section explores whether mifepristone is risky enough to warrant a REMS, and if not, whether the harms of the REMS outweigh any benefits. It concludes that mifepristone fails to meet the statutory criteria for a REMS because the benefits of the drug outweigh the risks even without any distribution limitations.

II. THE MIFEPRISTONE REMS IS UNNECESSARY, HARMFUL, AND IMPROPER UNDER THE STATUTE

The mifepristone REMS has increasingly been challenged by physician organizations, including the American Medical Association, the American College of Obstetricians & Gynecologists, and the American Academy of Family Physicians, who have all concluded that it is unnecessary.¹⁴² The benefits of the REMS are negligible, but the harms are large. Not only does the REMS reduce access to abortion throughout the United States—which can cause physical, mental, and emotional harms—and increase abortion stigma, but it may also increase a reliance on self-induced abortion, where women buy the drug illegally online without the assistance of a doctor. Women suffering from an incomplete miscarriage also have less access to the drug, even though a combination of mifepristone and misoprostol is safer and more effective than misoprostol alone.¹⁴³

A. The Benefits of the Mifepristone REMS are Negligible

As highlighted above, the safety data on mifepristone is extensive. The FDA has been tracking adverse events closely since the drug was approved in 2000. According to the drug's label, which was last modified in 2016, only 0.03-0.5% of women who took mifepristone needed a blood transfusion, only 0.2% of women

¹⁴² *Improving Access to Mifepristone for Reproductive Health Indications*, ACOG (June 2018), <https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications>; Letter to the FDA, AAFP (June 20, 2019), <https://www.aafp.org/dam/AAFP/documents/advocacy/legal/administrative/LT-FDA-REMSFlexibility-032520.pdf>; *Mifepristone*, AMA POLICY (2018), <https://policysearch.ama-assn.org/policyfinder/detail/mifepristone?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml>.

¹⁴³ *Improving Access to Mifepristone for Reproductive Health Indications*, *supra* note X.

experienced sepsis, and only 0.04-0.5% of women needed hospitalization.¹⁴⁴ The risk that someone who had taken mifepristone would make a visit to the ER was slightly higher, at 2.9-4.6%.¹⁴⁵ These adverse events are all treatable without any permanent issues.¹⁴⁶ FDA's website notes that "[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"¹⁴⁷ compared to 3.7 million women who have taken the drug.¹⁴⁸ However, these "adverse events cannot with certainty be causally attributed to mifepristone."¹⁴⁹ There is some reason, for instance, to believe that at least eleven of the deaths were unrelated to the drug.¹⁵⁰ But even assuming all twenty-four deaths were caused by mifepristone, the risk of death from the drug would be 0.65 deaths per 100,000 (or 0.00065%).¹⁵¹

The adverse events listed above are serious and should not be minimized, but all drugs have some risk of serious adverse events, and the vast majority of them are not subject to a REMS. For instance, Viagra has a fatality rate of 4 deaths per 100,000, which is six times higher than mifepristone, yet it is not subject to a REMS.¹⁵² Penicillin's fatality rate is 2 deaths per 100,000, roughly three times higher than mifepristone, but again, it is not subject to a REMS.¹⁵³ And drugs with equivalent adverse events, like misoprostol and anti-coagulants, are available at all pharmacies without a REMS.¹⁵⁴ Finally, the background risk associated with the alternative—carrying the pregnancy to term—is also much higher: "the pregnancy related mortality ratio is 18 deaths per 100,000 live births, and it is even higher for Black women—40

¹⁴⁴ Label for Mifeprex (mifepristone) tablets, FOOD & DRUG ADMIN. 8, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf

¹⁴⁵ *Id.*

¹⁴⁶ REMS Study Group, *supra* note X, at 791.

¹⁴⁷ *Questions and Answers on Mifeprex*, *supra* note X.

¹⁴⁸ *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, FOOD & DRUG ADMIN., <https://www.fda.gov/media/112118/download>

¹⁴⁹ *Questions and Answers on Mifeprex*, *supra* note X.

¹⁵⁰ *Analysis of Medication Abortion Risk and the FDA report, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"*, ADVANCING NEW STANDARDS IN REPRODUCTIVE HEALTH (April 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ Mifeprex REMS Study Group, *supra* note X, at 792.

deaths per 100,000 live births.”¹⁵⁵

Moreover, it is worth noting that mifepristone is approved without a REMS under the brand name Korlym when used to treat Cushing’s Syndrome, a condition related to exposure to excessive amounts of the hormone cortisol.¹⁵⁶ Though the agency’s risk-benefit calculus will inevitably differ when the same drug is used to treat a different condition, the risks are larger when mifepristone is used for Cushing’s Syndrome. “Korlym is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex” that is used for abortion; as a result, “the rate of adverse events with Mifeprex is much lower.”¹⁵⁷

One could always speculate that mifepristone’s safety record is so good *because of* the REMS, and therefore, the REMS is necessary. But new data suggests that is not true. In 2016, Gynuity Health Projects received an Investigational New Drug Approval to conduct a study on Telabortion—mediation abortion services offered without an in-person appointment, mailed directly to the patient’s home.¹⁵⁸ An Investigational New Drug Approval allows research to be conducted on either a non-approved drug or an approved drug like mifepristone to test a non-approved use.¹⁵⁹

According to Gynuity’s protocol, a provider meets with the patient through videoconference to discuss the regimen and obtain written consent electronically.¹⁶⁰ The provider would order a blood test and ultrasound to confirm the gestational age of the pregnancy and check the patient’s blood type; the patient would have these orders filled at a convenient location of her choice.¹⁶¹ Then, after the doctor reviews the results remotely, the medication abortion regimen would be mailed to the patient’s house and she would complete the abortion

¹⁵⁵ *Analysis of Medication Abortion Risk and the FDA report, supra* note X.

¹⁵⁶ *Improving Access to Mifepristone for Reproductive Health Indications, supra* note X.

¹⁵⁷ U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RES., MEDICAL REVIEW 62 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Me dR.pdf

¹⁵⁸ Elizabeth Raymond et al., *Telabortion: Evaluation of a Direct to Patient Telemedicine Abortion Service in the United States*, 100 *CONTRACEPTION* 173, 174 (2019).

¹⁵⁹ *Investigational New Drug (IND) Application*, FOOD & DRUG ADMIN. (last updated May 12, 2020), <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>

¹⁶⁰ Raymond et al., *supra* note X, at 174.

¹⁶¹ *Id.* It is worth noting that Gynuity has created a new protocol in light of the COVID-19 pandemic that would allow abortion medication to be dispensed without these tests if women meet certain conditions. Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol for Increasing Access During A Pandemic And Beyond*, 101 *CONTRACEPTION* 361 (2020).

at home.¹⁶² The provider would also meet with the patient over videoconference seven to fourteen days after the medication was mailed.¹⁶³ The majority of the patient population in the Gynuity study was from Hawaii, where the study began, but since then, the study has expanded to thirteen states.¹⁶⁴

Three years after the study began, Gynuity published the first set of results from their clinical trial.¹⁶⁵ One hundred and eighty-eight women completed the study; the mifepristone / misoprostol regimen was effective at fully expelling the pregnancy in 171 women (94%).¹⁶⁶ The remaining six percent (eleven women) needed a procedure to complete the abortion—although two of those eleven women did not take the mifepristone, only the misoprostol.¹⁶⁷ Only two women (1%) reported serious adverse events, including a case of severe anemia and a seizure that occurred after a procedure, although “neither event would have been averted had the abortion medications been provided in person.”¹⁶⁸ Finally, sixteen women (7%) visited the emergency room or urgent care center; though this number is higher than historical controls, nine of the sixteen women received no medical treatment there, and their visit might have been avoided “by stronger encouragement to contact the TelAbortion provider for advice before seeking unplanned in-person care.”¹⁶⁹ All participants were either satisfied (20%) or very satisfied (80%) with their experience.¹⁷⁰ The same study was conducted on over 1,000 women in Australia with similar results: the medication was effective at ending the pregnancy in 96% of the patients, 3% needed a procedure to finish the abortion, and 3% were admitted to a hospital.¹⁷¹ This data confirms the experience of other countries, like Mexico, Australia, and parts of Canada, which allow mifepristone to be filled by pharmacists without an in-person appointment.¹⁷²

¹⁶² Raymond et al., *supra* note X, at 174.

¹⁶³ *Id.*

¹⁶⁴ Raymond et al., *supra* note X, at 175; *Get Started*, TELABORTION, <https://telabortion.org/get-started>.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.* at 176.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ Paul Hyland, Elizabeth G. Raymond & Erica Chong, *A Direct-To-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis Of The First 18 Months*, AUSTRALIAN & NEW ZEALAND J. OBSTETRICS & GYNECOLOGY 335, 337 (2018).

¹⁷² Daniel Grossman & Philip Goldstone, *Mifepristone by Prescription: a Dream in the United States but Reality in Australia*, 92 CONTRACEPTION 186, 186 (2015); Sarah

The positive results of the Gynuity study are expected given that the REMS is not actually correlated with any of mifepristone's safety risks. First, the requirement that a woman obtain the drug from a medical facility does nothing to reduce her risk of hemorrhage, infection, or incomplete abortion, which would all take place at home.¹⁷³ It is worth noting that the FDA only subjects thirteen other drugs (of roughly 20,000 FDA-regulated drugs) to an ETASU that requires a patient obtain a medication in a clinic.¹⁷⁴ Of those thirteen drugs, all must be taken in the presence of a doctor because the drug requires intravenous administration, could cause an immediate adverse reaction that a physician must monitor, or is highly addictive.¹⁷⁵ None of those three justifications would apply to mifepristone, which is a single use drug, administered by the patient, that does not cause immediate adverse events. As noted by Justice Sotomayor, "mifepristone is the only [drug] that the FDA requires to be picked up in person for patients to take at home."¹⁷⁶

The District of Maryland recently found, in the context of litigation challenging the mifepristone REMS during the pandemic, that the in-person dispensing requirement is "medically unnecessary and illogical on its face: it requires patients to obtain a pill only in clinical settings, even when they are not receiving any clinical services at that time and will take the medicine at home without clinical supervision."¹⁷⁷ The Court continued, "[t]here is no other drug that the FDA treats in this manner and for evident reason: it plainly serves no medical interest to dictate where a patient is standing when handed a pill she will put in her pocket to swallow later."¹⁷⁸

Second, because almost any provider could become certified to prescribe mifepristone, the certified provider requirement is largely "an empty formality."¹⁷⁹ In fact, in the *June Medical* litigation, the state was often critical of the fact that June Medical had hired an ophthalmologist and radiologist in the past to provide medication

Raifman et al., *Medication Abortion: Potential for Improved Patient Access Through Pharmacies*, 58 J. AM. PHARMACIST ASSN. 377, 379-80 (2018).

¹⁷³ Mifeprex REMS Study Group, *supra* note X, at 792.

¹⁷⁴ Plaintiff's Motion Summary Judgement, *Chelius v. Azar*, No. 1:17-cv-00493-JAO-RT 11-12 (Nov. 27, 2019); 592 U. S. ____ (2021) (Sotomayor, J., dissenting).

¹⁷⁵ *Id.*

¹⁷⁶ 592 U. S. ____ (2021) (Sotomayor, J., dissenting).

¹⁷⁷ Mem. Supporting Order for Preliminary Injunction, *Am. College of Obstetrics & Gynecologists v. FDA*, No. 8:20-cv-01320-TDC 25 (D. Md. Jul. 13, 2020).

¹⁷⁸ *Id.* at 26.

¹⁷⁹ Mifeprex REMS Study Group, *supra* note X, at 793.

abortion.¹⁸⁰ This is not to suggest these providers cannot adequately provide medication abortion—the opposite—but to note that any healthcare provider can meet this requirement and safely provide these services. The requirement therefore provides no independent credentialing function outside of a license to practice, and therefore seems to offer no purpose other than to limit the number of providers offering early abortion care.

The final component of the mifepristone REMS—that patients must sign a Patient Agreement Form—is also unnecessary, although it doesn’t create the same issues with abortion access. Even the FDA’s own scientists recommended removing the Patient Agreement Form because it was duplicative of informed consent.¹⁸¹ Taken together, the mifepristone REMS confers marginal, if any, benefits to patients. If the REMS did not create significant harms, it may not matter that REMS is unnecessary, but as discussed below, the harms are substantial.

B. The Harms of the Mifepristone REMS are Large

The most significant harm associated with the mifepristone REMS is the reduced access to early and safe abortion. Such reduced access leads to delays in seeking care, which can force women to receive a more expensive and risky surgical abortion procedure, increase the reliance on self-managed abortion, and even risk the possibility that women may be timed out of receiving abortion care altogether by exceeding the gestational age limits of state abortion bans. Women who are unable to get an abortion must experience the much greater risks of childbirth and are more likely to have mental and physical health issues over time as a result. These harms disproportionately fall on poor women, rural women, and women of color.

As noted above, the requirements that (1) only certified providers can prescribe mifepristone and (2) the drug must be dispensed at a healthcare facility have made it undesirable for physicians who do not typically provide abortions to prescribe and dispense mifepristone. Not only must these physicians opt into a prescribing system, they must also agree to buy and sell the drug in house. Physician offices are typically not equipped to handle such drug sales, creating large disincentives for providers to become certified to

¹⁸⁰ *June Medical v. Russo*, 59 U.S. ___ (2020) (Gorsuch, *J.*, dissenting) (“Clinics have even hired physicians whose specialties were unrelated to abortion—including a radiologist and an ophthalmologist.”).

¹⁸¹ Joint Stipulation of Facts, *supra* note X, at 13-14.

dispense mifepristone.¹⁸² The result is that only 261 physician offices provided medication abortion in 2017, providing only 1% of abortions in the United States.¹⁸³ The only providers with any incentive to provide mifepristone despite the ETASU are abortion and family planning clinics, which provide 95% of abortions in this country.¹⁸⁴ Thus, the ETASU have contributed to the segregation of abortion care outside of traditional healthcare settings into separate facilities.

This reality means that the overwhelming majority of women obtain an abortion at a clinic. But the number of clinics is steadily dropping, and six states only have one abortion provider left.¹⁸⁵ From 2011 to 2014, there were six percent fewer clinics in the United States; the numbers are starker in the South and Midwest, where the number of clinics had decreased thirteen and twenty-three percent respectively.¹⁸⁶ The result is that many women do not live within 100 miles of a clinic: “27 cities with populations of 50,000 or more had no abortion clinic within a 100 mile radius.”¹⁸⁷ These long distances can make abortion care even more expensive as women must take time off work, procure childcare, and pay for travel costs.¹⁸⁸ Of course, the requirement that women physically present at a clinic is problematic even when the clinic is close: “[e]ven people who live near a clinic may have difficulty attending in person due to scheduling conflicts, long wait times for appointments, the high cost of travel, child care, and lost wages, concerns about confidentiality, and anticipated harassment at clinics.”¹⁸⁹

For these reasons, the in-person dispensing requirement causes some women to delay abortion care, which can lead to a more complicated, risky procedure.¹⁹⁰ Each week an abortion is delayed increases the risk of the procedure by 38%.¹⁹¹ Women who must travel

¹⁸² See *supra* Section I.C.

¹⁸³ Jones, Witwer & Jerman, *supra* note X, at 16.

¹⁸⁴ *Id.* at 9.

¹⁸⁵ *Id.* at 3; Holly Yan, *These 6 States Have Only 1 Abortion Clinic Left. Missouri Could Become the First with Zero*, CNN (June 21, 2019), <https://www.cnn.com/2019/05/29/health/six-states-with-1-abortion-clinic-map-trnd/index.html>.

¹⁸⁶ Jones, Witwer & Jerman, *supra* note X, at 3.

¹⁸⁷ Raymond et al., *supra* note X, at 174.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, *THE SAFETY AND QUALITY OF ABORTION CARE IN THE UNITED STATES*, 10 (2018).

¹⁹¹ Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion–Related Mortality in the United States*, 103 *OBSTETRICS & GYNECOLOGY* 729, 731 (2004).

more than fifty miles to a clinic are more likely to seek an abortion in the second trimester, and women who must travel more than three hours to a clinic are more likely to need an abortion at or after twenty weeks.¹⁹² Delayed abortions can also be more expensive and difficult to find: “If a first-trimester abortion is delayed until the second trimester, this would result in increased and perhaps prohibitive cost and access barriers, as second trimester abortions are more expensive, require more time (2-3 days), and have fewer providers able to perform them.”¹⁹³ Consequently, “delays may ultimately impede women from having an abortion procedure entirely.”¹⁹⁴

When women are denied access to an abortion, it comes at a cost to their health. In the landmark Turnaway Study, researchers compared women who had been denied abortions from those able to obtain them. They found:

Compared to women who received abortions, those who were denied abortion were more likely to experience financial distress that was sustained for years following the intended abortion. Women denied abortion also had higher rates of anxiety and stress, and lower self-esteem and life satisfaction in the short term, and were more likely to experience potentially life-threatening conditions associated with pregnancy such as preeclampsia and postpartum hemorrhage. These women were also more likely to report worse long-term physical health.¹⁹⁵

And of course, the risks associated with pregnancy and birth are higher than abortion, so any woman denied an abortion increases her risks, even if she doesn’t suffer acute pregnancy-related conditions like pre-eclampsia.¹⁹⁶

By contrast, if mifepristone could be dispensed by pharmacies, which are much more prevalent throughout the United States than clinics, women could more easily access early abortion without delays. For instance, in Australia, when the government allowed pharmacies to dispense mifepristone, early abortion access increased, especially in

¹⁹² Rachel K. Jones & Jenna Jerman, *Characteristics and Circumstances of U.S. Women Who Obtain Very Early and Second-Trimester Abortions*, 12 PLOS ONE 1, 12-13 (2017); Diana Greene Foster & Katrina Kimport, *Who Seeks Abortions after Twenty Weeks?*, 45 PERSPECTIVES SEXUAL & REPRODUCTIVE HEALTH 210, 212 (2013).

¹⁹³ Donley, Chen, Borerro, *supra* note X, at 13.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* (describing results from the Turnaway study).

¹⁹⁶ For instance, the risk of death is 14 times higher for birth than abortion. Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion And Childbirth In The United States*, 119 OBSTETRICS & GYNECOLOGY 215 (2012).

rural areas.¹⁹⁷ Early research in the United States has shown that more OBGYNs would prescribe mifepristone if it could be filled at a pharmacy.¹⁹⁸ Allowing telemedicine and medication-by-mail for early abortion care would improve access further. In Gynuity’s Telabortion study, eighty-nine percent of women in the study reported enrolling because of the “speed, convenience, lack of local options, or cost.”¹⁹⁹ Twenty-one percent reported an interest in Telabortion for the sake of “privacy or to avoid harassment.”²⁰⁰

Another underreported consequence associated with difficulties accessing abortion care is that women will turn to self-managed abortion.²⁰¹ Self-managed abortion occurs when “when a person ends a pregnancy outside the medical care setting, typically by ordering abortion pills online.”²⁰² Though recent data suggests that self-managed abortion can be safe,²⁰³ abortion care through a healthcare provider is still the gold-standard and self-management can come with legal risks. The practice has been increasing in recent years; though it is difficult to estimate the true number of self-managed abortions, eighteen percent of clinics have “reported that they had seen one or more patients for a missed or failed abortion due to self-induction . . . , up from 12% in 2014.”²⁰⁴ “The majority of these facilities (54%) had seen only one or two such patients, but four facilities (all high-volume) reported 50 or more.”²⁰⁵ Unsurprisingly, self-managed abortion is more common in areas with fewer clinics and greater abortion restrictions: “Reports of self-managed abortion were highest in the South (25%) and the West (21%), compared with 10% in the Midwest and 14% in the Northeast.”²⁰⁶ The relationship between strict abortion laws and self-managed care is also supported by “a media analysis,” which “found that interest in self-induced abortion—as measured via Google searches—was higher in states with restrictive abortion laws than in states without them.”²⁰⁷

Self-managed abortion is not legal in the United States. The only legal way to obtain the FDA-approved medication abortion

¹⁹⁷ Grossman & Goldstone, *supra* note X, at 187.

¹⁹⁸ COHEN & JOFFE, *supra* note X, at 223.

¹⁹⁹ Raymond et al., *supra* note X, at 175.

²⁰⁰ *Id.* at 175.

²⁰¹ Jones & Jerman, *supra* note X, at 2.

²⁰² *The Availability and Use of Medication Abortion*, *supra* note X.

²⁰³ *See infra* Section IV.B.

²⁰⁴ Jones, Whitwer & Jerman, *supra* note X, at 8.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ Jones & Jerman, *supra* note X, at 2.

regimen is through the REMS protocol.²⁰⁸ Even if the REMS were removed, FDA-approved drugs require the prescription of a provider unless the FDA has approved them for over-the-counter use.²⁰⁹ The same is true for misoprostol, which some women use on its own to try to terminate a pregnancy because it is easier to access without a REMS. (Though women can safely and effectively terminate a pregnancy with misoprostol alone, misoprostol combined with mifepristone is more effective and has fewer side-effects.²¹⁰)

Nevertheless, women have found ways to order these drugs online from international sources. And in 2018, an international organization, Aid Access, began helping American women access medication abortion through international pharmacies by mail with the assistance of a doctor.²¹¹ A woman who contacts Aid Access will have an online consultation with a doctor abroad; if the physician decides medication abortion would be safe, she will prescribe the medication, which is filled by a pharmacy in India and mailed to the patient.²¹² In 2018, over 11,000 U.S. women requested Aid Access's help, and the organization filled 2,500 of those requests.²¹³ The following year, 21,000 U.S. women requested care from Aid Access, and more than a third were provided medication.²¹⁴ On March 8, 2019, the FDA issued a warning letter to Aid Access that its actions violated the Food, Drug & Cosmetic Act.²¹⁵ Nevertheless, the organization has refused to stop offering its services to American women.²¹⁶

Though there is no evidence that self-managed abortion is

²⁰⁸ Catherine Shaffer, *REMS Violations Fines*, 27 NATURE BIOTECHNOLOGY 1068, 1068 (2009).

²⁰⁹ Megan K. Donovan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, 21 GUTTMACHER POLICY R. 41, 44 (2018) [Hereinafter *Self-Managed Abortion*].

²¹⁰ Nguyen Thi Nhu Ngoc et al., *Comparing Two Early Medical Abortion Regimens: Mifepristone+Misoprostol vs. Misoprostol Alone*, 83 CONTRACEPTION 410, 410 (2011).

²¹¹ Jones, Whitwer & Jerman, *supra* note X, at 10.

²¹² *Letter to the Food & Drug Administration*, AIDACCESS 2 (May 16, 2019), https://aidaccess.org/en/media/inline/2019/5/16/19_05_16_gomperts_letter_and_exhibit_a.pdf.

²¹³ Jones, Whitwer & Jerman, *supra* note X, at 10; *Who Are We*, AIDACCESS, <https://aidaccess.org/en/page/561>.

²¹⁴ COHEN & JOFFE, *supra* note X, at 226.

²¹⁵ *Warning Letter to Aid Access*, FOOD & DRUG ADMIN. (March 8, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019>.

²¹⁶ *Letter to the Food & Drug Administration*, *supra* note X; *Who Are We*, *supra* note X.

unsafe,²¹⁷ the FDA has in other contexts loosened regulations when they caused consumers to seek care outside of the traditional healthcare system, presumably with greater health risks. For instance, when there was a risk that patients might attempt fecal transplants on their own outside of the medical setting, the FDA loosened the regulations on them to make it easier to access within in the medical context.²¹⁸ Moreover, there are some notable cases that highlight possible legal and medical risks when the medication is obtained without any physician involvement. For instance, in 2013, Purvi Patel purchased medication abortion online through a pharmacy in Hong Kong without any medical consultation.²¹⁹ Because Patel had underestimated the length of her pregnancy, the medication caused her to deliver a live baby at home, who died shortly after birth, and Patel needed urgent medical attention at the hospital.²²⁰ Some studies have suggested that patients' underestimation of a pregnancy's length is uncommon; for instance, only 1% of medication abortion patients who were certain that their last missed period had started less than seventy-eight days ago were proved wrong on ultrasound.²²¹ But still, there may be reasons that the FDA would prefer abortion to occur under the guidance of a U.S. doctor, and "there is widespread agreement that those attempting an abortion on their own should have access to a trusted provider if questions arise."²²²

Moreover, even if the health risks of self-managed abortion are small, there are serious legal risks. Purvi Patel was prosecuted in Indiana and sentenced to thirty years in prison for feticide and felony neglect of a minor.²²³ She served two of those years before an appellate court invalidated part of her conviction and sentenced her to time served.²²⁴ Jennie McCormack and Kenlissia Jones similarly used medication abortion to terminate pregnancies outside the ten week window, and were also prosecuted when they delivered a much older fetus.²²⁵ And Jennifer Whalen was sentenced to eighteen months in jail

²¹⁷ See *infra* Section IV.B; *Letter to the Food & Drug Administration*, *supra* note X (noting that Aid Access is not aware of any serious adverse event); *Self-Managed Medication Abortion*, *supra* note X.

²¹⁸ *Id.*

²¹⁹ *Patel v. State*, 60 N.E.3d 1041, 1043 (Ind. Ct. App. 2016).

²²⁰ *Id.* at 1046-47.

²²¹ Raymond et al., *supra* note X, at 363.

²²² COHEN & JOFFE, *supra* note X, at 228.

²²³ *Patel*, 60 N.E.3d at 1044.

²²⁴ *Id.* at 1062.

²²⁵ *Woman Who Took Abortion Pill Charged in Death of Fetus*, CBS NEWS (June 9, 2015), <http://www.cbsnews.com/news/woman-who-took-abortion-pill-charged-in-death-of-fetus/>.

after purchasing abortion medication for her sixteen year old daughter online.²²⁶ Though her pregnancy was within the ten-week window, Whalen and her daughter went to the Emergency Room after her daughter started to feel stomach pain and the hospital staff reported them to the police.²²⁷ Of course, the legal risks associated with medication abortion almost always impact women of color disproportionately.²²⁸

As described above, in the age of COVID-19, the REMS also creates unnecessary infection risks that are associated with in-person care. Up until recently, the consistent public health message has been for individuals to stay home as much as possible and to socially distance.²²⁹ By requiring women and providers to come into a clinic to prescribe and dispense a medication that can easily be mailed to patients or distributed by a pharmacy, the FDA created transmission risks that were easily avoided. At a time when the entire U.S. healthcare system started adapting to telehealth, the REMS prevented abortion care from modernizing.

Finally, the REMS does not only burden abortion access, but also access to the best protocol for miscarriage management. Miscarriage occurs when a fetus or embryo dies independently in the womb.²³⁰ Though the body typically expels a dead fetus or embryo, it can take time for the body to register the death, and thousands of women every year learn on ultrasound that their pregnancy has ended before having any symptoms of miscarriage.²³¹ In those cases, women can often choose whether they want to have the fetus or embryo removed or to wait for the miscarriage to end naturally, which can take weeks or longer.²³² Many women understandably do not want to prolong their suffering or grief and opt to have the fetus or embryo

²²⁶ Emily Bazelon, *A Mother in Jail for Helping Her Daughter Have an Abortion*, N.Y. TIMES (Sept. 22, 2014), <https://www.nytimes.com/2014/09/22/magazine/a-mother-in-jail-for-helping-her-daughter-have-an-abortion.html>.

²²⁷ *Id.*

²²⁸ Ushma D. Upadhyay et al, *Sociodemographic Characteristics of Women Able to Obtain Medication Abortion Before and After Ohio's Law Requiring Use of the Food and Drug Administration Protocol*, 2.1 HEALTH EQUITY 122, 124 (2018).

²²⁹ Janice Hopkins Tanne, *Covid-19: Women's Health Campaigners Sue FDA Over Access to Medical Abortion Pills*, BMJ (2020), <https://doi.org/10.1136/bmj.m2187>; *ACOG v. FDA*, 592 U. S. ____ (2021) (Sotomayor, J., dissenting).

²³⁰ *Missed or Incomplete Miscarriage*, MISCARRIAGE ASSN., <https://www.miscarriageassociation.org.uk/information/information-on-coronavirus-covid-19/missed-or-incomplete-miscarriage-information-for-you/>.

²³¹ *Id.*

²³² *Id.*

removed.²³³ This can occur surgically or with medication.²³⁴ When women choose medication, they are typically only given misoprostol, even though recent research suggests that the combination of mifepristone and misoprostol would be more effective.²³⁵ But because of the REMS, it is impossible for this regimen to be adopted into regular clinical care, harming women experiencing miscarriage as well as those who need abortion.²³⁶ Section IV further explores the impact that using mifepristone for miscarriage could have on de-stigmatizing abortion care.

Though the benefits of the mifepristone REMS are marginal at best, the risks are significant. As explored below, this suggests that mifepristone does not meet the statutory standard for imposing a REMS because the benefits of mifepristone outweigh the risks without one. And because the REMS is particularly burdensome on patients in rural or underserved areas, and is not commensurate with how the agency treats similar drugs, it is especially unwarranted.

C. Mifepristone Fails to Meet the Statutory Standard for a REMS

The FDA may demand a REMS only if it “determines that a [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug.”²³⁷ When the FDA issues a REMS with an ETASU as it has done with mifepristone, the standard is higher and requires the agency to determine that the drug “is associated with a serious adverse drug experience” and that the ETASU is necessary to “to mitigate a specific serious risk listed in the labeling of the drug.”²³⁸ Furthermore, the statute requires the ETASU be “commensurate with the specific serious risk listed in the labeling of the drug;” “not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas);” and “conform with elements to assure safe use for other drugs with similar, serious risks.”²³⁹

It is unlikely that mifepristone should be subject to any

²³³ *Id.*

²³⁴ *Id.*

²³⁵ Schreiber et al., *supra* note X.

²³⁶ *Id.*

²³⁷ 21 U.S. Code § 355–1(a).

²³⁸ *Id.* at § 355–1(f)(1).

²³⁹ *Id.* at § 355–1(f)(2).

REMS—as demonstrated above, the REMS does not reduce the risks of the drug, so by definition, it cannot be necessary to “ensure that the benefits of the drug outweigh the risks.”²⁴⁰ And the benefits of mifepristone are much larger than the risks, even without the REMS. For one, mifepristone benefits women by helping them avoid the greater medical risks associated with pregnancy and childbirth.²⁴¹ This alone would ensure that the benefits of the drug outweigh the risks, and was the basis for FDA’s original approval. But even beyond those therapeutic benefits, mifepristone also helps women exercise their constitutional and human right to control the number and spacing of their children.²⁴² It therefore serves important mental health, civil rights, and public health benefits, which the FDA should also consider in its risk-benefit calculus.²⁴³

But even assuming a REMS could be appropriate, the FDA would surely fail to meet the statutory requirements of an ETASU. First, the restrictions are not “commensurate with the specific serious risks listed in the labeling of the drug.”²⁴⁴ As argued above, the REMS requirements are divorced from the drug’s risks. The certification requirement serves no credentialing function, and the in-person dispensing requirement does not reduce any risks associated with the drug, which will all occur at home where the drug is taken.²⁴⁵ Studies have shown that mifepristone and misoprostol are very effective at expelling a pregnancy with a low risk of serious adverse events even without an in-person dispensing requirement.²⁴⁶ Moreover, the Patient Agreement Form is iterative of informed consent; a review team within the agency even recommended removal of this part of the REMS in 2016 for the same reason, but the FDA Commissioner overruled this determination.²⁴⁷

Second, the ETASU for mifepristone does not “conform with

²⁴⁰ See Raymond et al., *supra* note X.

²⁴¹ REMS Study Group, *supra* note X, at 791.

²⁴² See *Reproductive Rights*, UNITED NATIONS, <https://www.un.org/en/development/desa/population/theme/rights/index.asp>; *Roe v. Wade*, 410 U.S. 113 (1973).

²⁴³ Though FDA typically focuses on therapeutic benefits, Patricia Zettler has documented the FDA’s recent trend of considering non-therapeutic benefits as well, including public health and cosmetic benefits. See Patricia J. Zettler, Margaret Foster Riley & Aaron S. Kesselheim, *Implementing a Public Health Perspective in FDA Drug Regulation*, 73 FOOD & DRUG L. J. 221 (2018); See Patricia J. Zettler, *The FDA’s Power Over Non-Therapeutic Uses of Drugs and Devices*, WASH & LEE L. R. (forthcoming 2021).

²⁴⁴ 21 U.S. Code § 355–1(f)(2).

²⁴⁵ See Section II.

²⁴⁶ Raymond et al., *supra* note X, at 175; Hyland, Raymond & Chong, *supra* note X, at 335.

²⁴⁷ Joint Stipulation of Facts, *supra* note X, at 13-14.

[ETASU] for other drugs with similar, serious risks.”²⁴⁸ Other drugs with similar, serious risks, like misoprostol, do not have a REMS at all; drugs that are riskier, like Viagra and penicillin, also don’t have a REMS.²⁴⁹ And much riskier drugs, like opioids, actually have much more lenient ETASUs.²⁵⁰ Even though opioids are highly addictive and have caused tens of thousands of fatalities *per year* from overdoses, the REMS only requires that opioid manufacturers offer training to healthcare providers that prescribe opioids.²⁵¹ The FDA acknowledges that “[t]here is no mandatory federal requirement that prescribers or other HCPs take the training and no precondition to prescribing or dispensing opioid analgesics to patients.”²⁵²

But most importantly, the mifepristone REMS is “unduly burdensome on patient access to the drug,” especially “patients in rural or medically underserved areas.”²⁵³ It is well documented that travel time to an abortion or family planning clinic delays care and reduces access to abortion.²⁵⁴ The mifepristone REMS effectively requires this travel to occur. Of note, in Gynuity’s Telabortion study, “[m]ore than half of the participants lived more than 150 miles from the project sites or on a Hawaiian island without an abortion clinic, suggesting that the TelAbortion option filled an evident need.”²⁵⁵ The same phenomenon occurred in the Telabortion study in Australia, where “60% of women who received abortion drugs from the Foundation lived in regional and remote communities.”²⁵⁶

Furthermore, the FDA’s record for explaining the need for the REMS is thin. The agency at no point has provided explanation for how mifepristone meets the statutory definition for a REMS—i.e., how a REMS is necessary to ensure the benefits of the drug outweigh the harms.²⁵⁷ In 2016, the agency gave four potential justifications for the in-person dispensing requirement: (1) patients might not be

²⁴⁸ 21 U.S. Code § 355–1(f)(2).

²⁴⁹ See Section II.

²⁵⁰ *Risk Evaluation and Mitigation Strategy (REMS) Document, Opioid Analgesic REMS Program*, FOOD & DRUG ADMIN. (Sept. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/rem/s/Opioid_Analgesic_2019_11_14_REMS_Document.pdf.

²⁵¹ *Id.*

²⁵² *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, FOOD & DRUG ADMIN. (Sept. 2018), <https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems>.

²⁵³ 21 U.S. Code § 355–1(f)(2).

²⁵⁴ See Section I.C.

²⁵⁵ Raymond et al., *supra* note X, at 176.

²⁵⁶ Hyland, Raymond & Chong, *supra* note X, at 339.

²⁵⁷ See Joint Stipulation of Facts, *supra* note X

properly counseled at a pharmacy about what to do if they experience an adverse event, (2) patients may not pick up the prescription quickly, leading to inappropriate use (i.e., taking the drug outside of the first nine weeks), (3) some pharmacies might refuse to stock the drug, also leading to delays, and (4) patient confidentiality could be threatened at a pharmacy.²⁵⁸

These explanations are invalid. First, as with all medications, informed consent laws require doctors to properly inform patients of risks, so patients should know what to do if they experience an adverse event long before arriving at the pharmacy. Second, the REMS does not eliminate the risks associated with delays in care as women can easily pick up the mifepristone at a clinic and then delay taking it by days or weeks at home. Third, pharmacies are able to protect patient confidentiality on all sorts of drugs; mifepristone should not be any different. And finally, though it is true that some pharmacies might choose not to stock the drug, this does not justify making it impossible for women to obtain the drug from the pharmacies that would, or by mail through telemedicine.

This Section argued that the mifepristone REMS is improper, has few benefits, and significant harms. It also demonstrated that the statutory basis for issuing a REMS with ETASU is not met. So why would the FDA have required it? Abortion exceptionalism. The political controversy surrounding mifepristone clouded the FDA's judgment. I argue below that the FDA's decision is a part of a larger pattern of bias from the agency that has harmed women's health. Though reproductive rights are political, the FDA should not be. Rather, the agency should be bound by its scientific mission.

III. THE FDA'S TROUBLING PATTERN OF DEVALUING WOMEN'S HEALTH

Though the mifepristone REMS may seem like an outlier, the FDA in fact has a troubling history of implicit bias that harms women, especially when considering reproductive health.

FDA has shown particular vulnerability to sociopolitical influences on matters of women's health. The agency displays a number of biases that distort scientific analysis, from normative judgments about women's sexuality to a patronizing sense that women require heightened protection against the risks posed

²⁵⁸ *Id.* at 19-20.

by otherwise effective drugs.²⁵⁹

Below, I describe many instances in which the FDA has acted unusually with regard to women's health. Some of these instances were overturned by court order or statute; others resolved only after a public awareness campaign launched. In almost all cases, advocates attacked the FDA's decisions by showing unusual treatment compared to other products. Such a comparison is almost always needed to show bias as any one decision, when viewed in isolation, may not necessarily seem problematic.

A. Plan B

The most famous instance of gender bias at the FDA occurred in its regulation of Plan B. The FDA approved Plan B as emergency contraception in 1999.²⁶⁰ Two years later, a group of sixty-six organizations petitioned the FDA to approve the drug for over-the-counter use.²⁶¹ Obtaining over-the-counter approval was incredibly important for a time-sensitive drug like Plan B—without it, women and girls could only access Plan B after a doctor's appointment that resulted in a prescription. This could easily cause days of delays, which threatened the efficacy of the medication. Plan B works best when women can pick up the drug quickly and easily within twenty-four hours (or, at most, three days) after unprotected sex.²⁶²

The FDA rejected the switch to over-the-counter, even though its experts recommended approval; this led to a GAO investigation, which found that FDA's decision was atypical.²⁶³ In 2006, the FDA agreed to allow over-the-counter sale of Plan B, but limited its approval to adult women “despite nearly uniform agreement among FDA scientific review staff that women of all ages could use Plan B without a prescription safely and effectively.”²⁶⁴ The manufacturer objected to the restriction that prevented women under 18 from purchasing Plan B over-the-counter, and sued the agency under the Administrative

²⁵⁹ Mara Sanders, *Sex, Drugs, and Advisory Committees: An Analysis of Pharmaceutical Industry Manipulation of FDA Vulnerability to Sociopolitical Influences on Matters of Women's Health*, 48 COLUM. HUM. RTS. L. REV. 149, 150 (2017).

²⁶⁰ *Tummino v. Torti*, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).

²⁶¹ The Plan B sponsor also submitted a formal sNDA seeking the same over-the-counter approval. *Id.* at 526-27.

²⁶² *Tummino*, 603 F. Supp. 2d at 522.

²⁶³ GOVERNMENT ACCOUNTABILITY OFFICE, GAO-906-109, FOOD AND DRUG ADMINISTRATION DECISION PROCESS TO DENY INITIAL APPLICATION FOR OVER-THE-COUNTER MARKETING OF THE EMERGENCY CONTRACEPTIVE DRUG PLAN B WAS UNUSUAL 5-6 (2005), <https://www.gao.gov/new.items/d06109.pdf>.

²⁶⁴ *Tummino*, 603 F. Supp. at 523.

Procedures Act.

The first time this case made it to court, the Eastern District of New York found that the agency's decision-making with regard to Plan B was contaminated with "political considerations, delays, and implausible justifications."²⁶⁵ The court also determined that the "FDA's course of conduct regarding Plan B departed in significant ways from the agency's normal procedures regarding similar applications to switch a drug product from prescription to non-prescription use."²⁶⁶ In particular, the court was alarmed that the FDA disregarded an expert panel and its own staff, who had determined Plan B would be safe for women and girls of all ages over the counter.²⁶⁷ As a result, the court held that the FDA had acted arbitrarily and capriciously.²⁶⁸ The court remanded back to the agency to reconsider its decision regarding access to Plan B, noting that because the new Obama administration had replaced the FDA Commissioner, it expected that the new leadership would ensure that fair scientific review would occur.²⁶⁹

Three years later, the FDA agreed to approve Plan B for over-the-counter use for all ages. The agency concluded that:

[T]he product was safe and effective in adolescent females, that adolescent females understood the product was not for routine use, and that the product would not protect them against sexually transmitted diseases. Additionally, the data supported a finding that adolescent females could use Plan B One-Step properly without the intervention of a healthcare provider.²⁷⁰

Though this would have ordinarily put the matter to rest, the Secretary of the Department of Health & Human Services, which oversees the FDA, overruled the Commissioner's decision.²⁷¹ The Secretary ordered the Commissioner to deny the sNDA on the grounds that "the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages."²⁷² The Commissioner's main objection was that the data did not adequately

²⁶⁵ *Id.*

²⁶⁶ *Id.*

²⁶⁷ *Id.* at 545-46.

²⁶⁸ *Id.* at 545.

²⁶⁹ *Id.* at 549.

²⁷⁰ *Tummino v. Hamburg*, 936 F. Supp. 2d 162, 166-67 (2013).

²⁷¹ *Id.* at 167.

²⁷² *Id.*

take into account the “significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age.”²⁷³ President Obama agreed.²⁷⁴

The petitioners sued again, and the court for a second time held that the agency—this time, HHS—acted arbitrarily and capriciously in denying the sNDA.²⁷⁵ The court again relied on the unusual political involvement in what should have been a scientific decision.²⁷⁶ The court noted that it was the first time the Secretary had overruled the Commissioner on a drug approval matter,²⁷⁷ and concluded that the Secretary’s rationale was “so unpersuasive as to call into question her good faith.”²⁷⁸ The court relied on the fact that less safe drugs were available over-the-counter with no age restrictions: “levonorgestrel-based contraceptives would be probably among the safest drugs approved for over-the-counter sale for the pediatric population.”²⁷⁹ The *New England Journal of Medicine* published an opinion, cited by the court, which argued the agency’s denial “cannot be based on issues of safety, since a 12-year-old can purchase a lethal dose of acetaminophen in any pharmacy for about \$11, no questions asked. The only documented adverse effects of a \$50 dose of levonorgestrel are nausea and delay of menses by several days.”²⁸⁰ The court also described the evidence that the prescription requirement for adolescents would delay and even prevent young women and girls from “accessing the drug within the short time frame during which it will be effective, thereby exposing them to increased risk of unwanted pregnancy and making the product’s limited OTC status useless.”²⁸¹

As a result, the court remanded to the agency, ordering it to approve the sNDA and allow over-the-counter sale of Plan B to women and girls of all ages.²⁸² Though the court acknowledged the political reasons why Plan B was controversial, it noted that its role was quite simple: “the issue in this case involves the interpretation of a general statutory and regulatory scheme relating to the approval of drugs for over-the-counter sale. The standards are the same for aspirin

²⁷³ *Id.*

²⁷⁴ *Id.* at 167-68.

²⁷⁵ *Id.* at 197.

²⁷⁶ *Id.* at 170.

²⁷⁷ *Id.*

²⁷⁸ *Id.* at 171.

²⁷⁹ *Id.* at 173-74.

²⁸⁰ *Id.*

²⁸¹ *Id.* at 168.

²⁸² *Id.*

and for contraceptives.”²⁸³ The Obama administration decided not to appeal the decision and instead comply with the order. But the lengthy plan B drama had lost the FDA and HHS a great deal of credibility.²⁸⁴ “Plan B is an excellent example of what happens when the public health standard is replaced by a public morality standard that has not been determined by a democratic process through the appropriate government institutions.”²⁸⁵

B. Importation of Mifepristone for Personal Use

Long before mifepristone was approved as an abortifacient and subject to a REMS, the FDA had treated it as special. In the decade or so where the drug was approved in European countries, but not the U.S., some American women attempted to import mifepristone for their personal use under the personal use exemption.²⁸⁶ Though the FDA bans the sale of unapproved drugs, in 1989, it created the personal use exemption.²⁸⁷ The exemption was born out of the HIV / AIDS crisis, during which time the FDA sought creative solutions to allow access to treatments not approved in the United States without sacrificing their rigorous drug approval process.²⁸⁸ Under the exemption, individuals could import small quantities of drugs for personal use under the supervision of a physician if the drug was used to treat conditions that were life-threatening, serious, or less serious conditions where the product “is not known to represent a significant health risk.”²⁸⁹ Quickly thereafter, members of Congress complained to the FDA that mifepristone (then known as RU 486) could be permitted under this exemption, and the FDA issued Import Alert 66-47, which stated that RU 486 was subject to automatic detention because it “could pose a risk to the safety of the user.”²⁹⁰

In 1992, Leona Benton returned to the U.S. after a trip abroad with a small amount of mifepristone, which had been prescribed by

²⁸³ *Id.* at 169.

²⁸⁴ For instance, medical journals declaring that the government was prioritizing politics over science. *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101, 102 (Jan 12, 2012).

²⁸⁵ John H. Fielder, *Ethics and FDA*, 61 FOOD & DRUG L.J. 809, 810 (2006).

²⁸⁶ Elizabeth A. Silverberg, *Looking Beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to Ru 486?*, 59 BROOK. L. REV. 1551, 1557-58 (1994).

²⁸⁷ *Id.* at 285.

²⁸⁸ *Id.*

²⁸⁹ *Id.*

²⁹⁰ *Id.* at 286.

her doctor to end an early pregnancy.²⁹¹ She was detained and the drug was seized.²⁹² She sued under the Administrative Procedures Act.²⁹³ The district court granted her motion for preliminary injunction on the grounds that she was likely to show that the agency failed to follow the required notice and comment procedures in issuing the import letter.²⁹⁴ Though not central to the court's analysis, it nevertheless noted that the agency's determination was politically motivated and inconsistent with its treatment of other drugs: "it appears much more likely from the history outlined above that the decision to ban the drug was based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."²⁹⁵ It ordered the FDA to "immediately release the impounded dosage of RU486 to plaintiff."²⁹⁶

On appeal, the Second Circuit stayed the injunction. Benton filed an application to vacate the stay, which the Supreme Court denied in a per curiam opinion with no analysis.²⁹⁷ Scholars have suggested that the FDA's decision was as politically motivated as its decision over Plan B: "What RU-486 and Plan B have in common, however, is that both were very controversial FDA decisions because of their connection (or perceived connection, in the case of Plan B) to abortion. In addition, the FDA appears to have deviated from its standard procedures in regard to both."²⁹⁸ "[T]he FDA appears to have responded to political pressure rather than a public health mandate when it issued its import alert on RU-486."²⁹⁹

On November 19, 1990, the House of Representatives called a hearing to consider the appropriateness of the FDA's decision.³⁰⁰ There, many scientists testified that they believed the FDA's decision was politically motivated, and harmed not only women, but also

²⁹¹ *Id.* at 1551.

²⁹² *Id.* at 1552.

²⁹³ *Benten v. Kessler*, 799 F. Supp. 281 (E.D.N.Y. 1992).

²⁹⁴ *Id.* at 289.

²⁹⁵ *Id.* at 286.

²⁹⁶ *Id.* at 291.

²⁹⁷ *Benten v. Kessler*, 505 U.S. 1084, 1085 (1992).

²⁹⁸ Gillian E. Metzger, *Abortion, Equality, and Administrative Regulation*, 56 EMORY L.J. 865, 878 (2007).

²⁹⁹ Reichertz & Friend, *supra* note X, at 520.

³⁰⁰ RU486: The Import Ban and its Effects on Medical Research, Hearings Before the Subcommittee on Regulation, Business Opportunities and Energy of the House Committee on Small Business, 101st Cong., 2d Sess. (Nov. 19, 1990), <https://babel.hathitrust.org/cgi/pt?id=pst.000017583336&view=1up&seq=5>.

researchers' ability to find other clinical uses for the drug.³⁰¹ For instance, a representative from the American Public Health Association testified: "The FDA should be making their decisions based on scientific fact, pure and simple. If you allow the FDA to become politicized as it seems to be in this case, then their credibility and the credibility of our Government and country suffers dramatically, and the American people will end up suffering."³⁰²

On President Clinton's third day in office, he ordered the FDA to reconsider the policy, noting that "RU-486 has been held hostage to politics."³⁰³ His order stated that "the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug."³⁰⁴ "[I]f the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47."³⁰⁵

C. Female Sex Drugs

The FDA was again accused of bias when it refused to approve the female sex drug, flibanserin, which was used to treat hypoactive sexual desire disorder in women.³⁰⁶ Flibanserin was touted as the "pink Viagra," a pill that could help women increase their sexual interest.³⁰⁷ In 2010, the FDA first declined to approve the drug.³⁰⁸ The agency concluded that the eligibility criteria for the clinical trials were too restrictive, and therefore not generalizable; it found that more data was needed to demonstrate the product was effective and safe.³⁰⁹ It also required more data on the drug's interactions with other substances, including alcohol.³¹⁰ After the failed FDA review, the pharmaceutical company sponsoring the NDA decided to cancel the project instead

³⁰¹ *Id.* at 31.

³⁰² *Id.* at 33.

³⁰³ Noah, *supra* note X, at 578 (quoting President Clinton).

³⁰⁴ Memorandum of January 22, 1993, Importation of RU-486, 58 Fed. Reg. 7459 (1993).

³⁰⁵ *Id.*

³⁰⁶ Jessica Leber, *The "Female Viagra" Is Here: The Story Of How It Almost Never Happened*, FASTCOMPANY (Aug. 18, 2015), <https://www.fastcompany.com/3049926/the-female-viagra-is-coming-the-story-of-how-it-almost-never-happened>.

³⁰⁷ *Id.*

³⁰⁸ *Id.*

³⁰⁹ Sanders, *supra* note X, at 190.

³¹⁰ *Id.*

of conducting more clinical trials.³¹¹

Instead, a small pharmaceutical company, Sprout, bought the rights to the drug and decided to invest in it.³¹² The company conducted fourteen new clinical trials, composed of over 3,000 women (in addition to the 8,000 women who had participated in the initial clinical trials).³¹³ The results were modest, but positive—“[o]n average, women on the drug had 0.5 to 1 additional sexually satisfying events per month (from a 2 to 3 ‘event’ baseline) compared to those on a placebo.”³¹⁴ Sprout resubmitted its NDA in 2013, but the FDA again found that more data was needed.³¹⁵ This time, the FDA expressed concerns about the marginal benefit of the drug and the drug’s safety, especially if used with alcohol.³¹⁶

At that point, Sprout helped launch a public interest campaign, called Even the Score, which was run by members of congress and a dozen women’s advocacy groups.³¹⁷ The goal was to demonstrate that the FDA’s decision reflected bias—the group frequently noted that Viagra was associated with much more serious health risks, but was approved much more quickly.³¹⁸ “I think there’s been some unconscious bias at the FDA and an overly protective mentality about the risks women are allowed to undertake when it comes to sexual health, especially compared to men.”³¹⁹ The FDA rejected claims that gender bias was influencing its decision.³²⁰

Sprout eventually applied for approval a third time, and an advisory committee met in 2015 to review the drug again.³²¹ Sprout relied on the same efficacy data from the previous trials, but submitted additional data related to the drug’s safety with alcohol. At that meeting, the FDA heard testimony from individuals who supported the approval of the drug, including individuals affected by the disorder and women’s rights advocates generally.³²²

³¹¹ Leber, *supra* note X.

³¹² *Id.*

³¹³ *Id.*

³¹⁴ *Id.*

³¹⁵ *Id.*

³¹⁶ Sanders, *supra* note X, at 190-91.

³¹⁷ Leber, *supra* note X.

³¹⁸ *Id.*

³¹⁹ *Id.*

³²⁰ Sanders, *supra* note X, at 177.

³²¹ *Id.* at 173.

³²² *Id.* at 177-78.

These speakers often spoke in the language of the women's reproductive rights movement, stressing a woman's right to sexual autonomy and implying that a rejection of flibanserin would be an intolerable imposition of patronizing sexual norms in a treatment decision that should be made privately between a patient and her doctor.³²³

The testimony also “implied both that the FDA had patronizingly over-assessed risks that women were capable of evaluating with their doctors, and also undervalued the problem of female sexual dysfunction.”³²⁴ Two women’s health advocates, however, also testified against approval of the drug, arguing that the drug’s risks were not worth its modest benefits.³²⁵ These speakers accused Even the Score of “an unprecedented misinformation campaign that hijacked the feminist movement to pressure the FDA to approve a risky drug for a diagnosis of dubious legitimacy.”³²⁶

This time, the advisory committee voted to approve the drug. Though it found the benefits marginal, they were statistically significant and clinically meaningful.³²⁷ However, the FDA remained concerned about the drug’s interaction with alcohol.³²⁸ Though Sprout had conducted a study on the interaction of the drug with alcohol, it surprisingly included almost all men.³²⁹ As a result, the committee recommended a REMS.³³⁰ The initial REMS only allowed certified providers to prescribe the drug, but after negotiations with the agency in the years following approval, the ETASU was removed; now, the REMS only includes a medication guide that informs women of the drug’s risks, especially with regard to alcohol.³³¹ More recent data appears to suggest, however, that the drug is both effective and safe to use with alcohol.³³²

³²³ *Id.* at 184.

³²⁴ *Id.* at 186.

³²⁵ *Id.* at 187, 189.

³²⁶ *Id.* at 189.

³²⁷ *Id.* at 193.

³²⁸ *Id.*

³²⁹ *Id.*

³³⁰ *Id.* at 195.

³³¹ *Flibanserin REMS*, FOOD & DRUG ADMIN. (last updated Oct. 2019), <https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=350>.

³³² James A. Simon et al., *Effects of Alcohol Administered with Flibanserin in Healthy Premenopausal Women: A Randomized, Double-Blind, Single-Dose Crossover Study*, 17 J. SEXUAL MEDICINE 83 (2020). *Sprout Pharma Says Data Supports Efficacy of Addyi, the Female Viagra?*, WRAL TECHWIRE (March 5, 2020),

D. Medical Research involving Women and Female Animals

In addition to bias in approving products, the FDA has been attacked for its role in excluding women from medical research. Historically, medical research was conducted primarily in men, after which the results were considered generalizable to both sexes.³³³ This approach has been condemned over the past seventy-five years as research mounted that “women are not just smaller men: male and female bodies differ down to a cellular level.”³³⁴ Women and men are afflicted by different diseases, respond to different treatments, and experience different side effects in response to drugs.³³⁵ The exclusion of women from medical trials has therefore led to a dearth of research on how to treat women most effectively.³³⁶

Women were historically excluded from medical research on the grounds that their menstrual cycles introduced too much variability into the data.³³⁷ Of course, it is this very difference that demonstrates the need to study both sexes; if women’s bodies are too different from men’s bodies, then their drug response could be too.³³⁸ It also led to the unfortunate reality that diseases affecting women were hardly ever studied.³³⁹ In the wake of *Roe v. Wade*, the FDA decided to explicitly exclude all women of childbearing potential from participation in early-phase medical research.³⁴⁰ “The vocal pro-life community, galvanized in the wake of the U.S. Supreme Court’s 1973 *Roe v. Wade* decision, expressed concern for the unborn fetuses by pushing for stringent

<https://www.wraltechwire.com/2020/03/05/sprout-pharma-says-data-supports-efficacy-of-addyi-the-female-viagra/>.

³³³ CAROLINE CRIADO PEREZ, INVISIBLE WOMEN: DATA BIAS IN A WORLD DESIGNED FOR MEN 199 (2019).

³³⁴ *Id.*; R. Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS U. L.J. 135, 140 (1993).

³³⁵ CRIADO PEREZ, *supra* note X, at 198-99.

³³⁶ *Id.*

³³⁷ *Id.* at 202.

³³⁸ MAYA DUSENBERY, DOING HARM: THE TRUTH ABOUT HOW BAD MEDICINE AND LAZY SCIENCE LEAVE WOMEN DISMISSED, MISDIAGNOSED, AND SICK 32 (2018).

³³⁹ CRIADO PEREZ, *supra* note X.

³⁴⁰ FDA was also likely motivated to ban women of childbearing age from research after the thalidomide scandal, where a drug that was initially thought of as safe ended up causing over 10,000 birth defects. CRIADO PEREZ, *supra* note X, at 201.

limits on women’s research participation.”³⁴¹ The FDA’s over-inclusive and ultimately harmful decision bowed to political pressure and codified the presumption of the male norm in medical research.³⁴²

In the late 1980s and early 1990s, “a coalition of women’s health advocates, biomedical researchers, and lawmakers came up with a strategy to put this knowledge gap on the public’s radar.”³⁴³ In 1992, the Government Accountability Office (GAO) issued a report, titled “Women’s Health: FDA Needs to Ensure More Study of Gender Differences in Prescription Drug Testing,” which found that more than 60% of drugs did not enroll a representative sample of women in their clinical trials.³⁴⁴ In 1993, President Clinton signed the NIH Revitalization Act, which required all NIH-funded studies to include women and minorities.³⁴⁵ Thereafter, the FDA abandoned its policy excluding women of child-bearing age from research and started to encourage drug companies to include a representative sample of women in all clinical trials.³⁴⁶ In the FDA’s *mea culpa*, it admitted that its previous policy had been “rigid and paternalistic” and may have led to “a paucity of information about the effects of drugs in women.”³⁴⁷

By 2001, GAO issued another report, which found significant improvement, but also areas of concern.³⁴⁸ For instance, GAO noted that the FDA lacked any system to track the inclusion of women in research and did not evaluate sex differences in its review process.³⁴⁹ The lack of analysis into sex differences means that the inclusion of women is not leading to the information that matters: “it’s been twenty-five years and we now have a lot of research that includes

³⁴¹ Christine Grady & Colleen Denny, *Research Involving Women*, in THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 409 (Ezekiel J. Emanuel, Christine Grady, Robert A. Crouch, Reidar K. Lie, Franklin G. Miller & David Wendler eds., 2008); see also Charles R. McCarthy, *Historical Background of Clinical Trials Involving Women and Minorities*, 69 ACAD. MED. 695, 696 (1994) (“The highly emotional abortion debate, including its connotations, had a chilling effect on research involving women of childbearing potential and human fetuses.”).

³⁴² *Id.*

³⁴³ DUSENBERY, *supra* note X, at 24.

³⁴⁴ GOVERNMENT ACCOUNTABILITY OFFICE, GAO-93-17, WOMEN’S HEALTH: FDA NEEDS TO ENSURE MORE STUDY OF GENDER DIFFERENCES IN PRESCRIPTION DRUG TESTING 2-3 (1992), <https://www.gao.gov/assets/220/216966.pdf>.

³⁴⁵ DUSENBERY, *supra* note X, at 33.

³⁴⁶ *Id.*

³⁴⁷ *Id.*; Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 51 Fed. Reg. 39406, 39406 (1993).

³⁴⁸ *Id.* at 3-4

³⁴⁹ *Id.* at 4.

women but women are still invisible.”³⁵⁰ “[I]nclusion is one thing, analysis is something else[,] [a]nd that’s not there yet.”³⁵¹ After a request from Congress in 2012, the FDA acknowledged this lack of analysis remained a problem, and in 2014, released a twenty-seven-point action plan to “enhance the collection and availability of demographic subgroup data” for underrepresented populations, including women.³⁵²

These policy changes have unfortunately not translated to serious gains. In 2015, the director of the women’s health research center at Yale Medical School noted that “progress has been painfully slow—stalling for long periods or sometimes reversing direction—and, consequently, not nearly enough progress has been made.”³⁵³ The FDA has been criticized for doing nothing to improve women’s participation in clinical trials “apart from dropping the policy that actively excluded them.”³⁵⁴ Beyond women, the FDA still does not require pre-clinical studies to include female animals or cell lines,³⁵⁵ and many researchers still use exclusively male animals and cell lines in their research.³⁵⁶ This is despite the fact that sex differences in female animals and cells can also lead to different outcomes in research.³⁵⁷ As a result, some have questioned: “how many treatments have women missed out on because they had no effect on the male cells on which they were exclusively tested?”³⁵⁸ Researchers who focus exclusively on male cells and male animals are missing possible medical breakthroughs for women’s health.

E. Labeling Regulations in Pregnancy

³⁵⁰ DUSENBERY, *supra* note X, at 36 (quoting Dr. Jan Werbinski, executive director of the Sex and Gender Women’s Health Collaborative); Charo, *supra* note X, at 151.

³⁵¹ *Id.* at 37 (quoting Phyllis Greenberger).

³⁵² *Id.*; FOOD & DRUG ADMIN., FDA ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY DEMOGRAPHIC SUBGROUP DATA (2014), <https://www.fda.gov/media/89307/download>.

³⁵³ DUSENBERY, *supra* note X, at 33.

³⁵⁴ *Id.* at 34.

³⁵⁵ See *Guidance Document: M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals*, FOOD & DRUG ADMIN. (Oct 17, 2019) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/m3r2-nonclinical-safety-studies-conduct-human-clinical-trials-and-marketing-authorization>.

³⁵⁶ CRIADO PEREZ, *supra* note X, at 206.

³⁵⁷ *Id.*

³⁵⁸ *Id.* at 207.

Another area where the FDA has shown bias is in its regulations governing the labeling of drugs for use in pregnancy. Research in pregnant women has been almost non-existent, creating a dearth of information about how pregnant women metabolize drugs.³⁵⁹ Pregnant women are not just women with bigger bellies: “Pregnancy-related changes in the gastrointestinal tract, the cardiovascular system, the kidneys, and other organs may profoundly alter the ways that drugs are processed by the body (pharmacokinetics) or the ways that drugs act on the body (pharmacodynamics).”³⁶⁰ For instance, a pregnant woman’s blood volume increases by 50% during pregnancy, which can have a huge impact on how her body metabolizes drugs.³⁶¹

The FDA’s involvement here is related to its labeling regulations, where the agency has historically over warned pregnant women about drug risks to their detriment.³⁶² Before 2015, the FDA required all drugs to be categorized as either A, B, C, D, or X, which was supposed to help pregnant women understand a drug’s safety during pregnancy.³⁶³ Category A is the safest; a drug only received Category A status if there were clinical trials in pregnant women that failed to show additional risks.³⁶⁴ Because it was so hard to conduct clinical trials in pregnant women, very few drugs were able to meet this standard. But “[e]ven if a drug [was] able to gain Class A status—a status only 0.7% of drugs hold—the drug label [was required to] contain a warning against taking the drug unless doing so is clearly needed.”³⁶⁵ This warning was exclusively required in the pregnancy context; even though the FDA can never rule out drug risks for any population, the FDA does not recommend any other population avoid pharmaceuticals that were shown to be safe in clinical trials.³⁶⁶ This labeling requirement stood in stark contrast to the labeling requirements for pediatric use, where the FDA does not require labeling to discourage use even when there are known risks or no available data about whether drugs are safe for use in kids. Thus, “the FDA permits drugs that are known to be risky to children to contain

³⁵⁹ Greer Donley, *Encouraging Maternal Sacrifice: How Regulations Governing the Consumption of Pharmaceuticals During Pregnancy Prioritize Fetal Safety Over Maternal Health and Autonomy*, 39 N.Y.U. R. L. & SOCIAL CHANGE 45 (2015).

³⁶⁰ Anne Drapkin Lyerly, Margaret Olivia Little & Ruth Faden, *The Second Wave: Toward Responsible Inclusion of Pregnant Women in Research*, 1 INT’L J. FEMINIST APPROACHES TO BIOETHICS 8 (2008).

³⁶¹ F. Hytten, *Blood Volume Changes In Normal Pregnancy*, 14 CLINICAL HAEMATOLOGY 601, 601 (1985).

³⁶² See Donley, *supra* note X.

³⁶³ *Id.* at 69-70.

³⁶⁴ *Id.*

³⁶⁵ *Id.* at 70.

³⁶⁶ *Id.* at 70-71.

less precautionous labeling than drugs tested in pregnant women without any demonstration of risk.”³⁶⁷

The pregnancy labeling regulations also “focused exclusively on fetal (as opposed to maternal) risks from drug consumption.”³⁶⁸ This created the result that “[w]arnings for fetuses are much more protective than those for children; yet pregnant women, who are also susceptible to increased drug risks, received no warnings for their own safety.”³⁶⁹ By ignoring maternal harms, the FDA sent the clear message that fetal risks were more important than maternal risks, and that “only legitimate factors in drug consumption are fetal risk and benefit.”³⁷⁰

And though the pregnancy labeling was always required to recommend that pregnant women avoid drugs during pregnancy—which as noted, was an unnecessary, unusual, and paternalistic—the labeling “failed to present information on the risks associated with drug avoidance.” This is a problem because women can experience serious complications when they avoid needed drugs in pregnancy too, harming both themselves and their babies.³⁷¹ For instance, the recommendation to avoid anti-depressants in pregnancy can lead to premature birth, fetal growth restriction, and increased drug and substance abuse in pregnancy, among other complications.³⁷² Thus, the risks pregnant women faced from both taking drugs and avoiding drugs was never disclosed because the FDA regulations only cared about fetal risks. Finally, the pregnancy regulations were the only instance that the FDA required the labeling to display animal data, which can be highly unreliable, even when data in pregnant women existed.³⁷³

After great criticism, the FDA finalized a rule that updated its labeling requirements for use in pregnancy, which were phased in from 2015-2020.³⁷⁴ The new regulations were an improvement: they eliminated the drug categories, required the disclosure of risks to both the pregnant woman and her fetus, required the risks of untreated medical conditions to be displayed, and removed the blanket statement encouraging women to avoid drug use.³⁷⁵ Nevertheless, the modified regulations continue to rely on animal data over objections from

³⁶⁷ *Id.* at 71-72.

³⁶⁸ *Id.* at 73.

³⁶⁹ *Id.*

³⁷⁰ *Id.* at 81.

³⁷¹ *Id.* at 57.

³⁷² *Id.*

³⁷³ *Id.* at 73-75.

³⁷⁴ *Id.* at 49.

³⁷⁵ *Id.* at 76-78.

toxicologists, even low-quality animal data.³⁷⁶

* * *

In each of the cases described above, the FDA showed bias and exceptionalism that harmed women’s health. Though each one might seem like an isolated incident, their aggregate demonstrates that the agency has a blind spot. It either allows politics to override science, or fails to see how its decisions downgrade the needs of women. The mifepristone REMS is another instance where the FDA is failing to follow its own mandate. In the next section, I describe the various avenues for challenging the mifepristone REMS. I then explore the future of abortion care without the mifepristone REMS, arguing that its removal has the potential to desegregate early abortion care away from clinics, which would increase access to early abortion care and reduce the violence and harassment that patients and providers experience at clinics. These benefits would only be realized in states without their own laws limiting medication abortion use; abortion access in conservative states, however, might still be improved through easier access to self-managed abortion.

IV. REMOVAL OF THE REMS WILL TRANSFORM ABORTION CARE

The mifepristone REMS is unnecessary, harmful, and not supported by the statute. It reflects a history of bias at the FDA related to women’s health. The good news is that it is likely to be released or substantially modified in the near term under the Biden administration. This Section first describes the current state of the effort to remove the REMS, which started as a legal challenge under the Trump administration, but has moved to a direct request with the agency under Biden.

This Section then concludes with an exploration of how early abortion care will be transformed if the REMS is removed or substantially modified. The impact of the REMS removal will be bifurcated—conservative states with their own laws limiting the use of medication abortion might not see much of a change in their legal abortion model. In liberal states, however, early abortion will look completely different than it did a year ago. In these states, early abortion care will move out of clinics and into telehealth, which will dramatically improve access to early abortion and reduce the violence and harassment of abortion patients and providers. These benefits would be felt even if *Roe v. Wade* is limited or overturned. And regardless of where a woman lives, the removal of the REMS would

³⁷⁶ *Id.* at 78-80.

allow mifepristone to be used for additional gynecological purposes, like miscarriage management, which would in turn, reduce the stigma associated with the drug. Finally, we can also expect to see a rise in illegal, self-managed abortion in conservative states once mifepristone becomes easier to access in other parts of the country.

A. Paths Toward Removing the Mifepristone REMS

Under the Trump administration, the only path to remove the REMS was through litigation. In 2017, the ACLU launched the first challenge attempting to invalidate the REMS. The case, *Chelius v. Azar*,³⁷⁷ is ongoing—though currently stayed—in the District of Hawaii. It is based on two separate legal theories: first, that the mifepristone REMS creates an undue burden in violation of the Fourteenth Amendment, and second, that the agency acted arbitrarily and capriciously in instituting the REMS. I briefly explain these theories below, but neither are likely to be successful under the current Supreme Court. Nevertheless, there is a way to remove the REMS directly without the involvement of Congress or the courts—the sponsor can submit a modification request to the agency, catalyzing a reevaluation process. Once President Biden took office, this became the new strategy and the Biden administration is currently re-evaluating the REMS. I describe that process below.

1. *Constitutional Challenge*

The most common way litigants invalidate abortion laws is under the Due Process Clause—specifically, they argue that the law constitutes an undue burden under *Planned Parenthood v. Casey*.³⁷⁸ An abortion law is unconstitutional under this standard when it has “the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.”³⁷⁹ In *Whole Woman’s Health v. Hellerstadt*, the Court strengthened the undue burden standard by requiring that the law’s benefits outweigh its burdens.³⁸⁰ Relying on *Whole Woman’s Health* or similar balancing tests, some lower courts have held that laws similar to the REMS create an undue burden. For instance, the Iowa Supreme Court in 2015 found a state regulation requiring physicians to perform a physical exam and be physically present when dispensing abortion medication was unconstitutional

³⁷⁷ *Chelius v. Azar*, No. 1:17-cv-00493-JAO-RT 11-12 (Nov. 27, 2019).

³⁷⁸ 505 U.S. 833, 836–38 (1992).

³⁷⁹ *Id.* at 877.

³⁸⁰ *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2309 (2016).

under the state constitution, using a balancing test.³⁸¹ And the year before, the Ninth Circuit granted a preliminary injunction that prevented Arizona from requiring that mifepristone be prescribed only according to its label, relying on a balancing test.³⁸²

But in *June Medical v. Russo*, Chief Justice Roberts penned a concurrence, effectively overruling the balancing test from *Whole Woman's Health*.³⁸³ Instead, he indicated that he would utilize a less rigorous version of the undue burden standard in future cases because he thought the balancing test was inconsistent with *Planned Parenthood v. Casey*.³⁸⁴ In his view, the proper undue burden standard only looks to the law's burdens and questions whether they are undue—not the law's benefits.³⁸⁵ Because Justice Roberts's vote is now necessary to invalidate any abortion restriction, his perspective matters enormously. Thus, the reasoning in these earlier cases is inconsistent with the Supreme Court's current understanding of abortion precedent.

The impact of the newly composed Supreme Court on abortion restrictions was on display in *ACOG v. FDA*—the case concerning the FDA's failure to temporarily suspend the in-person dispensing requirements of the mifepristone REMS during the COVID-19 pandemic. *ACOG v. FDA* is the first abortion case Justice Barrett participated in and was largely thought to signal the Court's receptivity to the *Chelius* case. Before *ACOG v. FDA* reached the Supreme Court, the District of Maryland had temporarily invalidated the in-person dispensing requirements associated with the mifepristone REMS.³⁸⁶ The district court, relying on *Whole Woman's Health* before *June Medical* had been decided, found that:

Forcing a patient to travel in person to a hospital, clinic, or medical office to pick up a pill she will swallow unsupervised at home offers no medical benefit. And, in the present circumstances, any conceivable benefit is far outweighed by the burdens it imposes on patients

³⁸¹ *Planned Parenthood of the Heartland, Inc. v. Iowa Bd. of Med.*, 865 N.W.2d 252, 254 (Iowa 2015).

³⁸² *Planned Parenthood Arizona v. Humble*, 753 F.3d 905 (9th Cir. 2014). Though *Humble* was decided before *Whole Woman's Health*, the Ninth Circuit had already adopted a balancing test like the one relied on *Whole Woman's Health*. *Id.* In the Western District of Texas, a similar law was not invalidated because the court did not use a balancing test. *See Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 951 F. Supp. 2d 891, 905 (W.D. Tex. 2013).

³⁸³ *June Medical Services v. Russo*, 591 U.S. __ (2020) (C.J. Roberts, concurring).

³⁸⁴ *Id.*

³⁸⁵ *Id.*

³⁸⁶ Mem. Supporting Order for Preliminary Injunction, *Am. College of Obstetrics & Gynecologists v. FDA*, No. 8:20-cv-01320-TDC 25 (D. Md. Jul. 13, 2020) (citing *Whole Woman's Health*, 136 S. Ct. at 2309).

seeking care: needless exposure to the severe risks of illness and death associated with COVID-19.³⁸⁷

The district court also sustained an equal protection challenge, noting that the FDA is “irrationally requiring mifepristone prescribers to dispense pills to their patients onsite during the COVID-19 pandemic while otherwise facilitating clinicians’ ability to avoid unnecessary in-person visits in accordance with their professional judgment.”³⁸⁸ The court relied on evidence that the FDA had loosened the REMS requirements for other drugs that served an actual medical purpose during the pandemic, including for dangerous drugs like opioids, while refusing to loosen the mifepristone REMS.³⁸⁹

The Supreme Court reversed the preliminary injunction.³⁹⁰ The majority did not issue reasoning; rather, the short order only contained a brief concurrence by Chief Justice Roberts and a dissent by Justice Sotomayor that Justice Kagen joined.³⁹¹ This outcome in *ACOG v. FDA* is certainly a bellwether for how the Court might have ruled in the *Chelius* case. It is unlikely that the Court would overrule the mifepristone REMS whole cloth as constituting an undue burden in *Chelius* if it were not even willing to allow a lower court to relinquish the in-person dispensing requirements under the same theory in a global pandemic. “[B]y allowing the FDA to enforce in-person requirements for mifepristone during the pandemic, the Court heavily-handedly insinuates that these same requirements would be acceptable in a non-pandemic world.”³⁹² Perhaps more importantly, at a time where the Supreme Court is expected to overturn or gut *Roe v. Wade* in the near future, there is little hope that it would use that doctrine to affirm abortion rights in this case.

2. *Arbitrary and Capricious Challenge*

Given the current Supreme Court and the expected hostility it will have to future constitutional challenges to abortion regulation,

³⁸⁷ *Id.* at 25.

³⁸⁸ *Id.* at 29.

³⁸⁹ *Id.* at 29-30.

³⁹⁰ *ACOG v. FDA*, 592 U. S. ____ (2021). Justice Roberts relied on deference to the agency, finding that the case did not concern the undue burden standard. *Id.* (Roberts, C.J., concurring).

³⁹¹ *Id.*

³⁹² Jareb A. Gleckel & Sheryl Wulkan, *Abortion and Telemedicine: Beyond COVID-19 and the Shadow Docket*, UC Davis L. Rev. Online (Forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3801124&dgcid=ejournal_htmlmail_women;gender:the:law:ejournal_abstractlink.

administrative law may be a more promising route. As Gillian Metzger noted in 2007, “[a]dministrative law does not offer the permanent protections of constitutional law and can be quite deferential to administrative determinations. Nonetheless, administrative law’s requirements of explanation and reasoned decisionmaking may in the end offer the greatest protection against regulations that single out abortion for disfavored treatment.”³⁹³

There is solid evidence that the FDA has acted arbitrarily and capriciously in subjecting mifepristone to a REMS. An agency’s decision is generally considered arbitrary and capricious under the Administrative Procedures Act when the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”³⁹⁴ Similarly, an agency acts illegally when “it announces and follows—by rule or by settled course of adjudication—a general policy” and then commits “an irrational departure from that policy (as opposed to an avowed alteration of it).”³⁹⁵ In other words, the agency must follow its own standards and fairly assess the evidence in applying those standards.

In the Plan B litigation described above, the court invalidated the agency’s refusal to grant over-the-counter status to Plan B for minor girls because it failed to follow its own procedures and practices.³⁹⁶ The FDA’s history of bias and political involvement in reproductive health decisions should increase the skepticism regarding its decision here. “[W]here the agency has demonstrated undue bias” towards particular interests, “[m]ore exacting scrutiny” under the APA is “particularly useful.”³⁹⁷ As Metzger noted, “[o]ften what triggers greater scrutiny is judicial perceptions of perceived agency arbitrariness, expansion of power, or improper influences.”³⁹⁸ She continues: “Inconsistent agency actions in addressing abortion or reproduction issues similarly may trigger greater judicial scrutiny. Such inconsistency not only raises the impression of arbitrary administrative action, but it also suggests that the agency’s stated rationale is not what is actually

³⁹³ Metzger, *supra* note X, at 869.

³⁹⁴ *Id.* at 899.

³⁹⁵ *INS v. Yang*, 519 U.S. 26, 117 S.Ct. 350, 136 L.Ed.2d 288 (1996).

³⁹⁶ *Tummino*, 936 F. Supp. at X.

³⁹⁷ *Nat’l Res. Defense Council, Inc. v. Sec. & Exchange Comm’n*, 606 F.2d 1031, 1049 n.23 (D.C. Cir. 1979).

³⁹⁸ Metzger, *supra* note X, at 900.

motivating its actions.”³⁹⁹

This Article has demonstrated that the evidence supports a showing that the FDA irrationally departed from its standards when it issued the mifepristone REMS.⁴⁰⁰ But there is nevertheless reason to doubt that this line of attack would ultimately prove successful, at least in the Supreme Court.

The outcome of any abortion case is likely to be influenced by the values and ideologies of the judges hearing the case. Though the *ACOG v. FDA* case did not lodge an arbitrary and capricious challenge, it is still unlikely that the Court would affirm the agency’s decision to limit distribution during a pandemic, but refuse it during normal times. Second, overruling agency action can be a tall task. Courts can highlight ample precedent that supports deference for agencies, especially for decisions that depend on an interpretation of scientific data.⁴⁰¹ In fact, Chief Justice Roberts’s concurrence in *ACOG v. FDA* used this reasoning to find “that courts owe significant deference to the politically accountable entities with the ‘background, competence, and expertise to assess public health.’”⁴⁰² This position may not be popular with the rest of the conservative wing of the Court, which has spent years attempting to weaken deference to administrative agencies,⁴⁰³ but it could nevertheless provide an easy justification to allow the Court to maintain the mifepristone REMS while simultaneously appearing politically neutral. As explored below, this presumptive deference to the FDA would also make it difficult for a future anti-abortion litigant to successfully challenge the Biden administration’s decision to release or significantly weaken the mifepristone REMS after a reasoned decision.

3. *Submit a Modification Request to the Agency*

Under the Trump Administration, litigation was the best hope for invalidating the mifepristone REMS—there was no chance that a Trump-appointed FDA Commissioner would have allowed the agency to loosen an abortion restriction. Indeed, we saw the agency fight to

³⁹⁹ *Id.*

⁴⁰⁰ *See supra* Section X.

⁴⁰¹ Metzger, *supra* note X, at 903-04 (“It is important not to oversell the potential of administrative law as a constraint on abortion restrictions. While offering a basis for searching scrutiny, administrative law also puts strong emphasis on deferring to agency expertise and policy choices, an emphasis reflected (among other ways) in ostensibly deferential standards of review.”)

⁴⁰² *ACOG*, 592 U.S. at 2 (Roberts, C.J., concurring).

⁴⁰³ Joshua Matz, *The Imminent Demise of Chevron Deference?*, TAKE CARE (June 21, 2018), <https://takecareblog.com/blog/the-imminent-demise-of-chevron-deference>.

keep the REMS in the middle of a deadly pandemic when it was otherwise temporarily suspending other medications' REMS.⁴⁰⁴ But with Biden's 2020 victory, activists shifted their approach to working directly with the agency to re-evaluate the REMS.

The President historically has only been able to affect abortion rights indirectly, but “mifepristone offer[s] the federal government a direct and significant occasion for affecting the availability of abortion and, with it, the balance of power between pro-choice and pro-life forces.”⁴⁰⁵ By modifying the mifepristone REMS, President Biden can give the progressive women's groups who supported his candidacy a win while also promoting “science and truth” as he has promised.⁴⁰⁶ Moreover, first-trimester abortion is supported by a majority of Americans (60%), and he could reasonably argue that loosening the mifepristone REMS will reduce reliance on the less popular second-trimester abortion.⁴⁰⁷

The Biden administration clearly has some of this in mind, as he has already taken steps to alter the mifepristone REMS. First, on April 12, 2021, the FDA sent a letter to the CEO of the American College of Obstetricians and Gynecologist (ACOG) and the President of the Society for Maternal-Fetal Medicine indicating that it would use its enforcement discretion to stop enforcing the in-person dispensing requirement during the COVID-19 pandemic.⁴⁰⁸ In reaching its decision, the agency reviewed evidence gathered while litigation had paused the in-person dispensing requirements over the summer of 2020; the agency concluded that the “studies do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic.”⁴⁰⁹ It also found “no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to” the adverse events reported over the same time period for mifepristone.⁴¹⁰ The agency explicitly allowed the

⁴⁰⁴ POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, *supra* note X.

⁴⁰⁵ Noah, *supra* note X, at 573.

⁴⁰⁶ Bill Barrow & Seth Borenstein, *Biden Says His Advisers Will Lead With 'Science and Truth'*, ABC NEWS (Jan. 18, 2021), <https://abcnews.go.com/Technology/wireStory/correction-biden-science-story-75329323>.

⁴⁰⁷ Lydia Saad, *Trimesters Still Key to U.S. Abortion Views*, GALLUP (June 13, 2018), <https://news.gallup.com/poll/235469/trimesters-key-abortion-views.aspx>.

⁴⁰⁸ Letter from FDA to Maureen G. Phipps and William Grobman (April 12, 2021), <https://www.aclu.org/letter/fda-response-acog-april-2021>.

⁴⁰⁹ *Id.*

⁴¹⁰ *Id.*

medication to be dispensed by mail during the pandemic.⁴¹¹ As a result, ACOG agreed to dismiss its case against the agency.⁴¹² The FDA’s decision brought its application of the mifepristone REMS in line with the agency’s handling of other REMS during the pandemic, where in-person requirements were suspended.⁴¹³

Even more recently, the FDA indicated that it was reconsidering the mifepristone REMS more broadly. On May 7, 2021, the FDA jointly filed with the plaintiffs a motion to stay the *Chelius* case pending a review of the REMS.⁴¹⁴ As a reminder, the *Chelius* case was filed before the pandemic and challenged the REMS on due process and administrative law grounds. The joint motion noted that “FDA is reviewing the elements of the REMS for Mifeprex and its approved generic, Mifepristone Tablets, 200 mg, in accordance with the REMS assessment provisions of Section 505-1 of the Federal Food, Drug, and Cosmetic Act.”⁴¹⁵ The parties agreed that “the outcome of FDA’s review of the REMS could have a material effect on the issues before this Court.”⁴¹⁶ They requested that the stay remain in place until December 1, 2021.⁴¹⁷ The judge immediately granted the stay.⁴¹⁸

The process of modifying a REMS involves the FDA reviewing new evidence, typically submitted from the sponsor, which would create “adequate rationale” for a change.⁴¹⁹

The rationale may include, but is not limited to, the reason(s) why the proposed modification is necessary; the potential effect of the proposed modification on how the REMS addresses the serious risk(s) for which the REMS was required, on patient access to the drug,

⁴¹¹ *Id.*

⁴¹² Joint Motion to Stay Pending Agency Review, *Chelius v. Becerra*, NO. 1:17-00493 JAO-R (May 7, 2021), <https://www.aclu.org/legal-document/joint-motion-stay-case-pending-agency-review>.

⁴¹³ See POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, *supra* note X at 7. The FDA under the Trump administration had issued a guidance document indicating that it would stop enforcing the in-person requirements of most REMS, but that document implicitly excluded mifepristone in a footnote. *Id.* at n.13.

⁴¹⁴ *Id.*

⁴¹⁵ *Id.*

⁴¹⁶ *Id.*

⁴¹⁷ *Id.*

⁴¹⁸ Order Granting Joint Motion To Stay Case Pending Agency Review, *Chelius v. Becerra*, NO. 1:17-00493 JAO-R (May 7, 2021).

⁴¹⁹ RISK EVALUATION AND MITIGATION STRATEGIES: MODIFICATIONS AND REVISIONS, GUIDANCE FOR INDUSTRY, FOOD & DRUG ADMIN. 12 (June 2020), <https://www.fda.gov/media/128651/download>.

and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change.⁴²⁰

The FDA has also committed to conducting an independent literature review and considering the evidence submitted by the *Chelius* plaintiffs, which includes providers and organizations that promote abortion rights.⁴²¹ Once all this evidence is gathered, the Division of Risk Management (D-RISK) will review it and issue a decision within 180 days.⁴²² In that time, the FDA could convene an advisory committee—an independent committee of experts—to provide preliminary recommendations to the agency about how to proceed.⁴²³ An advisory committee could help the agency de-politicize the process and cover its bases with an eye toward future litigation. Not only would there be evidence from the FDA’s scientists that the REMS could be safely removed or modified, but an outside group of experts as well.

Assuming the FDA does decide to remove or modify the mifepristone REMS, it would be difficult for anti-abortion activists to successfully challenge that decision in litigation. Without a doubt, these activists will sue the agency to try to get the decision overturned on administrative law grounds. But their lawsuit will be unlikely to succeed. The FDA’s decision would be realigning mifepristone with its treatment of similar drugs, ending the kind of special treatment that gave rise to a strong arbitrary and capricious challenge in *Chelius*. If the FDA is following the proper procedures for releasing or modifying the REMS, and its scientists conclude based on the best scientific evidence (perhaps bolstered by an advisory committee opinion) that the release or modification of the REMS is justified, then it would be difficult to argue that the scientific agency acted improperly by listening to scientists. Due to the high-profile nature of the decision, it will be vital for the FDA to take the time to ensure that its decision follows the proper procedures perfectly and documents the scientific evidence. Any procedural misstep will likely be used to invalidate the decision.

This is not to say it would be impossible for a motivated court to find fault with the FDA’s decision to remove the mifepristone REMS. Antiabortion activists have argued since the FDA approved mifepristone in 2000 that the drug is dangerous and should not only

⁴²⁰ *Id.* The sponsor could also submit a modification request based on a new use of the drug—for instance, mifepristone’s use in miscarriage management in addition to abortion. *Id.* at 12-13.

⁴²¹ Joint Motion, *supra* note X, at 2.

⁴²² RISK EVALUATION AND MITIGATION STRATEGIES, *supra* note X, at 15.

⁴²³ *Advisory Committees*, FOOD & DRUG ADMIN., <https://www.fda.gov/advisory-committees>.

be restricted, but entirely removed from the market.⁴²⁴ They have also suggested that the Clinton administration acted politically and unusually by seeking out a sponsor to support a New Drug Application for mifepristone.⁴²⁵ These arguments will likely get recycled in litigation about the mifepristone REMS.⁴²⁶

But just as precedent on judicial deference to administrative agencies would have harmed abortion rights activists in the *Chelius* lawsuit, it would similarly harm antiabortion activists in a lawsuit challenging the removal or modification of the REMS.⁴²⁷ It is not the role of the courts to review scientific evidence and decide whether a drug's risks can only outweigh its benefits without a REMS—even a conservative jurist would recognize that such a judgment should be made by the agency to which it was delegated. Rather, the courts role is to consider whether the agency's decision was arbitrary and capricious. It is particularly noteworthy that Chief Justice Roberts relied on deference to the FDA in his concurrence overturning the preliminary injunction in *ACOG v. FDA*.⁴²⁸ This could signal how he might be inclined to vote if the opposite case reached the Supreme Court. And importantly, even if a court were to find a procedural flaw that warranted a reversal of the agency's decision, the agency would be free to re-issue the decision, correcting the flaws identified by the court.

B. The Future of Abortion Care Without the Mifepristone REMS

Assuming the mifepristone REMS is released or modified during the Biden administration, how would it affect the future of

⁴²⁴ See Response to Opposition Comments filed by The Population Council, Inc. and Danco Laboratories (Oct. 10, 2003), <https://www.aaplog.org/wp-content/uploads/2002/08/ResponseToDanco10-03reRU-486.pdf>; Letter to FDA Commissioner Stephen Hahn from Senator Ted Cruz and nineteen other senators (Sept. 1, 2020), <https://www.cruz.senate.gov/files/documents/Letters/2020.09.01%20--%20Pro-Life%20Mifeprex%20Letter%20to%20FDA%20-%20FSV.pdf>.

⁴²⁵ Letter to FDA Commissioner, *supra* note X, at 2-3.

⁴²⁶ The arguments were made again in 2020 when Ted Cruz tried to get the FDA to remove mifepristone from the market. *Id.*

⁴²⁷ It is true that the Supreme Court in *Gonzales v. Carhart* showed a willingness to ignore the bulk of scientific evidence about when an abortion procedure could be medically necessary because a minority view contradicted it. *Gonzales v. Carhart*, 550 U.S. 124 (2007) (“The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty.”). But that precedent relied on the Court deferring to the fact-finding of conservative states, which relied on that minority view, not overriding a fact-finder—in this case the agency—with its own judgment on the science.

⁴²⁸ *ACOG*, 592 U.S. at 2 (Roberts, C.J., concurring).

abortion rights? It is worth noting at the outset that many states have their own regulations that limit the distribution of medication abortion. Nineteen states either require medication abortion to be distributed in the presence of a physician, or ban the use of telemedicine for abortion.⁴²⁹ More states are likely to pass similar laws in the next few years—although only a handful of additional states are conservative enough to secure the necessary political will to pass such laws.⁴³⁰ As a result, these restrictive states will likely remain in the (slim) minority. In the states with their own restrictive laws, even if the REMS were removed, early abortion care may not change much, at least when practiced by traditional, in-state providers.

In the remaining states, removing the REMS has the potential to create an enormous expansion of access. Thirty-one states have no prohibitions that would prevent medication abortion from being prescribed by any doctor and dispensed in any pharmacy or by mail.⁴³¹ Sure, doctors in these states would still need to be educated about, and act in compliance with, local abortion laws before prescribing mifepristone, and some providers and pharmacists would refuse to prescribe or dispense mifepristone based on conscience,⁴³² but abortion medication in a majority of states would immediately become much easier to access for a variety of reasons.

First, without the in-person dispensing requirement, telemedicine abortion will be cemented as the standard of care for early abortion. I say cemented because the COVID-19 pandemic has already radically changed the nature of early abortion care in the United States.⁴³³ Legal, remote abortion care before the pandemic was limited to the Gynuity study, but COVID-19 pushed remote abortion care

⁴²⁹ *Medication Abortion*, GUTTMACHER INST. (July 1, 2020), <https://www.guttmacher.org/state-policy/explore/medication-abortion>.

⁴³⁰ See Alice Miranda Ollstein & Darius Tahir, *Will At-Home Abortions Make Roe V. Wade Obsolete?*, POLITICO (March 20, 2021), <https://www.politico.com/news/2021/03/20/abortion-pills-telemedicine-477234>.

⁴³¹ *Medication Abortion*, *supra* note X.

⁴³² *Self-Managed Abortion*, *supra* note X, at 43-44.

⁴³³ 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*, CONTRACEPTION 2 (forthcoming 2021, but available online) (noting that demand for the Gynuity trial tripled during the pandemic); Ruth Reader, *The Pandemic Sparked The Rise Of Tele-Abortion. Is It Here To Stay?*, FAST COMPANY (Oct. 2, 2020), <https://www.fastcompany.com/90550536/telehealth-abortion-pill-supreme-court-ruling>; Carrie N. Baker, *How Telemedicine Startups Are Revolutionizing Abortion Health Care in the U.S.*, MS. MAGAZINE (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/>.

from a long-term hope to an urgent necessity.⁴³⁴ After the District of Maryland temporarily suspended the in-person dispensing requirement, a variety of start-ups launched, including HeyJane, Choix, and Just the Pill, which started providing remote abortion care.⁴³⁵ Some of these organizations are innovating, like sending the abortion pills in a care package that includes herbal tea and anti-nausea medication.⁴³⁶ More traditional providers also began mailing abortion medication after meeting with patients via telemedicine.⁴³⁷ Now that the Biden administration has suspended the in-person dispensing requirement for the remainder of the pandemic, telemedicine is quickly becoming the norm for early abortion care in these states.⁴³⁸ This trend is unlikely to change once the pandemic ends: ““The genie’s out of the bottle. And once the genie is out of the bottle, it’s really hard to get it back in.”⁴³⁹

Telemedicine for early abortion care means that women would no longer need to travel to clinics to end a pregnancy in the first ten weeks. As noted in Section I.C, this would immediately improve access for women by reducing the cost and logistical burdens associated with travel, especially for women who live hundreds of miles from the nearest clinic.⁴⁴⁰ This would be a welcome improvement as states in the South and Midwest have witnessed a dramatic reduction in brick and mortar clinics over the past decade.⁴⁴¹ “In 2017, 95% and 94% of counties in the Midwest and the South, respectively, did not have a facility that provided abortion care.”⁴⁴² Perhaps even more importantly, remote abortion care itself is also less expensive—almost half the price of clinic-based care.⁴⁴³ Given that most women are paying for abortion

⁴³⁴ See Reader, *supra* note X (noting that these start-ups started offering remote abortions after the District of Maryland suspended the in-person dispensing requirements); Baker, *supra* note X (same).

⁴³⁵ Reader, *supra* note X.

⁴³⁶ Susan Rinkunas, *A Bitter Pill*, MARIE CLAIRE (Jan. 13, 2021), <https://www.marieclaire.com/politics/a35203155/pandemic-abortion-telemedicine/>

⁴³⁷ See *id.* (noting that Whole Women’s Health is offering remote appointments).

⁴³⁸ Baker, *supra* note X (describing remote abortion as the new standard of care).

⁴³⁹ Rinkunas, *supra* note X.

⁴⁴⁰ See *supra* Section I.C.

⁴⁴¹ Jones, Witwer & Jerman, *supra* note X, at 16; Yan, *supra* note X.

⁴⁴² Chong et al., *supra* note X, at 2.

⁴⁴³ Rinkunas, *supra* note X.

out of pocket⁴⁴⁴ and half of women needing an abortion live in poverty,⁴⁴⁵ this benefit will be very impactful for patients.

Another huge advantage of telemedicine is that women would no longer need to endure the stigma and violence associated with abortion clinics.

Encountering protestors who intimidate, shame, harass, and harangue people who are doing nothing more than entering a medical clinic is normal around the country for patients trying to get an abortion. In no other areas of medicine are patients subjected to this kind of harassment just for walking into a doctor's office.⁴⁴⁶

There is a recent rise of picketing and obstructing abortion facilities--the National Abortion Federation's 2019 annual report on violence and disruption statistics documented 3387 incidents of obstructing facilities (up from 3038 in 2018), and 123,228 incidents of picketing (up from 99,409 in 2018).⁴⁴⁷ In addition to traditional harassment and picketing, protestors have recently started posing as clinic staff to try to trick patients into giving them their names so that they can publicly disclose their abortion and shame them online; protestors have also started recording women walking into clinics, often streaming them on Facebook Live, to further shame them on social media.⁴⁴⁸ Women using telemedicine can avoid this stressor entirely and end their pregnancy in the privacy of their homes.⁴⁴⁹ This shift could radically reduce the everyday stigma of abortion care.

Furthermore, the less abortion is tied to physical locations, the harder it will become for extremists to target and attack providers and clinics. Abortion providers have been murdered, threatened, and physically attacked simply for providing abortion, and their clinics have been bombed, broken into, and defaced.⁴⁵⁰ By concentrating all abortion care in certain locations like clinics, it makes it easy for protestors and extremists to target providers and patients. For instance,

⁴⁴⁴ *How do Women Pay for Abortions*, GUTTMACHER (2013), <https://www.guttmacher.org/sites/default/files/graphics/infographics/HowDoWomenPay-740.pdf>.

⁴⁴⁵ Sabrina Tavernise, *Why Women Getting Abortions Now Are More Likely to Be Poor*, N.Y.TIMES (July 9, 2019), <https://www.nytimes.com/2019/07/09/us/abortion-access-inequality.html>.

⁴⁴⁶ COHEN & JOFFE, *supra* note X, at 114.

⁴⁴⁷ Chong et al., *supra* note X, at 2.

⁴⁴⁸ *Id.* at 119.

⁴⁴⁹ Lindgren, *supra* note X, at X.

⁴⁵⁰ *Anti-Abortion Violence*, NARAL PRO-CHOICE AMERICA, <https://www.prochoiceamerica.org/issue/anti-abortion-violence/>.

hospitals that provide abortions experience almost no protests or violence—abortions are only a tiny fraction of the care hospitals provide, and it would be practically impossible for the protesters to determine which patients and providers at the hospital were there for an abortion.⁴⁵¹ If early abortion occurred online through telemedicine or moved to physician offices, it would be similarly difficult to target doctors and offices providing that early care. And by making it safer and less stigmatizing for providers to offer early abortion care, more physicians would likely be willing to offer it.⁴⁵²

Though this de-linking of early abortion from physical spaces would be ideal, clinics would still be necessary for surgical abortions after ten weeks. Mounting evidence suggests that medication abortion is safe and effective through twelve weeks, and a modified REMS might also extend the time period it can be offered.⁴⁵³ Nevertheless, surgical abortion will still be necessary for second-trimester abortions.⁴⁵⁴ Given that these later abortions tend to be more controversial, one potential consequence could be that violence at abortion clinics actually increases—all of a sudden, the majority of clinic-based abortion care could flip from first-trimester abortions to second-trimester abortions.⁴⁵⁵ Thus, while patients and providers involved with early abortion care could see a real improvement in their safety and wellbeing, those needing and providing later abortions might feel even more threatened. Clinics might also struggle to stay open if demand for their services drops, which could also lead to more clinic closures, even in states with abortion friendly laws.⁴⁵⁶ Given that it is already difficult for women to find a provider who offers second-trimester abortion care, the closure of clinics could exacerbate this problem.⁴⁵⁷ In other words, the removal of the REMS could make

⁴⁵¹ COHEN & JOFFE, *supra* note X, at 114.

⁴⁵² See COHEN & CONNOR, *supra* note X, at ix-x (noting that “partly because abortion providers are not safe, there are very few abortion providers in the United States”).

⁴⁵³ Nathalie Kapp et al., *Medical Abortion in the Late First Trimester: A Systematic Review*, 99 *CONTRACEPTION* 77, 77 (2019); *What Will Happen If You Do An Abortion With Pills After The First 12 Weeks?*, WomenOnWeb (last visited Mar 23, 2021), <https://www.womenonweb.org/en/page/573/what-will-happen-if-you-do-an-abortion-with-pills-after-the-first-12>.

⁴⁵⁴ Rinkunas, *supra* note X

⁴⁵⁵ Given that the majority of abortions occur in the first trimester, see *Second-Trimester Abortion*, ACOG (June 2013), <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2013/06/second-trimester-abortion>, when all abortion care occurred in clinics, the majority of clinic-based care was in the first trimester. However, the would change if telemedicine “skim[s] off all the early abortion” from clinics. Rinkunas, *supra* note X

⁴⁵⁶ Rinkunas, *supra* note X.

⁴⁵⁷ See *Later Abortion*, GUTTMACHER (Nov. 2019), <https://www.guttmacher.org/evidence-you-can-use/later-abortion>.

first-trimester abortion care much more accessible, but second-trimester abortion care even less accessible.

The move away from clinic-based care will also make it harder to regulate abortion spaces. Clinics not only attract violence and harassment, but also legislative attention. “Abortion opponents have taken aim at stand-alone clinics, describing them as “abortion mills” and seeking to undermine the legitimacy of abortion providers.”⁴⁵⁸ States have historically attempted to regulate the physical space of abortion clinics so dramatically that compliance is so difficult and expensive that it compromises the entire operation.⁴⁵⁹ For instance, “9 states specify the size of the procedure rooms,” “8 states specify corridor width,” and “8 states require abortion facilities to be within a set distance from a hospital.”⁴⁶⁰ When abortion is happening entirely online and in the privacy of one’s home, there are no physical spaces to regulate.⁴⁶¹ This is not to say that antiabortion legislatures will not find new ways to regulate abortion provided online—if not outright banning it—but it does undercut one strategy.

Unfortunately, the states with the fewest clinics are likely to have laws that prevent telemedicine for abortion. Thus, in the states where remote abortion access could be the most beneficial because there are the fewest clinics and greatest hostility at those clinics, it will likely be prohibited. As a result, removing the mifepristone REMS will accelerate the existing polarization of abortion access across state lines. States in the South and Midwest already limit abortion access as much as possible, while more liberal states have recently sought to codify and expand abortion protections.⁴⁶² Abortion providers, like Planned Parenthood, have predicted that this trend will continue and are opening large centers that can accommodate regional demand for abortion care in liberal states.⁴⁶³ For instance, in 2019, Planned

⁴⁵⁸ Yvette Lingren, *When the Patient is Their Own Doctor: Roe v. Wade in an Era of Self-Managed Care*, 107 CORNELL L. REV. ___, 24 (forthcoming 2021).

⁴⁵⁹ See *Targeted Regulation of Abortion Providers*, GUTTMACHER INST. (May 1, 2021), <https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers#>.

⁴⁶⁰ *Id.*

⁴⁶¹ See Lindgren, *supra* note X, at 358-64 (describing the privacy benefits associated with medication abortion in the home).

⁴⁶² See Elizabeth Nash, *Unprecedented Wave of Abortion Bans is an Urgent Call to Action*, GUTTMACHER (May 2019), <https://www.guttmacher.org/article/2019/05/unprecedented-wave-abortion-bans-urgent-call-action>; Elizabeth Nash et al., *State Policy Trends 2019: A Wave of Abortion Bans, But Some States Are Fighting Back*, GUTTMACHER (Dec. 2019), <https://www.guttmacher.org/article/2019/12/state-policy-trends-2019-wave-abortion-bans-some-states-are-fighting-back>.

⁴⁶³ See Grace Hauck, *Planned Parenthood To Open Major Clinic In Illinois As 'Regional Haven' For Abortion Access*, USA TODAY (Oct. 2, 2019),

Parenthood opened an 18,000 sq-ft facility in Illinois that is only a handful of miles from the last abortion clinic left in Missouri.⁴⁶⁴ This growing disparity of abortion access across states will continue to disproportionately harm poor women, rural women, and women of color living in the South and Midwest, who are less able to travel to obtain care.⁴⁶⁵

If removing the mifepristone REMS accelerates polarization by increasing abortion access in liberal states, the Supreme Court's upcoming abortion decisions are expected to further intensify polarization by allowing conservative states to decrease (and perhaps eliminate) abortion access. In May 2021, the Court announced that it would hear a case that is a direct challenge to the viability standard in *Roe* and *Casey*.⁴⁶⁶ The case concerns whether a state can ban abortion starting at fifteen weeks, long before a fetus is viable.⁴⁶⁷ With Justice Barrett replacing Justice Ginsburg and Justice Kavanaugh replacing Justice Kennedy, there is a genuine fear that the constitutional right to abortion may become a relic of a different era.⁴⁶⁸ If the Supreme Court does move to further limit or overturn *Roe*, states will have even more power to determine their own abortion regulations, and many will move to ban abortion entirely.⁴⁶⁹ Nevertheless, women living in the thirty-one states without limits on medication abortion will still continue to see the benefits described in this Section. As a result, the removal of the mifepristone REMS has the power to transform and improve abortion access even if the constitutional right to abortion falls.

Even assuming a substantial minority of states limit medication abortion or ban abortion entirely, increased access to mifepristone in parts of the United States will improve access everywhere through illegal, self-managed abortion. Though illegal abortion conjures up images of the back-alley abortions from generations ago, self-managed abortion in today's world couldn't be more different. It essentially involves women taking the same or similar medications, but purchased

<https://www.usatoday.com/story/news/nation/2019/10/02/illinois-planned-parenthood-mega-clinic-haven-abortion-access/3840714002/>.

⁴⁶⁴ *Id.*

⁴⁶⁵ Megan K. Donovan, *In Real Life: Federal Restrictions on Abortion Coverage and the Women They Impact*, 20 GUTTMACHER POLICY REV. 1 (2017).

⁴⁶⁶ Mary Ziegler, *This Could Be The Case That Takes Down Roe V. Wade*, CNN (May 18, 2021), <https://www.cnn.com/2021/05/17/opinions/abortion-mississippi-supreme-court-dobbs-v-jackson-womens-health-ziegler/index.html>.

⁴⁶⁷ *Id.*

⁴⁶⁸ *Id.*

⁴⁶⁹ *Id.*

outside of the traditional healthcare setting, often without the help of a physician.⁴⁷⁰

Many abortion rights activists believe self-managed abortion is the future of abortion care, especially if *Roe v. Wade* is overturned or dramatically weakened.⁴⁷¹ Already, the practice has grown as abortion has gotten increasingly difficult to access in parts of the country,⁴⁷² with a greater incidence in states with harsher abortion restrictions.⁴⁷³ But once mifepristone becomes easier to access in parts of the United States, women will likely be able to obtain the drug more easily from other states (instead of relying on unknown, international pharmacies). Instead, women in restrictive states could meet with an out-of-state provider by telemedicine who mails them the medication directly or calls the prescription into an out-of-state, mail-in pharmacy that ships them the drug. Not only would this practice be almost impossible to police, but it might also be legally difficult to restrict.⁴⁷⁴ The Dormant Commerce Clause generally prevents states from regulating commerce outside of their borders.⁴⁷⁵ Even if abortion providers continued to only ship abortion medication to addresses within their state, where doing so was legal, one could easily imagine a world in which a patient in a restrictive state lies about their location and gives the provider an address of a friend, family member, or ally within a liberal state, who would then ship the out-of-state patient the drug once it arrives.⁴⁷⁶

In restrictive states, abortion care might leave the healthcare setting entirely. According to the World Health Organization, there are three components to fully self-managed abortion care (sometimes

⁴⁷⁰ See *Donovan*, *supra* note X, at 41.

⁴⁷¹ See e.g., *How Activists Can Prepare for a Post-Roe World*, REPROACTION (Sept. 21, 2018), <https://reproaction.org/resource/how-activists-can-prepare-for-a-post-roe-world/> (describing how medication abortion has been used in other countries where abortion is criminalized). In 2021, the Supreme Court agreed to hear a case that would directly challenge *Roe v. Wade*.

⁴⁷² Abigail R. A. Aiken et al., *Demand for Self-Managed Medication Abortion Through an Online Telemedicine Service in the United States*, 110 AM. J. PUBLIC HEALTH 90, 90, 92 (2020).

⁴⁷³ See Aiken et al., *supra* note X at 94.

⁴⁷⁴ See Rachel Rebouche, *The Public Health Turn in Reproductive Rights*, 78 WASH. & LEE L. REV. ___, 40 (2021) (noting, and citing scholarship for the proposition, that in the context of interstate travel for an abortion at a clinic, “there are mixed views about whether states could limit residents from seeking abortion outside of state lines”).

⁴⁷⁵ For instance, the Fourth Circuit recently invalidated Maryland’s attempt to pass a drug pricing law that would have incidentally regulated drug prices outside its borders. *Ass’n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018). Thus, even if states can impose limitations on the provision of mifepristone within their borders, states may not be able to regulate the sale of medication abortion across state lines. I hope to explore this possibility in another paper.

⁴⁷⁶ Rebouche, *supra* note X, at 40; Gleckel & Wulkan, *supra* note X, at 15-16.

referred to as self-sourced abortion): “[1] self-assessing eligibility; [2] managing the mifepristone and misoprostol medication without direct supervision of a health care provider; and [3] self-assessing completeness of the abortion process using pregnancy tests and checklists.”⁴⁷⁷ Evidence endorsed by the WHO suggests that the latter two components can be done safely.⁴⁷⁸ Even under the REMS, most women already take the abortion medication drugs at home—albeit after a consultation with a physician—and assess the abortion’s completion on their own; as a result, it makes sense that women do not need a doctor’s direct involvement during those phases of the abortion, so long as they have “a source of accurate information and access to a health-care provider should they need or want it at any stage of the process.”⁴⁷⁹

However, there are still outstanding questions regarding the first component—i.e., how accurately women can assess their own eligibility. This self-assessment primarily relies on a woman’s ability to accurately assess the gestational age of her pregnancy, which evidence suggests that women can accurately do.⁴⁸⁰ As mentioned above, only 1% of medication abortion patients who were certain that their last missed period had started less than seventy-eight days ago were proven wrong on ultrasound.⁴⁸¹ But other eligibility concerns are more complicated, and relate to risk factors, like whether a woman could have a rare ectopic pregnancy, which is contraindicated for the medication, or a negative blood type and might therefore need an additional medication to protect her future fertility.⁴⁸² Fewer women know their blood type and only an ultrasound can diagnose an ectopic pregnancy.⁴⁸³

The traditional medication abortion model based on clinic care eliminated these risks by recommending that all women get blood work and an ultrasound before receiving the medication abortion.⁴⁸⁴ The ultrasound could rule out ectopic pregnancy and verify the length of pregnancy, and the blood work could identify women who are Rh negative and might need additional medication. But the pandemic catalyzed a paradigm shift that is altering the early abortion model that

⁴⁷⁷ *Self-Managed Abortion*, *supra* note X, at 44.

⁴⁷⁸ *Id.*

⁴⁷⁹ *Id.*

⁴⁸⁰ *Id.*

⁴⁸¹ Raymond et al., *supra* note X, at 363.

⁴⁸² *Id.*

⁴⁸³ Elizabeth G. Raymond et al., *Commentary: No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 *CONTRACEPTION* 361, 363 (2020).

⁴⁸⁴ *Id.* at 361.

had been used for decades.⁴⁸⁵ Telehealth models that seemed cutting edge only months earlier, like Gynuity’s Telabortion study—where women were mailed medication abortion after an online appointment, but only after first obtaining an ultrasound and blood work at a facility of their choosing—are now seen as overly conservative.⁴⁸⁶

The zeitgeist now prefers “no touch abortions,” where most women can obtain abortion care without any in-person testing, unless it is medically indicated.⁴⁸⁷ Not only does this remove even more logistical burdens associated with care, but it also reduces the cost of the abortion, making abortion even more accessible.⁴⁸⁸ More recent data suggests that even women who are Rh negative will not develop antibodies to a pregnancy in the first ten weeks, and therefore the additional medication is not necessary;⁴⁸⁹ and because ectopic pregnancy often comes with symptoms like bleeding or pain, ultrasound could be safely avoided for asymptomatic women.⁴⁹⁰ The start-up describe above are already offering no-touch abortions, and even traditional clinics are moving in this direction and altering their protocols so that women never need to set foot in a healthcare facility to receive abortion care.⁴⁹¹ As a result, it appears that even when it comes to self-assessment of eligibility, a physician’s involvement is not

⁴⁸⁵ *Id.*

⁴⁸⁶ See Chong et. al., *supra* note X, at 2, 4 (noting that “[e]xperts have advocated for adoption of ‘no-test medication abortion,’ but that “[i]ndividuals were required to obtain a pre-abortion ultrasound or pelvic exam” to participate in the study, even though 52% of sites did not enforce the requirement); Alice Mark et al., *Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation’s Clinical Policies Committee*, 99 *Contraception* 265, 265 (2019) (“Across all fields of medicine, changes in practice models are occurring rapidly. For patients seeking abortion, urgent modifications of current protocols are needed to ensure that patients can continue to obtain this timesensitive treatment while limiting transmission of infection by maintaining distance between and among patients and providers.”).

⁴⁸⁷ Elizabeth G. Raymond et al., *supra* note X, at 361; *No Touch Medication Abortion Protocol*, Reproductive Access (March 2020), <https://www.reproductiveaccess.org/wp-content/uploads/2020/03/03-2020-no-touch-MAB.pdf>.

⁴⁸⁸ Baker, *supra* note X; see Chong et. al., *supra* note X, at 4 (noting that Months with high enrollment were also months in which large percentages of abortions occurred without screening ultrasounds”).

⁴⁸⁹ Alice Mark et al., *supra* note X, at 265.

⁴⁹⁰ Elizabeth G. Raymond et al., *supra* note X, at 363-34.

⁴⁹¹ Baker, *supra* note X (describing remote abortion as the new standard of care); Carrie N. Baker, *No-Test Medication Abortion Increases Safety and Access During COVID-19*, *MS. MAGAZINE* (May 13, 2020), <https://msmagazine.com/2020/05/13/no-test-medication-abortion-increases-safety-and-access-during-covid-19/> (interviewing a provider who is already using the new protocol and describing it as the new standard of care).

required. Scholars have similarly started criticizing as paternalistic the doctrinal link that has woven physician involvement into the right to abortion.⁴⁹²

Nevertheless, as described in Section II, there will still be serious legal risks associated with self-management given the fact that many states have enforced a variety of laws against pregnant women who self-induced an abortion.⁴⁹³

There are 7 states with laws directly criminalizing self-induced abortions, 10 states with laws criminalizing harm to fetuses that lack adequate exemptions for the pregnant person, and 15 states with criminal abortion laws that have been and could be misapplied to people who self-induce. There are also a variety of laws that have been used when other grounds are unavailable, including those governing the disposal of human remains and concealment of a birth.⁴⁹⁴

Motivated prosecutors have found a variety of arcane legal avenues to criminalize women who self-manage, and if abortion becomes illegal in certain states, prosecuting abortion will become easier. Though it has historically been politically undesirable to prosecute *women* for abortions, and laws typically prefer to criminalize providers, this might change if providers are out of state and harder to control.⁴⁹⁵ On the other hand, as self-management becomes more commonplace and organized, there will also be more information for women about how to avoid detection, even when experiencing side-effects and risks that require medical care.⁴⁹⁶

Though releasing the REMS will likely increase the trend toward self-managed abortion in conservative states, it will have the opposite effect in liberal states where telehealth is the norm. Self-management will become less desirable when it is easy to access medication abortion from a U.S. physician while still ending the pregnancy in the privacy of their home, avoiding the harassment, travel,

⁴⁹² See Lindgren, *supra* note X, at 24.

⁴⁹³ See *supra* Section II.

⁴⁹⁴ *Self-Managed Abortion*, *supra* note X, at 45.

⁴⁹⁵ Georgia's recent abortion law would start subjecting women who get illegal abortions to criminal prosecution, including life imprisonment and the death penalty. Mark Joseph Stern, *Georgia Just Criminalized Abortion. Women Who Terminate Their Pregnancies Would Receive Life in Prison*, SLATE (May 7, 2019), <https://slate.com/news-and-politics/2019/05/hb-481-georgia-law-criminalizes-abortion-subjects-women-to-life-in-prison.html>.

⁴⁹⁶ So long as the abortion is in the first trimester, women should be able to seek medical care by indicating that they were suffering from a miscarriage, not an abortion. Reader, *supra* note X.

and obstacles associated with clinic care, and the legal risks associated with self-management.⁴⁹⁷ And as argued above, the very possibility of self-management with abortion care should encourage the FDA to release or modify the REMS to encourage women to obtain care through a doctor given that self-management through international sources is an option for American women already.⁴⁹⁸

If the certified provider requirement is removed along with the in-person dispensing requirement, additional benefits will accrue. Primarily, we can expect to see an increase in physicians providing early abortions.⁴⁹⁹ Physicians will likely be more willing to provide early abortion care if they could do so from their home offices or via telemedicine without the threat of harassment or violence.⁵⁰⁰ These fears would further diminish if providers do not need to opt-into a prescribing system that collects the identities of all abortion providers—the fear being that their identities could be released and publicized after a data breach.⁵⁰¹ And if all pharmacies could similarly dispense the drug without certification, providers would no longer need to deal with the logistical burdens associated with dispensing the drug in house.⁵⁰² Given that 87% of counties in the United States lack an abortion provider, and 34% of women of reproductive age live in a county without an abortion provider,⁵⁰³ increasing the number of providers could reduce the burden on existing abortion providers and improve access to abortion generally.

Removing the mifepristone REMS will also have an impact on miscarriage management. As mentioned above, recent research has suggested that the same combination that is used for abortion (a combination of mifepristone and misoprostol) is more effective to treat a missed or incomplete miscarriage than the current protocol,

⁴⁹⁷ See Aiken et al., *supra* note X at 93 (describing the various reasons women sought self-managed abortion, including the desire for privacy and the burdens associated with clinics); *A Roadmap for Research on Self-Managed Abortion in the United States*, GYNUITY HEALTH (Aug. 2018), <https://ibisreproductivehealth.org/sites/default/files/files/publications/US%20research%20roadmap%20self%20managed%20abortion.pdf>; Daniel Grossman, et al., *Self-Induction of Abortion Among Women in the United States*, 18 REPROD. HEALTH MATTERS 136-46 (2010)).

⁴⁹⁸ See *supra* Section II.

⁴⁹⁹ COHEN & JOFFE, *supra* note X, at 223.

⁵⁰⁰ *Id.*, at ix-x

⁵⁰¹ REMS Study Group, *supra* note X, at 792.

⁵⁰² *Self-Managed Abortion*, *supra* note X, at 43; REMS Study Group, *supra* note X, at 792.

⁵⁰³ Data Center, Guttmacher Inst., <https://data.guttmacher.org/states/table?state=US&topics=71+72+73&dataset=ata>.

which only involves misoprostol.⁵⁰⁴ Without the mifepristone REMS, providers could start prescribing the same protocol for missed or incomplete miscarriage as they do for abortion.⁵⁰⁵ Not only does this benefit women who are experiencing a missed or incomplete miscarriage, but it would also help to reduce the stigma of mifepristone. Pharmacists, for instance, would not know whether women picking up a prescription for mifepristone were using it for an abortion or for a miscarriage, making it more difficult for them to object to filling the prescription based on their conscience. This benefit would exist across the country as state laws are tied to medication abortion, not mifepristone specifically. As a result, state laws would not limit mifepristone's use outside of the abortion context.

Removing the mifepristone REMS would radically change abortion care in parts of the United States. No longer would women need to travel long distances to clinics for early abortion, nor will they need to deal with the harassment of protesters. Women will be able to terminate an early pregnancy at home, entirely through telemedicine. More providers will offer early abortion care, and there will be less of an incentive for women to rely on self-managed abortion to end a pregnancy. Mifepristone would be used for a variety of obstetric uses, making it harder to politicize. However, in other parts of the country, access to legal abortion will not improve; instead, state legislatures will continue to chip away at abortion rights. Self-managed abortion will likely become the norm in those states, which will be difficult to regulate and police. Though the best evidence suggests that self-managed abortion is safe, there are legal risks and many women would likely be troubled to lack access to legal abortion with a provider.

CONCLUSION

Medication abortion is an effective and safe way to end a pregnancy in the first seventy days. Nevertheless, the FDA has dramatically limited its distribution by imposing a REMS—a device to protect the public from particularly risky drugs. The REMS has segregated medication abortion care to abortion and family planning clinics and eliminated the potential for remote abortion through telehealth, dramatically reducing access to abortion across the country. Though legal challenges to the REMS have been lodged in recent years, and have merit, the onslaught of recent conservative appointments to the federal bench make the road to victory steep. Fortunately, the FDA under President Biden is poised to lift the REMS—a decision that would be difficult to legally challenge given the scientific support for doing so.

⁵⁰⁴ Schreiber et al., *supra* note X.

⁵⁰⁵ *Id.*

Removing the REMS could represent the largest increase in abortion access in decades, at least in the states that have not passed state laws that limit access to medication abortion. Women in those states will be able to receive abortion care entirely from the comfort of their own homes through telemedicine, never having to face the harassment associated with abortion clinics. More providers will be able to provide early abortion care—and do so anonymously without threats of violence. None of these benefits will be felt by women in states that continue to limit medication abortion, and as a result, one significant effect of removing the mifepristone REMS will be the acceleration of the trend toward polarization in abortion regulations across the United States. This trend will only increase if *Roe v. Wade* is limited or overturned as some states will outlaw abortion entirely, while women in other states will continue to experience the benefits associated with easier access to early medication abortion.