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MEDICATION ABORTION EXCEPTIONALISM

Greer Donley†

Though state laws dominate the abortion debate, there is a federal abortion policy that significantly curtails access to early abortion in all fifty states. The policy, known as a Risk Evaluation and Mitigation Strategy (REMS), 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 until December 2021, only allowed those providers to distribute the drug to patients directly, in person, not through pharmacies. This policy has segregated abortion care outside of the traditional healthcare setting and into abortion clinics, which provide ninety-five percent of abortions. This paper is the first to examine the burdens, benefits, and impacts 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 biased decision-making over sexual and reproductive health. It concludes by exploring impending modifications to the mifepristone REMS, what they mean for the future of early abortion care, and how the FDA can go further to remove unnecessary barriers to medication abortion.

† Greer Donley is an Assistant Professor at the University of Pittsburgh Law School. Donley's research for this Article earned her a 2020 Health Law Scholar Award by Saint Louis University and the American Society of Law, Medicine & Ethics. As part of this award, Donley was invited to workshop a draft of her paper to a large group of interdisciplinary scholars. She would particularly like to thank Saint Louis University School of Law, which organized the event, and Seema Mohapatra, Fred Rottnek, Robert Gatter, Jesse Goldner, Elizabeth Chiarello, Leslie Francis, Nathan Cortez, Sidney Watson, Elizabeth Pendo, Ruqaiijah Yearby, Stacey Tovino, Ana Santos Rutschman, Anya Prince, Jennifer D. Oliva, and Gabriel Scheffler for their valuable feedback at the workshop. She is also very grateful to Mary Ziegler, Yvonne (Yvette) Lindgren, David S. Cohen, Rebecca S. Eisenberg, W. Nicholson Price II, Patricia J. Zettler, Govind Persad, Myrisha S. Lewis, Amy J. Wildermuth, Deborah L. Brake, Sonya Borerro, Beatrice A. Chen, Susan Fritsche, Joshua Galperin, Grant MacIntyre, Andrele Brutus St. Val, and Jabeen Adawi for their helpful comments on earlier drafts of this Article.

INTRODUCTION

State abortion laws have received an enormous amount of attention in the national discourse and legal scholarship. But less known is a federal policy that dramatically limits access to abortion throughout the United States. The policy, created by the Food and Drug Administration (FDA), has burdened access to 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.[2] The mifepristone REMS has historically been quite stringent—it dramatically limited access to medication abortion and effectively isolated abortion care outside of traditional medical settings.[3] 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.[4] In light of this growing criticism, in December 2021, the FDA removed one of its most onerous restrictions; nevertheless, the agency maintained the mifepristone REMS and added a new restriction, continuing its exceptional treatment of the drug.

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. The future of abortion rights has only become more uncertain since then, with Texas enacting the harshest abortion ban since before *Roe v. Wade* and the Supreme Court reconsidering the right to abortion this term in *Dobbs v. Jackson Women's Health Organization*.[5] Nevertheless, the Biden administration has the ability and opportunity to remove or further loosen the mifepristone REMS, expanding 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 have an unchallenged background assumption that abortion occurs outside of the traditional healthcare setting, typically at an abortion or family planning clinic. That

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1 *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_REMS_Document.pdf [https://perma.cc/C5UE-UV9Q] (last updated Apr. 2019) [hereinafter *REMS*].

2 *Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/C45E-6U7Y] (last updated Aug. 8, 2019).

3 *See infra* Part I.

4 *See infra* Part II.

5 *See* Whole Woman's Health v. Jackson, 141 S. Ct. 2494, 2495 (2021).

is because 95% of abortions—including abortions that are completed with a simple medication regimen—have historically been provided by those clinics.[6] There is no reason, however, for medication abortion to be limited to any physical space. So long as abortion patients are within the first ten weeks of their pregnancies, they should simply be able to make an appointment with a general practitioner or OBGYN, obtain a prescription for medication abortion, pick up the medications at their regular pharmacy, and end their pregnancy in the privacy of their home. The primary obstacle blocking this scenario from coming to fruition in more than half the country is the FDA's REMS.[7]

The mifepristone REMS created distribution limitations that, in effect, isolated early abortion care to clinics. Until December 2021, the REMS barred pharmacies from distributing mifepristone and required patients to pick up the drug in person from a "certified prescriber" at a clinic, medical office, or hospital.[8] The logistical burdens associated with certification and distribution ensured that the vast majority of providers who became certified were abortion providers working at abortion and family planning clinics.[9] And given that clinics are few and far between in most southern and midwestern states, the REMS effectively required women to travel far distances—sometimes hundreds of miles—to simply pick up a prescription.[10] It also prevented women from obtaining the prescription through telehealth, which became an urgent necessity in the COVID-19 pandemic.

Quickly after taking office, the Biden administration used its discretion to suspend the in-person dispensing requirement associated with the mifepristone REMS[11]—an action the

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6 RACHEL K. JONES, ELIZABETH WITWER & JENNA JERMAN, ABORTION INCIDENCE AND SERVICE AVAILABILITY IN THE UNITED STATES, 2017, at 16 (2019), https://www.guttmacher.org/sites/default/files/report_pdf/abortion-incidence-service-availability-us-2017.pdf [https://perma.cc/Z6CM-BMCD]. As discussed in the final section of the Article, the COVID-19 pandemic, and the temporary suspension of the mifepristone REMS that resulted from it, has radically disrupted the provision of abortion care and moved abortion access increasingly online.

7 Some states have their own laws that would limit the distribution of mifepristone even if the REMS were lifted. *See infra* subpart IV.B.

8 *REMS*, *supra* note 1.

9 *See infra* Part I.

10 *See* JONES, WITWER & JERMAN, *supra* note 6, at 3.

11 Letter from FDA to Maureen G. Phipps, MD, MPH & FACOG, CEO of Am. Coll. of Obstetricians and Gynecologists, and William Grobman, MD & MBA, President of Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) (on file with the ACLU), https://www.aclu.org/letter/fda-response-acog-april-2021 [https://perma.cc/3JZM-XD2R].

Trump administration refused to take, and the Supreme Court found was not legally required.[12] In the months after the suspension took effect, abortion care started to change dramatically in many states, including the creation of virtual clinics, which provide medication abortions entirely through telehealth.[13] Remote abortion care is cheaper, more convenient, and allows patients to avoid the harassment associated with clinics. On December 16, 2021, the FDA permanently removed the in-person dispensing requirement, ensuring that these important changes could become permanent.[14] But the agency stopped short of removing the REMS entirely, keeping the certified provider requirement and patient agreement form, and adding a requirement that any pharmacy dispensing the drug also become certified.[15]

This Article starts with background on medication abortion, including its risks and benefits, the FDA's history regulating it, and the negative impact of that regulation on abortion access. Part 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 to the REMS. Medication 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 how to manage them. As a result, the Part concludes that mifepristone failed to meet the statutory criteria for a REMS.

In Part III, the Article describes how the FDA's mifepristone REMS is a part of a larger pattern of gender bias in the FDA's decision making. The Part traces a series of agency failures to protect women's health, especially reproductive and sexual health, over the course of decades. This Part 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, Part IV explores legal and political avenues for invalidating, removing, or loosening the mifepristone REMS, as

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12 FDA v. ACOG, 141 S. Ct. 578, 578 (2021).

13 *See infra* subpart IV.B.

14 Letter to Donna Harrison from the Food & Drug Admin. (Dec. 16, 2021) at 6-7, https://www.regulations.gov/document/FDA-2019-P-1534-0016 [https://perma.cc/ED3T-SUJM] [hereinafter FDA Letter].

15 *Id.*

the medical evidence supports. The Part then pivots to a discussion of how a removal of the REMS could reshape early abortion care in the United States, integrating it into the traditional healthcare system and making it more accessible than ever before. But perhaps the largest impact of loosening the REMS would be to accelerate the polarization in abortion access across state lines. Nineteen states have their own laws limiting the distribution of medication abortion, and more states might erect similar barriers.[16] In these states, the innovations in early abortion care, like virtual abortion clinics, would remain unavailable. If *Roe v. Wade* is further limited or overturned in the coming years, this disparity will grow again.[17] Women living in liberal states will continue to experience the benefits of remote abortion access, while women in conservative states could lose legal access to in-state abortion care altogether. Since SB 8 took effect in Texas—a law that has, in effect, ended legal abortion starting roughly two weeks after a woman's missed period—this polarization is already on display.[18] Nevertheless, Texas also proves that modifications to the REMS will facilitate abortion access in these antiabortion states by making it easier for women to get medication abortion from neighboring states.[19]

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16 *Medication Abortion*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/medication-abortion [https://perma.cc/4JRF-NNT5] (last updated Nov. 1, 2021).

17 410 U.S. 113 (1973).

18 *See* Greer Donley, David S. Cohen & Rachel Rebouché, *The Messy Post-*Roe *Legal Future Awaiting America*, ATLANTIC (Sept. 27, 2021), https://www.theatlantic.com/ideas/archive/2021/09/after-roe-legal-mess-future-abortion-rights/620134/ [https://perma.cc/U53S-7X8P].

19 Already, in Texas, virtual clinics are working to serve Texas women in neighboring states where remote abortion is legal, like Colorado and Nevada. Carey Goldberg & Catarina Saraiva, *Texas Ban May Spur Tele-Abortions: Virtual Visits, Then Pills*, BLOOMBERG (Sept. 4, 2021), https://www.bloomberg.com/news/articles/2021-09-04/texas-ban-may-spur-tele-abortions-virtual-visits-then-pills [https://perma.cc/8BYS-K62V]. This will help patients obtain remote abortion care by simply crossing the border, instead of also needing to travel to an abortion clinic in that state. It will also help reduce pressure on the providers doing surgical abortion procedures, who have seen an influx of Texan patients. As argued in subpart IV.B, experts also expect to see an increase in illegal self-managed abortion for women who cannot travel, which appears to be already happening in Texas as well. Tanya Basu, *Activists Are Helping Texans Get Access to Abortion Pills Online*, MIT TECH. REV. (Sept. 15, 2021), https://www.technologyreview.com/2021/09/15/1035790/abortion-pills-online-texas-sb8/ [https://perma.cc/4VV9-C785].

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 also approved a generic version of the drug in 2019.[20] Mifepristone works by blocking the hormone progesterone, which is necessary for a pregnancy to continue.[21] 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).[22] By thinning the uterine lining, mifepristone detaches the gestational sac from the uterus and stops its growth.[23] It can also cause the cervix to soften and dilate, which can help express the pregnancy.[24]

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 that help expel the pregnancy.[25] It is typically taken 24–48 hours after mifepristone.[26] 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.[27] However, it has been used off label[28] for a variety of obstetric uses—including to induce labor or evacuate a pregnancy after an incomplete or missed

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20 This Article uses the term "mifepristone" to refer to both the generic and brand name drug. *Questions and Answers on Mifeprex*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex [https://perma.cc/F46V-34CP] (last updated Apr. 13, 2021). The agency consolidated both products under a single REMS, but otherwise made no substantive changes to the REMS protocol. *Id.*

21 Irving M. Spitz & C.W. Bardin, *Mifepristone (RU 486I) – A Modulator of Progestin and Glucocorticoid Action*, 329 NEW ENG. J. MED. 404, 405 (1993).

22 *Id.*

23 *Medical Abortion*, MAYO CLINIC (May 14, 2020), https://www.mayoclinic.org/tests-procedures/medical-abortion/about/pac-20394687 [https://perma.cc/Z284-2M7H].

24 Spitz & Bardin, *supra* note 21, at 405.

25 *Medical Abortion*, *supra* note 23.

26 *The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (June 16, 2021), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ [https://perma.cc/NN8S-R4DV].

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

28 Off-label use refers to when a physician prescribes medication for a use that was not approved by the FDA. *Understanding Unapproved Use of Approved Drugs "Off Label,"* U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label [https://perma.cc/DL5G-ZMWV] (last updated Feb. 5, 2018).

miscarriage.[29] 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.[30]

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.[31] With more than twenty years of safety data, there is ample evidence that mifepristone is both safe and effective. In 2018, the Government Accountability Office (GAO) published a report on mifepristone; it found that from September 2000 to June 2017, 3.2-million women used mifepristone to end a pregnancy.[32] Of those women, only 4,200 reported adverse events, including twenty deaths—some of which were later found to be unrelated to the medication.[33] The fatality rate was calculated at 0.0006%.[34] "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."[35] The rates 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.[36] As for efficacy, the drug's current label reports

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29 Allen & O'Brien, *supra* note 27, at 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 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 ENG. J. MED. 2161, 2161 (2018).

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

31 Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2014*, 49 PERSPS. ON SEXUAL & REPROD. HEALTH 1, 6 (2017), https://www.guttmacher.org/sites/default/files/article_files/abortion-incidence-us.pdf [https://perma.cc/6XZL-X8NL].

32 GOV'T ACCOUNTABILITY OFF., 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 [https://perma.cc/9MTN-EDK7] [hereinafter GAO-18-292].

33 *Id.*

34 *Id.*

35 Mifeprex REMS Study Grp., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENG. J. MED. 790, 791 (2017) [hereinafter *Mifeprex REMS Study Group*].

36 *Id.*

that it is over 96% effective at ending a pregnancy.[37] For the remaining cases, an additional dose of misoprostol will frequently expel the remaining tissue.[38] In roughly 1% of cases, a surgical procedure is required.[39]

The possibility of abortion by medication was enormously controversial from the moment it first entered the public debate: "[a]lmost no pharmaceutical product has captured the public imagination with the force of mifepristone."[40]

> 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.[41]

Thus far, none of these predictions have come to pass, including the drug's promise to dramatically increase the accessibility of abortion in the United States (though that might be changing).[42] In 2017, roughly forty percent of U.S. abortions are now completed with medication,[43] but accessing the drugs has not been easy.[44] Some have decried that mifepristone is, and must remain, "the moral property of women," but the potential for any woman[45] or pregnant person 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.[46] As explained below, this is largely due to an FDA policy that limits the distribution of mifepristone.

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37 Mifeprex Label, 13, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [https://perma.cc/PZ9U-NN6B]; Older studies using an outdated dosing regimen demonstrated a lower efficacy. *See* GAO-18-292, *supra* note 32, at 13.

38 GAO-18-292, *supra* note 32, at 14.

39 Mifeprex Label, *supra* note 37, at 13.

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

41 *Id.*

42 *See The Availability and Use of Medication Abortion*, *supra* note 26, at 8.

43 *Id.* As noted below, medication abortion for the first time became the majority of all abortions in 2020 (54%).

44 *See infra* subpart I.C.

45 Not every person capable of becoming pregnant identifies as a woman. As a result, I attempt to primarily use gender neutral language. There are times, however, where I use gendered language because gender is relevant, or the language is less clunky. But in those instances, the arguments apply with equal force to all people with uteruses, however they identify.

46 Winikoff & Westhoff, *supra* note 40, at 178 (quoting Claude Evin, the then-French Minister of Health).

A. Creation of the Drug

Researchers conceived of the idea for mifepristone after studies of hormone-based contraception; once scientists understood the role that progesterone plays in pregnancy, they began to theorize that anti-progestins could also interrupt an embryo's implantation in the uterus.[47] The pharmaceutical company, Roussel Uclaf, eventually created mifepristone and named it RU-486.[48]

In 1982, the first clinical trial for mifepristone began in Geneva.[49] Nine out of the eleven women who participated in the study successfully terminated their pregnancies.[50] Additional studies were conducted to expand this research, including the first U.S. study in 1983 involving 300 research subjects in California.[51] In 1988, after many successful clinical trials in France,[52] the French government approved mifepristone (still then known as RU-486) for use as an abortifacient.[53] The decision was highly controversial, and Roussel Uclaf even stopped selling the drug for a few days after anti-abortion organizations threatened the company.[54] Nevertheless, the drug reentered the market after the French government successfully intervened.[55] China also approved mifepristone as an abortifacient in 1988.[56] Britain and Sweden followed within a few years,[57] and the entire EU had access by 1999.[58]

Roussel Uclaf was hesitant to apply for new drug approval in the United States, fearing boycotts and lawsuits.[59] The risks were especially undesirable in the Bush administration, which

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47 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).

48 Carolina J. Abboud, *The Development of Mifepristone for Use in Medication Abortions*, EMBRYO PROJECT (Aug. 7, 2017), https://embryo.asu.edu/pages/development-mifepristone-use-medication-abortions [https://perma.cc/7DHD-JHG3].

49 *Id.* at 1.

50 *Id.*

51 *See* THE CASE FOR ANTIPROGESTINS: A REPORT OF THE REPRODUCTIVE HEALTH TECHNOLOGIES PROJECT, REPROD. HEALTH TECH. PROJECT 5–6 (1992).

52 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).

53 THE CASE FOR ANTIPROGESTINS, *supra* note 51, at 7.

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

55 *Id.* at 1–2.

56 *Id.* at 1.

57 Winikoff & Westhoff, *supra* note 40, at 177.

58 *Id.*

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

had already tried to ban the importation of mifepristone for personal use, as described in Part III below.[60] 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.[61] In 1994, "after lengthy negotiations" with the Clinton administration,[62] 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."[63] 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, sold under the brand name Mifeprex, to Danco Laboratories, LLC ("Danco") in 1997.[64]

B. Federal Regulation in the United States

In the United States, drug regulation is largely governed by the Food and Drug Administration (FDA). Drugs cannot be sold or distributed through interstate commerce unless they receive new drug approval from the FDA.[65] In 1996, mifepristone's sponsor, Danco, submitted a new drug application (NDA) for FDA approval.[66] 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 a clinical trial in the United States.[67] The FDA also requested that the sponsor submit a plan on how to restrict the drug's distribution.[68]

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60 *See infra* Part III; Benten v. Kessler, 799 F. Supp. 281, 285–86 (E.D.N.Y. 1992).

61 Noah, *supra* note 59, at 578–79.

62 *Id.* at 579.

63 Melody Petersen, *Abortion Pill Distributor Energized by New Mission*, N.Y. TIMES (Sept. 30, 2000), https://www.nytimes.com/2000/09/30/us/abortion-pill-distributor-energized-by-new-mission.html [https://perma.cc/MB6W-RGPL].

64 *Id.*

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

66 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 OFF., GAO-08-751, APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 4 n.12 (2008), https://www.gao.gov/assets/280/279424.pdf [https://perma.cc/3MMJ-ESDD] [hereinafter GAO-08-751].

67 *Id.* at 5–6.

68 *Id.*

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.[69] By this time, the Clinton administration's previous enthusiasm to approve mifepristone had faded as President Clinton sought to rehabilitate his image after his cheating scandal.[70] 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."[71] Nevertheless, after reviewing the new information Danco 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."[72] The FDA finally approved mifepristone in 2000 after reaching an agreement with the sponsor on the limited distribution plan, labeling, and manufacturing processes.[73]

The FDA's initial approval of mifepristone was through the first forty-nine days of pregnancy.[74] It used the agency's Subpart H authority to restrict mifepristone's distribution; Subpart H allows distribution restrictions for drugs treating serious or life-threatening illnesses.[75] The sponsor objected to this classification, but the "FDA concluded that termination of an unwanted pregnancy is a serious condition and that the drug can allow patients to avoid a surgical procedure."[76] The FDA's primary restrictions were to prohibit pharmacies from distributing the drug—only qualified physicians could do so.[77] A physician was qualified only if she could "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," "provide surgical intervention" or had "plans to provide such care

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69 *Id.* at 19.

70 Noah, *supra* note 59, at 583.

71 *Id.*

72 *Id.* at 584; GAO-08-751, *supra* note 66, at 5.

73 GAO-08-751, *supra* note 66, at 5.

74 Memorandum entitled NDA 20-687 Mifeprex (mifepristone) Population Council, at 1 (Sept. 28, 2000), http://wayback.archive-it.org/7993/20170113112743/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf [https://perma.cc/FZ2Q-8S6R] [hereinafter Mifepristone Memorandum].

75 *Id.* at 6, 8.

76 GAO-08-751, *supra* note 66, at 6. The GAO reviewed this determination in 2008 and found it appropriate. *Id.* at 25–28.

77 Mifepristone Memorandum, *supra* note 74, at 6. The initial restrictions included many other provisions related to informed consent, shipping controls, and additional research. *Id.* at 3–8.

through other qualified physicians" in the case of complications.[78]

At the time, physicians 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.[79] Patients were also required to return to the office a few days later to take the second drug in the regimen, misoprostol, in person.[80] Finally, the drug also was given a black box warning—the most aggressive warning the FDA can require.[81] Black box warnings are typically reserved for drugs that can cause serious injury or death.[82]

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.[83]

Nevertheless, the restrictions persisted and were recrafted into a REMS once Congress passed the Food and Drug Administration Amendments Act, which created the REMS program in 2007.[84] This statute created the REMS system, which it described as "a drug safety program that the [FDA] can require for certain medications with serious safety concerns."[85] The statute requires the FDA to issue a REMS if it "determines that [it] is necessary to ensure that the benefits of the drug outweigh

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78 *Id.* at 6.

79 *Id.* at 8.

80 *Id.* at 2–3.

81 A GUIDE TO DRUG SAFETY TERMS AT FDA, FOOD & DRUG ADMIN. (2012), https://www.fda.gov/media/74382/download#:~:text=this%20type%20of%20warning%20is,serious%20or%20life%2Dthreatening%20risks.&text=NOVEMBER%202012-,cause%20disability%2C%20are%20life%2Dthreatening%2C%20result%20in%20hospitalization%20or,death%2C%20or%20are%20birth%20defects [https://perma.cc/7HDN-5NB7].

82 The current black box warning notes, among other things, that "[s]erious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions." HIGHLIGHTS OF PRESCRIBING INFORMATION, FOOD & DRUG ADMIN. 1 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [https://perma.cc/FCD5-CXGG].

83 Noah, *supra* note 59, at 584 (citations omitted).

84 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.

85 *Risk Evaluation and Mitigation Strategies (REMS)*, *supra* note 2.

the risks of the drug."[86] 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 distribution limitations.[87] 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.[88]

A REMS does not always create limitations on drug distribution; it could simply involve a communication plan, including a medication guide for patients or risk disclosures from the manufacturer to the provider.[89] 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[90] that may include limits on distribution, including restrictions on who can prescribe the drug and under what conditions.[91] The FDA's mifepristone REMS includes ETASU.[92] Though there are only sixty-one REMS programs[93] covering less than 5% of all FDA-approved drugs,[94] the vast majority (90%) also include ETASU.[95]

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86 21 U.S.C. § 355-1(a)(1).

87 *See Questions and Answers on the Federal Register Notice on Drugs and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies*, U.S. FOOD & DRUG ADMIN., 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 [https://perma.cc/2KXT-HJBK] (last updated March 28, 2018).

88 Notice, 73 Fed. Reg. 16313, 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 [https://perma.cc/W9DP-ZHWW]. In response, Danco submitted a supplemental new drug application (sNDA) proposing a REMS that would satisfy the agency, which the FDA accepted. Letter from Dep't of Health & Hum. Servs. to Danco Laboratories, LLC (June 8, 2011), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/020687s014ltr.pdf [https://perma.cc/WL94-QVBR].

89 *What's in a REMS?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems [https://perma.cc/U4SE-ESPQ] (last updated Jan. 26, 2018).

90 *The Availability and Use of Medication Abortion*, *supra* note 26.

91 Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

92 Mifeprex REMS Study Group, *supra* note 35, at 790.

93 *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsData.page [https://perma.cc/4JZ5-6X7W] (last visited May 30, 2021).

94 *See* Mifeprex REMS Study Group, *supra* note 35, at 790 (identifying that there were "1750 prescription drug and therapeutic biologic active ingredients that [had] been approved by FDA and marketed in the United States" as of February 2017).

95 *Approved Risk Evaluation and Mitigation Strategies (REMS)*, *supra* note 93.

In May 2015, mifepristone's sponsor submitted a Supplemental New Drug Application (sNDA), which proposed several changes to the administration of the drug.[96] 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."[97] 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.[98] 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."[99] It also found that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low."[100]

As a result, in 2016, the agency approved the sNDA.[101] 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.[102] 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.[103]

Nevertheless, the mifepristone REMS and ETASU still required that (1) only certified healthcare providers[104] prescribe the

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96 GAO-18-292, *supra* note 32, at 1.

97 *Id.* at 2.

98 Joint Stipulation of Facts at 11–12, Chelius v. Azar, No. 1:17-cv-00493-JAO-RT (D. Haw. Nov. 27, 2019).

99 CTR. FOR DRUG EVALUATION & RSCH., FDA, MEDICAL REVIEW 8 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [https://perma.cc/XT3Q-P6KB].

100 *Id.* at 47.

101 GAO-18-292, *supra* note 32, at 6.

102 *Id.* at 7–8.

103 *Id.*

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

drug, (2) the drug be dispensed in certain healthcare settings, and (3) patients receive additional counseling and sign a Patient Agreement Form.[105]

In December 2021, as this Article was coming to press, the FDA announced an additional change to the mifepristone REMS, the details of which will be ironed out over the coming months with the drug's sponsor.[106] The FDA removed the requirement that mifepristone be dispensed in person at a healthcare facility (known as the in-person dispensing requirement) and allowed pharmacies to prescribe it for the first time.[107] This decision was in response to the mounting evidence that medication abortion can be safely and effectively prescribed without in-person care—data that surged during the COVID-19 pandemic when the in-person dispensing requirement was temporarily suspended by court order.[108] As described below, this temporary suspension transformed abortion care in the thirty-one states that did not have their own laws requiring in-person dispensation. Though the FDA decided to make these changes permanent in December, it otherwise maintained the REMS requirements that providers become certified to prescribe the drug and that patients be given extra informed consent; it also *added* a new requirement—that pharmacies dispensing mifepristone become certified.[109] As explored throughout this Article, these burdens are unnecessary and continue to impede access to early abortion care.

The following section describes how the FDA's history in regulating mifepristone has significantly reduced access to medication abortion and isolated abortion care outside of the traditional healthcare setting, perpetuating abortion stigma. Though some of these effects may start to change with the FDA's most recent modification of the REMS, its continued over-regulation of the drug perpetuates abortion exceptionalism.

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made plans to provide such care through others" are eligible for certification. REMS, *supra* note 1.

105 *Id.*

106 Mifeprex (mifepristone) Information, Food & Drug Admin., (last updated Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/SH6R-SP66] ("The revised REMS document and materials will be available within one day after approval on the FDA website," which has not yet occurred).

107 *Id.*

108 *See* FDA Letter, supra note 14, at 25-38.

109 *Id.* at 6-7.

C. How the FDA's Regulation of Mifepristone has Harmed Abortion Access

The mifepristone REMS has serious implications for abortion access. First, the certified provider requirement makes it difficult for abortion to occur in traditional healthcare settings—within the purview of any Primary Care Physician (PCP) or Gynecologist—and has instead kept it segregated to abortion and family planning clinics. Isolating abortion care to clinics creates unnecessary stigma and logistical barriers. These barriers were especially pronounced in the era of the in-person dispensing requirement, where abortion patients were required to travel to clinics to pick up their prescription, even though clinics are few and far between in many states. The FDA's new pharmacy certification requirement similarly prevents medication abortion from being treated like regular healthcare. Second, until very recently, the REMS prevented a pure model of telemedicine abortion from coming to fruition. In fact, it was only due to the efforts of researchers during the COVID-19 pandemic, who meticulously documented the safety and efficacy of remote abortion provision when a court temporarily suspended the in-person dispensing requirement, that the FDA decided to lift it.[110] Though the mifepristone REMS is not the only factor limiting early abortion access—state abortion laws also play an important role—the REMS is a major barrier that must be addressed in order to see significant improvements in access.

1. *Segregating Abortion Care Outside of the Traditional Healthcare Setting*

The REMS keeps abortion separate from traditional healthcare by making it difficult or impossible for patients to obtain mifepristone through their regular pharmacy after an appointment with their regular provider.[111] It is true that OBGYNs and PCPs could apply for certification to dispense mifepristone,[112]

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110 The FDA refused to suspend the mifepristone REMS during the pandemic, as it has done for other medications. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RSCH., CTR. FOR BIOLOGICS EVALUATION & RSCH., POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND HEALTH CARE PROFESSIONALS 7 n.13 (2020), https://www.fda.gov/media/136317/download [https://perma.cc/3JUP-T3AV] (suspending multiple REMS for public health reasons, but leaving in-person dispending requirements in place); FDA v. ACOG, 141 S.Ct. 578, 579 (2021) (Sotomayor, J., dissenting) (noting that mifepristone was subject to disparate treatment by the agency).

111 *See* REMS, *supra* note 1.

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

and would likely obtain certification if they tried, but the practical barriers may be as effective as a prohibition.[113] Unlike most drugs, where physicians are granted the power to prescribe noncontrolled substances through their medical license, doctors must affirmatively seek certification to prescribe mifepristone, a noncontrolled substance.[114] Research from other settings confirms the psychological reality that simply requiring an affirmative opt-in can discourage behavior.[115] This makes sense: opting in requires providers to commit their time and energy to filling out the certification paperwork.

But opting into prescribing *mifepristone* also comes with unique risks to providers that make it even less likely they would choose to commit the time and resources in applying for certification. Abortion providers have long faced stigma, harassment, and violence. In 2019, ninety-two abortion providers experienced death threats; 1,507 experienced trespassing; and 3,123 experienced hate mail or harassing phone calls.[116] There have also been eleven murders and six attempted murders of abortion providers since 1977.[117] Certification creates a list of providers who offer abortion care. And though the drug manufacturers presumably work hard to keep that list confidential, doctors reasonably worry that their certification as a mifepristone prescriber could get leaked, subjecting them to this harassment or violence.[118] 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 less stigmatized drugs that are subjected to a simi-

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113 *See* Jones & Jerman, *supra* note, at 6 (noting the lack of physician offices that provide abortion care).

114 *See* REMS, *supra* note 1.

115 *The Opt-Out Option*, ASS'N FOR PSYCH. SCI. (Sept. 13, 2013), https://www.psychologicalscience.org/news/minds-business/the-opt-out-option.html [https://perma.cc/S4DX-RUGK]; Alpha's Path, *Opt-in vs. Opt-out Psychology*, MEDIUM (Apr. 25, 2019), https://medium.com/@alphaspath/opt-in-vs-opt-out-psychology-61b974e39ee2 [https://perma.cc/CQD8-SW8N].

116 NAF Releases 2019 Violence & Disruption Statistics, Nat. Abortion Fed., (July 30, 2020), https://prochoice.org/naf-releases-2019-violence-disruption-statistics/ [https://perma.cc/L5ZX-GXH2].

117 *Id.*

118 Mifeprex REMS Study Group, *supra* note 35, at 792 ("[T]he 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.").

lar ETASU—that certification process would be less discouraging because it does not also come with these unique risks.[119]

Moreover, before December 16, 2021, the burdens of certification were perpetuated by the in-person dispensing requirement, which forced providers to also dispense the drug themselves instead of relying on pharmacies. This created logistical barriers that were difficult to overcome even if providers were willing to face the hassle and anxieties associated with certification:

> 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.[120] 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.[121]

In other words, because most physicians did not have the capability or infrastructure to sell and dispense medication, even if they became certified, they would not be able to dispense it themselves, as the REMS required.[122]

Forcing certified providers to dispense the medication themselves also imposed financial risks—physicians would have to buy the medication themselves and then eat the cost if the drug expired before a woman requested it.[123] Predicting demand would be especially difficult given that many providers may not feel comfortable advertising that they offer this service, so even if they were certified to prescribe mifepristone and had

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119 For instance, thalidomide—a drug used to treat multiple myeloma and leprosy—requires certification to prescribe because it can cause fatal birth defects James H. Kim & Anthony R. Scialli, *Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease*, 122 TOXICOLOGICAL SCIS. 1, 1–2 (2011). But because it treats multiple myeloma and leprosy, stigma is not an additional barrier. *Thalomid REMS*, FDA, https://www.accessdata.fda.gov/drugsatfda_docs/rems/Thalomid_2017-06-27_REMS_Document.pdf [https://perma.cc/G9HL-YYCV].

120 Note: the cost of mifepristone has recently decreased after the introduction of a generic. *See* Anna North, *America's First Generic Abortion Pill, Explained*, VOX (Aug. 20, 2019), https://www.vox.com/identities/2019/8/20/20750226/abortion-pill-mifepristone-pregnancy-genbiopro-mifeprex-generic [https://perma.cc/P2Q2-UQLQ] (noting that the producer of the generic version of Mifeprex expected that the introduction of the generic to the market would lead prices to decrease).

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

122 *Id.*

123 DAVID S. COHEN & CAROLE JOFFE, OBSTACLE COURSE: THE EVERYDAY STRUGGLE TO GET AN ABORTION IN AMERICA 223 (2020).

the capacity to dispense it, their patients may not request it frequently enough to justify having it in stock. It would have been entirely reasonable for doctors to decide they either did not want, or could not handle, these extra administrative burdens.[124] 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.[125]

The fact that the FDA recently removed the in-person dispensing requirement and allowed pharmacies to dispense mifepristone is an important step forward. But its decision to impose a certification requirement on pharmacies will only duplicate the harmful effects associated with the provider certification requirement, making it unlikely that the average pharmacy will opt into carrying the drug. Similar to the concerns of providers, pharmacies with physical storefronts might worry about vandalism, arson, or threats to their employees if their certification status becomes known.[126] The fact that pharmacies are business entities creates additional considerations. The antiabortion movement is known to stage boycotts, which could harm pharmacies' business interests.[127] And unlike individual providers, who might be willing to face some of the risks of certification due to a deep moral conviction about the necessity of abortion, pharmacies will only endure these risks if they are outweighed by financial benefits. Certainly, some pharmacies, especially mail-order pharmacies, will be incentivized to participate and take advantage of this new business, but it is less likely that the big corporate chains most Americans rely on[128] will opt in. Indeed, as this Article was

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124 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.*

125 *Id.* In a recent study, forty-three percent of internal medicine primary care providers believed medication abortion was within their scope of practice and were interested in offering it. Tierney Wolgemuth et al., *Perspectives of Internal Medicine Physicians Regarding Medication Abortion Provision in the Primary Care Setting*, 104 CONTRACEPTION 420, 421 (2021).

126 NAF Releases 2019 Violence & Disruption Statistics, *supra* note 116.

127 *See* Cynthia Greenlee, A Short History of Abortion-Related Boycotts, Rewire News Group (May 23, 2019), https://rewirenewsgroup.com/article/2019/05/23/a-short-history-of-abortion-related-boycotts/ [https://perma.cc/L6EY-HYW2].

128 Cory Stern, CVS and Walgreens are completely dominating the US drugstore industry, Yahoo (July 29, 2015), https://www.yahoo.com/entertainment/s/cvs-walgreens-completely-dominating-us-211840229.html [https://perma.cc/A5CS-ZRUS].

coming to press, Walgreens announced that it would not seek certification.[129]

Though these rules are technical, they have a big impact on access to early abortion. First, because the mifepristone REMS makes it difficult for average healthcare providers to prescribe medication abortion, there are fewer providers to provide abortion care. Thus, it can be more difficult for people to find a provider and more difficult for the small number of providers to meet the demand.[130] As discussed in more depth in Section IV, this is an especially important concern as we face the potential end of *Roe v. Wade*, where states with abortion-friendly policies may need to dramatically increase their number of abortion providers to meet the increase in demand from out-of-state patients.

Second, the certification requirements effectively isolate abortion care into clinics outside of the traditional healthcare system because the REMS disincentivizes regular providers from offering this care. And as a result, the vast majority of certified providers are those that already have an abortion practice at abortion and family-planning clinics.[131] As of 2017, it was estimated that only 261 physician offices in the United States offered abortion services (providing only 1% of abortions[132]), while abortion and family planning clinics provide 95% of abortions.[133] The remainder of abortions occur in hospitals.[134] The removal of the in-person dispensing requirement will likely lead to more physician offices providing abortions, but eliminating the REMS entirely would certainly lead to more. Though we have yet to see the effects of the pharmacy certification requirement, we can expect that the certification process will similarly disincentivize traditional pharmacies from dispensing abortion medication—again, isolating abortion care outside of traditional healthcare settings.

This isolation of abortion care was particularly problematic when patients were required to pick up the medication in per-

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129 Cynthia Koons, *The Abortion Pill Is Safer Than Tylenol and Almost Impossible to Get*, BLOOMBERG (Feb. 17, 2022), https://www.bloomberg.com/news/features/2022-02-17/abortion-pill-mifepristone-is-safer-than-tylenol-and-almost-impossible-to-get.

130 *See* David S. Cohen & Krysten Connon, 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").

131 *See* Jones & Jerman, *supra* note 6, at 6.

132 Jones & Jerman, *supra* note 6, at 16.

133 *Id.* at 9.

134 *Id.* at 16.

son, meaning they needed to travel to a clinic.[135] Some states have only a handful of clinics left—five states (as of 2017) only had one[136]—meaning that women in those states would often need to travel long distances to get their medication. Long travel often required women to pay extra travel costs, find childcare, and miss work, in addition to facing harassment from protesters.[137] Given that three quarters of abortion patients are low income, these costs made abortion much more difficult to access.[138] This physical separation from the rest of the healthcare system also contributes to abortion stigma.[139]

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. For instance, they must abide by state mandated waiting periods and disclosures.[140] These barriers, however, can be fixed with physician outreach and education, while the REMS and similar state laws impose logistical challenges that are more difficult to combat. The stigma associated with providing abortion might be more difficult to overcome, but allowing providers to prescribe mifepristone as any other drug—i.e., without becoming certified and with dispensing from traditional pharmacies—would certainly help assuage fears of harassment.

2. *Prohibiting Telemedicine for Abortion*

Another significant barrier associated with the mifepristone REMS is that until very recently, it prevented a pure model

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

136 Jones & Jerman, *supra* note 6, at 17.

137 Raymond et al., *supra* note 135, at 174.

138 *Abortion Patients Are Disproportionately Poor And Low Income*, GUTTMACHER INST. (May 9, 2016), https://www.guttmacher.org/infographic/2016/abortion-patients-are-disproportionately-poor-and-low-income [https://perma.cc/9KJQ-MUL3].

139 CAROL SANGER, ABOUT ABORTION: TERMINATING PREGNANCY IN TWENTY-FIRST-CENTURY AMERICA 22–23 (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.").

140 *See generally, An Overview of Abortion Laws*, GUTTMACHER INST. (May 1, 2021), https://www.guttmacher.org/state-policy/explore/overview-abortion-laws?gclid=EAIaIQobChMIvY6L66u-6gIVIfC1Ch06UAHoEAAYASAAEgJ6UPD_BwE# [https://perma.cc/P2JU-KBEY] (giving an overview of abortion laws in the United States).

of telemedicine from coming to fruition.[141] As discussed in more depth in Section IV, abortion will become remarkably more accessible when abortion patients can meet with a provider remotely from home and receive the abortion medication by mail.[142]

Over the course of the COVID-19 pandemic, telemedicine for abortion care quickly changed from a future dream to an urgent necessity.[143] 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 clinic-based care.[144] The pandemic made travel much more difficult, especially for those dependent on public transportation.[145] And many clinics 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 woman to pass the ten-week mark entirely.[146] Despite these hardships, the REMS demanded in-person pickup.

Women of color, rural women, and low-income women are always disproportionately harmed by disruptions to abortion care, but this was especially pronounced in the pandemic.[147] Not only were these women less able to afford the expense and hurdles of long-distance travel to an abortion clinic, but they were at much greater risk of contracting and dying of COVID-19 to do so: "[T]hree-quarters of abortion patients have low incomes, making them more likely to rely on public transporta-

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141 Megan K. Donovan, *Improving Access to Abortion Via Telehealth*, 22 GUTTMACHER POL'Y REV. 23, 26 (2019). 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. Julia E. Kohn et al., *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 143 OBSTETRICS & GYNECOLOGY 343, 344 (2019); Donovan, *supra* note 141, at 24 (noting that this model exists in at least ten states).

142 *See* COHEN & JOFFE, *supra* note 123, at 222.

143 *See* Laurie Sobel, Amrutha Ramaswamy, Brittni Frederiksen & Alina Salganicoff, *State Action to Limit Abortion Access During the COVID-19 Pandemic*, KAISER FAM. FOUND. (Aug. 10, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/state-action-to-limit-abortion-access-during-the-covid-19-pandemic/ [https://perma.cc/6QWV-JTZ7] ("[A]ccess 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.").

144 *See id.*

145 Greer Donley, Beatrice A. Chen & Sonya Borrero, *The Legal and Medical Necessity of Abortion Care Amid the COVID-19 Pandemic*, 7 J.L. & BIOSCIENCES 1, 13 (2020).

146 *Id.* at 2, 11.

147 *Id.* at 13; Plaintiff's Memorandum of Law in Support of Motion for Preliminary Injunction at 28, ACOG v. FDA, 472 F. Supp. 3d (D. Md. 2020) (No. 8:20-cv-01320-TDC).

tion 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 homes."[148] Given that "COVID-19's mortality rate is three times higher for Black and Hispanic individuals than non-Hispanic White individuals," this additional and unnecessary exposure had life-threatening consequences.[149]

Telemedicine created an obvious solution to this problem—after all, there is no medical justification for making patients pick up their prescription in person. For these reasons, the U.K. started allowing the remote administration of abortion medication during the pandemic,[150] as other countries, like Australia, had implemented even before the pandemic began.[151] When the FDA under the Trump administration temporarily suspended the in-person requirements of other medications' REMS, including opioids, but refused to do the same for mifepristone,[152] a medical organization sued the FDA and won a preliminary injunction. That injunction meant that for the first time, many Americans began to receive fully remote abortion care.[153] Though the Supreme Court eventually reinstated the in-person dispensing requirement,[154] in the meantime, researchers collected data demonstrating that there was no increased incidence of adverse events when the in-person dispensing requirement was suspended. As a result, the Biden administration decided to temporarily, and then permanently, remove the in-person dispensing requirement.[155]

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

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148 FDA v. ACOG, 141 S.Ct. 578, 582 (2021) (Sotomayor, J., dissenting).

149 *Id.*

150 Elizabeth C. Romanis, Jordan A. Parsons, & Nathan Hodson, *COVID-19 and Reproductive Justice in Great Britain and the United States: Ensuring Access to Abortion Care During a Global Pandemic*, 7 J.L. & BIOSCIENCES 1, 8 (2020).

151 Paul Hyland, Elizabeth G. Raymond & Erica Chong, *A Direct-to-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis of the First 18 Months*, 58 AUSTL. & N.Z. J. OBSTETRICS & GYNECOLOGY 335, 336 (2018).

152 *See* POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, *supra* note 110, at 7 n.13; *ACOG*, 141 S. Ct. at 579 (Sotomayor, J., dissenting) (noting that the FDA subjected mifepristone to disparate treatment).

153 *See* infra Section IV.

154 *ACOG*, 141 S. Ct. at 578.

155 *See* FDA Letter, *supra* note 14, at 25-38.

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 come under increasing attack in recent years. Many physician organizations, including the American Medical Association, the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Family Physicians, have issued statements concluding that the REMS serves no medical purpose.[156] Below, I argue that these negligible benefits are outweighed by significant harms. 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, it may also increase a reliance on self-managed abortion, where women buy the drug online without the assistance of a doctor. The REMS is also impacting other aspects of reproductive healthcare. Women suffering from a missed or incomplete miscarriage, for instance, have less access to the drug because of the REMS,[157] even though a combination of mifepristone and misoprostol is more effective at managing these miscarriages than misoprostol alone.[158]

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, 0.03-0.5% of women

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156 *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 [https://perma.cc/VJ53-X8YJ]; Letter to the FDA, AAFP (Mar. 25, 2020), https://www.aafp.org/dam/AAFP/documents/advocacy/legal/administrative/LT-FDA-REMSFlexibility-032520.pdf [https://perma.cc/6GCF-GB9J]; *Mifepristone*, AMA POL'Y (2018), https://policysearch.ama-assn.org/policyfinder/detail/mifepristone?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml [https://perma.cc/XF9A-JQNN].

157 *See* Amanda Allen & Cari Sietstra, *Miscarriages Are Awful, and Abortion Politics Make Them Worse*, N.Y. TIMES (June 22, 2021), https://www.nytimes.com/2021/06/22/opinion/miscarriage-abortion.html [https://perma.cc/N79Y-3L3X].

158 Divyah Nagendra et. al., *Cost-effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy: Secondary Analysis of a Randomized Trial*, JAMA NETWORK OPEN 1, 7 (2020).

who took mifepristone needed a blood transfusion, 0.2% of women experienced sepsis, and 0.04-0.6% of women needed hospitalization.[159] The risk that someone who had taken mifepristone would make a visit to the ER was slightly higher, at 2.9-4.6%.[160] These adverse events are all treatable without any permanent issues.[161] 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"[162] compared to 3.7 million women who had taken the drug.[163] However, these "adverse events cannot with certainty be causally attributed to mifepristone."[164] There is some reason, for instance, to believe that at least eleven of the deaths were unrelated to the drug.[165] But even assuming mifepristone caused all twenty-four deaths, the risk of death from the drug would be 0.65 deaths per 100,000 (or 0.00065%).[166]

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, phosphodiesterase type-5 inhibitors, which include Viagra, have a fatality rate of four deaths per 100,000, which is roughly six times higher than mifepristone, yet it is not subject to a REMS.[167] Penicillin's fatality rate is two deaths per 100,000, roughly three times higher than mifepristone, but again, it is not subject to a REMS.[168] And drugs with similar risks, like anti-coagulants, are available at all pharmacies without a REMS.[169] Finally, the background risk associated with the alternative—carrying the pregnancy to term—is also much higher: "the pregnancy related mortality

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159 *Label for Mifeprex (mifepristone) tablets*, FDA 8, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [https://perma.cc/Z53F-2SYL].

160 *Id.*

161 Mifeprex REMS Study Group, *supra* note 6, at 791.

162 *Questions and Answers on Mifeprex*, *supra* note 20.

163 *Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, FDA, https://www.fda.gov/media/112118/download [https://perma.cc/X5UD-B246].

164 *Questions and Answers on Mifeprex*, *supra* note 20.

165 *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 REPROD. HEALTH (April 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf [https://perma.cc/65WV-YRM4].

166 *Id.*

167 *Id.*

168 *Id.*

169 Mifeprex REMS Study Group, *supra* note 6, at 792.

ratio is eighteen deaths per 100,000 live births, and it is even higher for Black women—forty deaths per 100,000 live births."[170]

Moreover, it is worth noting that the FDA approved mifepristone 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.[171] 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."[172] Nevertheless, patients can buy Korlym through a specialty pharmacy and have it delivered directly to their home.[173]

One could always speculate that mifepristone's safety record is so good *because of* the REMS, and therefore, the REMS is necessary. But at least with the in-person dispensing requirement, data has proved the opposite. For instance, in 2019, a team of researchers published a study in American women showing that medication abortion was safe and effective with telehealth.[174] A similar 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.[175] This data supports the experiences in other countries, like Mexico, Australia, and parts of Canada, where mifepristone is safely filled by pharmacists without an in-person appointment.[176] And most recently, data collected when the in-person dispensing requirement was temporarily suspended demonstrated that there were no increases in adverse events.[177]

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170 *Analysis of Medication Abortion Risk and the FDA report*, *supra* note 165.

171 *Improving Access to Mifepristone for Reproductive Health Indications*, *supra* note 156; CTR. FOR DRUG EVALUATION & RSCH., *supra* note 99, at 10.

172 CTR. FOR DRUG EVALUATION & RES., *supra* note 99, at 10.

173 *Id.*

174 *See* Raymond et al., *supra* note 135, at 175.

175 Hyland, Raymond, & Chong, *supra* note 151, at 337–38.

176 Daniel Grossman & Philip Goldstone, *Mifepristone by Prescription: A Dream in the United States but Reality in Australia*, 92 CONTRACEPTION 186, 186 (2015); Sarah Raifman, Megan Orlando, Sally Rafie, & Daniel Grossman, *Medication Abortion: Potential for Improved Patient Access Through Pharmacies*, 58 J. AM. PHARMACIST ASS'N 377, 379–80 (2018).

177 *See* FDA Letter, *supra* note 14.

These results are not surprising given that the REMS is not actually correlated with any of mifepristone's safety risks. First, the requirement (now removed) that a woman obtain the drug from a medical facility does nothing to reduce her risk of hemorrhage, infection, or incomplete abortion, all of which would all take place at home.[178] It is worth noting that the FDA only subjects sixteen other drugs (of roughly 20,000 FDA-regulated drugs) to an ETASU that requires a patient to obtain a medication in a clinic.[179] Of those sixteen 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.[180] 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. It is for this reason that ACOG concluded 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."[181]

Second, because almost any provider could become certified to prescribe mifepristone, the certified provider requirement is largely "an empty formality,"[182] aimed largely at discouraging mifepristone's provision than credentialling providers. Conservative states have often pointed to the fact that any healthcare provider can become certified to prescribe mifepristone as evidence that additional credentialing is necessary when passing state abortion laws. For instance, in a recent abortion case before the Supreme Court, *June Medical*, Louisiana criticized the abortion clinic for hiring an ophthalmologist and radiologist to provide medication abortion.[183]

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178 *See* Mifeprex REMS Study Group, *supra* note 35, at 792.

179 Plaintiffs' Motion for Summary Judgement at 12–13, 29, Chelius v. Becerra sub nom. Chelius v. Azar, No. 1:17-cv-00493-JAO-RT 11–12 (Nov. 27, 2019); FDA v. ACOG, 141 S. Ct. 578, 579 (2021) (Sotomayor, J., dissenting).

180 Plaintiffs' Motion for Summary Judgement, at 12–13.

181 Plaintiff's Memorandum of Law in Support of Motion for Preliminary Injunction at 25, ACOG v. FDA, 472 F. Supp. 3d (D. Md. 2020) (No. 8:20-cv-01320-TDC). The ACOG 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." *Id.* at 26.

182 Mifeprex REMS Study Group, *supra* note 35, at 793.

183 June Med. Servs. L.L.C. v. Russo, 140 S. Ct. 2103, 2172 (2020) (Gorsuch, J., dissenting) ("Clinics have even hired physicians whose specialties were unrelated to abortion—including a radiologist and an ophthalmologist.").

This is not to suggest these providers cannot adequately provide medication abortion—the opposite—but to note that any healthcare provider can meet the certified provider requirement and safely provide these services. The requirement therefore provides no independent credentialing function outside of a license to practice and a plan for dealing with emergencies, accomplishing nothing more than limiting the number of providers offering early abortion care. Though we do not yet know what the pharmacy certification requirement will contain, one can suspect that it will be subject to the same criticism.

The final component of the mifepristone REMS—that patients must sign a Patient Agreement Form—is also unnecessary given that medical ethics requires providers to counsel patients on the risks and benefits of all medications, and tort law provides recourse when they fail to do so. Even the FDA's own scientists recommended removing the Patient Agreement Form in 2016 because it was duplicative of informed consent.[184] Though this requirement has a much less significant impact on abortion access, it is still exceptional and redundant. 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 the 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 patients to receive a more expensive and risky surgical abortion procedure, increase their reliance on self-managed abortion, and even risk the possibility of being 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. These harms disproportionately fall on poor women, rural women, and women of color.

As noted in Section I.C, the certification and in-person dispensing requirements made it undesirable for physicians who do not typically provide abortions to prescribe and dispense mifepristone. The result was that only 261 physician offices

184 Joint Stipulation of Facts at 13–14, Chelius v. Azar, No. 1:17-cv-00493-JAO-RT (D. Haw. Nov. 27, 2019).

provided medication abortion in 2017, providing only 1% of abortions in the United States.[185] The only providers with an incentive to jump through the hoops of the mifepristone REMS are those at abortion and family planning clinics, which provide 95% of abortions in this country.[186] Thus, the REMS has contributed to the segregation of abortion care outside of traditional healthcare settings.

This reality meant that the overwhelming majority of women obtained an abortion at a clinic. But the number of clinics is steadily dropping, and six states only have one abortion provider left.[187] 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.[188] "In 2017, 95% and 94% of counties in the Midwest and the South, respectively, did not have a facility that provided abortion care."[189] As a result, many people do not live within 100 miles of a clinic.[190] When the in-person dispensing requirement was in effect, these long distances made abortion care even more expensive as patients needed to take time off work, procure childcare, and pay for travel costs.[191] "Given that 75% of abortion patients were poor or low-income in 2014, any additional barriers to abortion care—including travel and its associated costs, such as lost wages and expenses for child care, transportation and accommodations—may be significant for many women."[192] And "[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."[193]

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185 Jones, Witwer & Jerman, *supra* note 6, at 16.

186 *Id.* at 14.

187 *Id.* at 3; Holly Yan, *These Six States Have Only One 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 [https://perma.cc/BXH5-DLZA].

188 Jones, Witwer & Jerman, *supra* note 6, at 3.

189 Erica Chong et al., *Expansion of a Direct-To-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 CONTRACEPTION 43, 44 (2021).

190 Raymond et al., *supra* note 135, at 174.

191 *Id.*

192 Jenna Jerman, Lori Frohwirth, Megan L. Kavanaugh & Nakeisha Blades, *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 PERSPS. IN SEXUAL AND REPROD. HEALTH 95, 95 (2017).

193 Raymond et al., *supra* note 135, at 174.

For these reasons, the REMS's effect of funneling abortion care into clinics—and until very recently, requiring patients to show up in person—caused some patients to delay abortion care, leading to a more complicated, risky procedure.[194] Each week an abortion is delayed increases the risk of death from the procedure by 38%.[195] Patients who must travel more than fifty miles to a clinic are more likely to seek an abortion in the second trimester, and those who must travel more than three hours to a clinic are more likely to need an abortion at or after twenty weeks.[196] 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."[197] Consequently, "delays may ultimately impede women from having an abortion procedure entirely."[198] "For example, among a group of women denied an abortion because of gestational age limits, 85% reported procedure and travel costs as the primary reason for not obtaining an abortion elsewhere."[199]

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.[200]

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194 THE NAT'L ACADS. SCIS., ENG'G, AND MED., THE SAFETY AND QUALITY OF ABORTION CARE IN THE UNITED STATES 10 (2018).

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

196 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 (2017); Diana Greene Foster & Katrina Kimport, *Who Seeks Abortions at or after 20 Weeks?*, 45 PERSPS. SEXUAL & REPROD. HEALTH 210, 212 (2013).

197 Donley, Chen & Borerro, *supra* note 145, at 11.

198 *Id.*

199 Jerman, Frohwirth, Kavanaugh & Blades, *supra* note 192, at 95.

200 Donley, Chen & Borerro, *supra* note 145, at 11 (describing results from the Turnaway study).

And of course, the risks associated with pregnancy and birth are higher than abortion, so any woman denied an abortion increases her health risks, even if she doesn't suffer acute pregnancy-related conditions like pre-eclampsia.[201] This is especially true for Black women who experience maternal mortality rates three to four times higher than those of white women.[202]

By contrast, if mifepristone could be dispensed by average pharmacies, which are much more prevalent throughout the United States than clinics, patients could more easily access early abortion without delays. For instance, when the government in Australia started allowing pharmacies to dispense mifepristone, early abortion access increased, especially in rural areas.[203] Early research in the United States has shown that more OBGYNs would prescribe mifepristone if it could be filled at a pharmacy.[204] Though the FDA has decided to allow certified pharmacies to prescribe it, its addition of a pharmacy certification requirement makes it unlikely that the pharmacies most Americans rely on (Walgreens and CVS) will choose to participate, reducing its positive impact.[205] Nevertheless, telemedicine and medication-by-mail, which were also recently allowed, dramatically improve access to medication abortion, reducing delays in care.

Another underreported consequence associated with difficulties accessing abortion is that women will turn to self-managed abortion.[206] "[C]onsequences of encountering barriers to abortion care" include women "consider[ing] ending the pregnancy on their own, either with medications (misoprostol, herbs or home remedies) or by blunt-force physical trauma."[207] Self-managed abortion occurs when "when a person ends a pregnancy outside the medical care setting, typically by ordering abortion pills online."[208] Though recent data, discussed in greater detail in Section IV, suggests that self-managed medi-

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201 For instance, the risk of death is approximately fourteen 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, 215 (2012).

202 *Black Women's Maternal Health: A Multifaceted Approach to Addressing Persistent and Dire Health Disparities*, NAT'L P'SHIP FOR WOMEN & FAMS. (2018), https://www.nationalpartnership.org/our-work/health/reports/black-womens-maternal-health.html [https://perma.cc/7N3Z-FJU3].

203 Grossman & Goldstone, *supra* note 176, at 187.

204 COHEN & JOFFE, *supra* note 123, at 222–23.

205 *See* discussion accompanying notes 130-32.

206 Jones & Jerman, *supra* note 31, at 2.

207 Jerman, Frohwirth, Kavanaugh & Blades, *supra* note 192, at 98.

208 *The Availability and Use of Medication Abortion*, *supra* note 26.

cation abortion is safe in most contexts,[209] abortion care through a healthcare provider is still the gold standard and self-management can come with legal risks.

The rate of self-managed abortion has been increasing in recent years; though it is difficult to estimate the true number of these abortions, in 2017, eighteen percent of clinics "reported that they had seen one or more patients for a missed or failed abortion due to self-induction . . . , up from 12% in 2014."[210] "The majority of these facilities (54%) had seen only one or two such patients, but four facilities (all high-volume) reported 50 or more."[211] 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."[212] 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."[213] Indeed, organizations that help women self-manage their abortions have reported a significant increase in requests from Texans since SB8 went into effect.[214]213

Self-managed abortion is not legal in the United States. The only legal way to obtain the FDA-approved medication abortion regimen is through the REMS protocol.[215] Even if the REMS were removed, legal use of mifepristone and misoprostol would still require the prescription of a provider unless the FDA approved them for over-the-counter use, which is not currently being considered and is a distant goal.[216]

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209 *See infra* subpart IV.B.

210 Jones, Witwer & Jerman, *supra* note 6, at 8.

211 *Id.*

212 *Id.*

213 Jones & Jerman, *supra* note 31, at 2.

214 Tanya Basu, *Activists are helping Texans get access to abortion pills online*, MIT TECH. R. (Sept. 15, 2021), https://www.technologyreview.com/2021/09/15/1035790/abortion-pills-online-texas-sb8/ [https://perma.cc/4VV9-C785].

215 Catherine Shaffer, *REMS Violations Fines*, 27 NATURE BIOTECH. 1068, 1068 (2009). Abortions can be completed without mifepristone by simply using misoprostol, which is not subject to a REMS on its own. This is generally considered less effective and its legal use still requires a physician prescription. Nguyen Thi Nhu Ngoc et al., *Comparing Two Early Medical Abortion Regimens: Mifepristone+Misoprostol vs. Misoprostol Alone*, 83 CONTRACEPTION 410, 410 (2011).

216 Megan K. Donovan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, 21 GUTTMACHER POL'Y REV. 41, 44 (2018) [hereinafter *Self-Managed Medication Abortion*].

Nevertheless, pregnant people have found ways to order these drugs online from international sources. In 2018, an international organization, Aid Access, began helping Americans access medication abortion through international pharmacies by mail with the assistance of a doctor.[217] A person who contacts Aid Access has an online consultation with a doctor abroad; if the physician decides the patient meets the criteria for medication abortion, the drugs will be prescribed, filled by a pharmacy in India, and mailed to the patient.[218] In 2018, over 11,000 U.S. women requested Aid Access's help, and the organization filled 2,500 of those requests.[219] The following year, 21,000 U.S. women requested care from Aid Access, and more than a third were provided medication.[220] On March 8, 2019, the FDA issued a warning letter to Aid Access that its actions violated the Food, Drug & Cosmetic Act.[221] Nevertheless, the organization has refused to stop offering its services to American women.[222]

Though self-managed medication abortion appears to be safe in most circumstances,[223] the FDA has in other contexts loosened regulations when those regulations caused consumers to seek care outside of the traditional healthcare system, presumably with greater health risks. For instance, when onerous FDA regulations created a risk that patients might attempt fecal transplants on their own outside of the medical setting, the FDA relaxed its regulations.[224]

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.[225] Because

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217 Jones, Witwer & Jerman, *supra* note 6, at 10.

218 Letter from Aid Access, to Thomas Christl, Director, Food & Drug Admin., 2 (May 16, 2019), https://aidaccess.org/en/media/inline/2019/5/16/19_05_16_gomperts_letter_and_exhibit_a.pdf [https://perma.cc/H536-Y9YD].

219 Jones, Witwer & Jerman, *supra* note 6, at 10; *Who Are We*, AID ACCESS, https://aidaccess.org/en/page/561 [https://perma.cc/QR3E-ELGT].

220 COHEN & JOFFE, *supra* note 123, at 226.

221 Warning Letter from Food & Drug Admin., to Aid Access (March 8, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019 [https://perma.cc/5L4N-AUZG].

222 Letter from Aid Access, *supra* note 218; *Who Are We*, *supra* note 219.

223 *See infra* subpart IV.B; Letter from Aid Access, *supra* note 218 (noting that Aid Access is not aware of any serious adverse event); Donovan, *Self-Managed Medication Abortion*, *supra* note 216.

224 *Id.*

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

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.[226] Rare reports of similar cases have also emerged in recent years.[227] 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 proven wrong on ultrasound.[228] But still, the FDA would nonetheless 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."[229] There is also the risk that the medication women are buying online could be fake or impure,[230] although this risk seems low.[231] Self-management as an option for abortion, therefore, should encourage the FDA to remove the REMS and make it easier for patients to access abortion from their regular providers.

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.[232] She served two of those years before an appellate court invalidated part of her conviction and sentenced her to time served.[233] 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.[234] And Jennifer Whalen was sentenced to eighteen months in jail after purchasing abortion medication for her

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226 *Id.* at 1046–47.

227 *See 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/ [https://perma.cc/28TE-ULB3].

228 Raymond, et al., *supra* note 135, at 363.

229 COHEN & JOFFE, *supra* note 123, at 228.

230 *See Warning, fake abortion pills for sale online!!*, WOMEN ON WAVES (last visited Nov. 7, 2021), https://www.womenonwaves.org/en/page/974/warning-fake-abortion-pills-for-sale-online [https://perma.cc/UR9K-Y4VM].

231 *See* Chloe Murtagh, Elisa Wells, Elizabeth G. Raymond, Francine Coeytaus & Beverly Winikoff, *Exploring the feasibility of obtaining mifepristone and misoprostol from the internet*, 97 CONTRACEPTION 287, 291 (2018) (finding no evidence that mifepristone and misoprostol products sold online were dangerous or ineffective).

232 *Patel*, 60 N.E.3d at 1044.

233 *Id.* at 1062.

234 *Woman Who Took Abortion Pill Charged in Death of Fetus*, *supra* note 227.

sixteen-year-old daughter online.[235] Of course, the legal risks associated with illegal use of medication abortion almost always impact poor women and women of color disproportionately.[236]

Finally, the REMS burdens not only abortion access, but also access to the best protocol for miscarriage management. A miscarriage occurs when a fetus or embryo dies independently in the womb.[237] Though the pregnant person's body typically expels the 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.[238] In those cases, patients can choose whether they want to expedite the miscarriage with medical intervention or to wait for the miscarriage to end naturally, which can take weeks or longer.[239] Many patients understandably do not want to prolong their suffering or grief and opt for medical intervention.[240] Miscarriage management can occur surgically or with medication.[241] When patients choose medication, they are typically only given misoprostol, even though recent research suggests that the combination of mifepristone and misoprostol is more effective.[242] But because the REMS requires certification to prescribe mifepristone—and most OBGYNs are not certified—it is impossible for this regimen to be adopted into regular clinical care, harming people experiencing miscarriage as well as those who need abortion.[243] Part IV further explores the impact that using mifepristone for miscarriage could have on destigmatizing abortion care.

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235 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 [https://perma.cc/SF67-ELUN].

236 Ushma D. Upadhyay, Nicole E. Johns, Alice F. Cartwright, & Tanya E. Franklin, *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).

237 *Missed or Incomplete Miscarriage*, MISCARRIAGE ASSN., https://www.miscarriageassociation.org.uk/information/information-on-coronavirus-covid-19/missed-or-incomplete-miscarriage-information-for-you/ [https://perma.cc/DG42-VBR3].

238 *Id.*

239 *Id.*

240 *Id.*

241 *Id.*

242 Schreiber et al., *supra* note 29, at 2162.

243 *Id.*; Allen & Sietstra, *supra* note 157.

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 "determine[s] that . . . a [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug."[244] 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 mitigate a specific serious risk listed in the labeling of the drug."[245] Furthermore, the statute requires that 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."[246]

Given the safety and efficacy of mifepristone, it would be difficult for the FDA to conclude that mifepristone should be subject to any 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."[247] The certification requirement serves no credentialing function, the patient agreement form is duplicative of informed consent, and the (recently removed) in-person dispensing requirement does nothing to prevent the risks of the drug that would occur at home.[248] Moreover, the benefits of mifepristone are larger than the risks even without a REMS. Mifepristone benefits women by helping them avoid the greater medical

244 21 U.S.C. § 355–1(a)(2).
245 *Id.* § 355–1(f)(1).
246 *Id.* § 355–1(f)(2).
247 *Id.* § 355–1(a)(2); *see* Raymond et al., *supra* note 135, at 176.
248 *See* Section II.A.

risks associated with pregnancy and childbirth.[249] This alone would ensure that the benefits of the drug outweigh the drug's much smaller risks and was the basis for the 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[250]—the deprivation of which leads to physical, mental, and financial challenges.[251] It therefore serves important secondary benefits, which the FDA may also be able to consider in its risk-benefit calculus.[252]

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."[253] As just described, the REMS requirements are divorced from the drug's risks.[254] Second, the ETASU for mifepristone does not "conform with [ETASU] for other drugs with similar, serious risks."[255] Other drugs with similar, serious risks, like misoprostol, are not subject to any REMS. Drugs that are riskier, like Viagra and penicillin, also do not have a REMS.[256] And much riskier drugs, like opioids, are subject to more lenient REMS.[257] Even though opioids are highly addictive and have caused tens of thousands of fatalities *per year* from overdoses, the opioid REMS only requires that opioid manufacturers offer

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249 Mifeprex REMS Study Group, *supra* note 6, at 791.

250 Roe v. Wade, 410 U.S. 113 (1973); *see Reproductive Rights*, UNITED NATIONS, https://www.un.org/en/development/desa/population/theme/rights/index.asp [https://perma.cc/G9PD-US7R].

251 *See* The Harms of Denying a Woman a Wanted Abortion Findings from the Turnaway Study, ANSRH, https://www.ansirh.org/sites/default/files/publications/files/the_harms_of_denying_a_woman_a_wanted_abortion_4-16-2020.pdf [https://perma.cc/JDN4-4AUP] (describing the findings from the Turnaway Study).

252 Though the 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); Patricia J. Zettler, *The FDA's Power Over Non-Therapeutic Uses of Drugs and Devices*, 78 WASH. & LEE L. REV. 379 (2021).

253 21 U.S.C. § 355–1(f)(2).

254 *See supra* Part II.

255 21 U.S.C. § 355–1(f)(2).

256 *See supra* Part II.

257 *Risk Evaluation and Mitigation Strategy (REMS) Document, Opioid Analgesic REMS Program*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_Analgesic_2019_11_14_REMS_Document.pdf [https://perma.cc/8NY9-PMAC].

training to healthcare providers that prescribe opioids.[258] 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."[259]

But most importantly, the mifepristone REMS is "unduly burdensome on patient access to the drug," especially for "patients in rural or medically underserved areas."[260] "Poor and low-income women and those who live in rural areas are often hit hardest by state restrictions that exacerbate long-standing inequalities in abortion access . . . ."[261] Because clinics exist in urban areas, funneling abortion care through clinics creates extra burdens for rural women. These burdens were especially pronounced with the in-person dispensing requirement, which forced rural women to travel long distances to pick up mifepristone; it also disproportionately harmed poor women, who struggled the most to afford the additional costs associated with travel and in-person care.[262] It is well documented that travel time to an abortion or family planning clinic delays care and reduces access to abortion.[263]

Furthermore, the FDA's record for explaining the need for the REMS is thin. The agency at has never provided a detailed 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.[264] This might be an accident of history: the restrictions were first approved under a different statute before the REMS program existed, and then converted to a REMS in 2011.[265] But ever since the REMS has been in place, the agency has required others to prove the requirements are unnecessary before removing them. Though the burden is originally on the FDA to justify the imposition of a

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258 *Id.*

259 *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*, U.S. FOOD & DRUG ADMIN. (Sept. 2018), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems [https://perma.cc/B6ZU-CSBY].

260 21 U.S.C. § 355–1(f)(2).

261 *Although Many U.S. Women of Reproductive Age Live Close to an Abortion Clinic, A Substantial Minority Would Need to Travel Far to Access Services*, GUTTMACHER INST. (Oct. 3, 2017), https://www.guttmacher.org/news-release/2017/although-many-us-women-reproductive-age-live-close-abortion-clinic-substantial [https://perma.cc/MB8U-99CC].

262 *Id.*

263 *See supra* subpart I.C.

264 *See* Joint Stipulation of Facts at 13–14, Chelius v. Azar, No. 1:17-cv-00493-JAO-RT (D. Haw. Nov. 27, 2019).

265 *See infra* Section I.

REMS, once issued, the drug's sponsor and others bear the burden of proving there is an "adequate rationale" to modify the REMS.[266] In 2021, when the agency concluded its reconsideration of the mifepristone REMS, it explained that it was retaining the certification and patient agreement form requirements because no new research has demonstrated that they could be removed safely.[267] Similarly, the agency imposed a new pharmacy certification requirement because there was not sufficient evidence that retail pharmacies could safely dispense it.[268] This burden shifting is problematic in the absence of an original justification that mifepristone's benefits can only outweigh its risks with a REMS.

This Section argued that the mifepristone REMS is improper, has few benefits, and contains significant harms. It also demonstrated that the statutory basis for issuing a REMS, much less an ETASU, is not met. So why would the FDA have required it? Abortion exceptionalism. Abortion exceptionalism is a term that first appeared in legal scholarship around 2012 and describes the phenomenon "in which abortion is singled out for more restrictive government regulation as compared to other, similar procedures."[269] Linda Greenhouse and Reva Siegel have noted that abortion exceptionalism also involves "the notion that there is a special moral valence to abortion that, because it concerns the unborn, warrants special forms of health regulation not imposed on procedures of comparable risk."[270] Abortion exceptionalism is not new, but it is underexplored in the context of the FDA. I argue below that the FDA's

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266 RISK EVALUATION AND MITIGATION STRATEGIES: MODIFICATIONS AND REVISIONS, GUIDANCE FOR INDUSTRY, FOOD & DRUG ADMIN. 12 (June 2020), https://www.fda.gov/media/128651/download [https://perma.cc/3NP7-D8XL]. 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, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. *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.

267 FDA Letter, *supra* note 14, at 22-24.

268 *Id.* at 34-35.

269 Ian Vandewalker, *Abortion and Informed Consent: How Biased Counseling Laws Mandate Violations of Medical Ethics*, 19 MICH. J. GENDER & L. 1, 3 (2012); *see also* Caitlin E. Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047, 1048 (2014) ("'Abortion exceptionalism' is a term that has been used to describe the tendency of legislatures and courts to subject abortion to unique, and uniquely burdensome, rules.").

270 Linda Greenhouse & Reva B. Siegel, *Casey and the Clinic Closings: When "Protecting Health" Obstructs Choice*, 125 YALE L.J. 1428, 1448 (2016).

decision to institute the mifepristone REMS is a part of a larger pattern of bias from the agency that has harmed women's health. Though abortion is political, the FDA should not be. Rather, the agency should act according to its scientific mission and neutrally administer the statute to which it is bound.

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

Though the mifepristone REMS may seem like an outlier, the FDA has a troubling history of implicit bias that harms women's sexual and reproductive health.

> [T]he 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 by otherwise effective drugs.[271]

Below, I highlight many instances in which the FDA has acted unusually with regard to women's sexual and reproductive health. Some of these instances were overturned by court order or statute; others were resolved only after public pressure mounted. In almost all cases, advocates attacked the FDA's decisions by showing the agency's unusual treatment compared to other products. Such comparisons can help uncover biases that may be hidden when any one decision is viewed in isolation.

A. Plan B

The most famous instance of reproductive health bias at the FDA occurred in its regulation of Plan B. The FDA approved Plan B as emergency contraception in 1999.[272] Two years later, a group of sixty-six organizations petitioned the FDA to approve the drug for over-the-counter use.[273] Obtaining over-the-counter approval was vital 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 extra step easily caused days of delays, threatening

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271 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).

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

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

the efficacy of the medication. Plan B is most effective when people take the drug within twenty-four hours (or, at most, three days) of unprotected sex.[274]

The FDA rejected the switch to over-the-counter, even though its experts recommended approval; this led to a Government Accountability Office (GAO) investigation, which found that the FDA's decision was atypical.[275] 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."[276] The manufacturer objected to the restriction that prevented women under eighteen from purchasing Plan B over-the-counter and sued the agency under the Administrative Procedures Act.

The first time this case made it to court, the Eastern District of New York found that the agency's decision with regard to Plan B was contaminated with "political considerations, delays, and implausible justifications."[277] 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."[278] 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.[279] As a result, the court held that the FDA had acted arbitrarily and capriciously.[280] 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.[281]

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

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274 *Id.* at 522.

275 U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-109, 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).

276 *Tummino*, 603 F. Supp. 2d at 523.

277 *Id.*

278 *Id.*

279 *Id.* at 545–46.

280 *Id.* at 545.

281 *Id.* at 549.

> [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.[282]

Though this would have ordinarily put the matter to rest, the Secretary of the Department of Health & Human Services (HHS), which oversees the FDA, overruled the Commissioner's decision.[283] The Secretary ordered the Commissioner to deny the manufacturer's request on the grounds that "the data submitted for this product do not establish that prescription dispensing requirements should be eliminated for all ages."[284] The Secretary's main objection was that the data did not adequately take into account the "significant cognitive and behavioral differences between older adolescent girls and the youngest girls of reproductive age."[285] President Obama agreed.[286]

The petitioners sued again, and the court for a second time held that an agency—this time, HHS—acted arbitrarily and capriciously.[287] The court again relied on the unusual political involvement in what should have been a scientific decision.[288] The court noted that it was the first time the Secretary had overruled the Commissioner on a drug approval matter[289] and concluded that the Secretary's rationale was "so unpersuasive as to call into question her good faith."[290] 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."[291] 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

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282 Tummino v. Hamburg, 936 F. Supp. 2d 162, 166–67 (E.D.N.Y. 2013).
283 *Id.* at 167.
284 *Id.* (quoting Memorandum from Kathleen Sebelius, Sec'y Health & Human Servs., to Margaret Hamburg, Comm'r Food & Drugs (Dec. 7, 2011), Case No. 05-cv-366, Doc. No. 339-1).
285 *Id.*
286 *Id.* at 167–68.
287 *Id.* at 197.
288 *Id.* at 170.
289 *Id.*
290 *Id.* at 171.
291 *Id.* at 173–74.

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."[292] 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 [over-the-counter] status useless."[293]

As a result, the court remanded to the agency, ordering it to allow the over-the-counter sale of Plan B to women and girls of all ages.[294] Though the court acknowledged the political reasons why Plan B was controversial, it noted that the agency's 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 and for contraceptives."[295] The Obama administration decided not to appeal the decision and instead complied with the order. But the lengthy Plan B drama lost the FDA and HHS a great deal of credibility.[296] "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."[297]

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 unusually. In the decade or so where the drug was approved in European countries, but not the United States, some American women attempted to import mifepristone under the personal use ex-

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292 *Id.* at 171.

293 *Id.* at 168 (quoting Wilkinson Decl. ¶ 7, Case No. 12-cv-763, Doc. No. 6).

294 *Id.* at 197.

295 *Id.* at 169.

296 For instance, medical journals declared that the government was prioritizing politics over science. *See e.g.*, Alastair J.J. Wood, M.D., Jeffrey M. Drazen, M.D., & Michael F. Greene, M.D., *The Politics of Emergency Contraception*, 366 NEW ENG. J. MED. 101, 102 (2012) ("Thus, we once again have a situation in which political considerations are forming the basis of public health policy—resulting in another sad day for women.").

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

emption.[298] Though the FDA bans the sale of unapproved drugs, the personal use exemption allows individuals to 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."[299] The exemption was created in 1989 in response to the HIV/AIDS crisis, during which time the FDA was heavily criticized for not acting quickly enough to approve life-saving drugs; the exception helped patients access treatments not approved in the United States without sacrificing the agency's rigorous drug approval process.[300] Quickly thereafter, members of Congress complained to the FDA that mifepristone—then known as RU 486—could be permitted under this exemption. The FDA under the Bush administration then 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."[301]

In 1992, Leona Benten traveled abroad and returned to the United States with a small amount of mifepristone, which had been prescribed by her doctor to end an early pregnancy.[302] She was detained and the drug was seized.[303] She sued under the Administrative Procedures Act.[304] The district court granted her motion for preliminary injunction on the grounds that the agency failed to follow the required notice and comment procedures in issuing the import alert.[305] Though not central to the court's analysis, the court 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."[306] It or-

298 *See* Elizabeth A. Silverberg, *Looking Beyond Judicial Deference to Agency Discretion: A Fundamental Right of Access to RU 486?*, 59 BROOK. L. REV. 1551, 1551 (1994).

299 Benten v. Kessler, 799 F. Supp. 281, 285 (E.D.N.Y. 1992) (quoting U.S. FOOD & DRUG ADMIN. REGUL. PROCS. MANUAL 9-71-30(C)).

300 *Id.*

301 *Id.* at 286 (quoting U.S. FOOD & DRUG ADMIN. IMPORT ALERT 66–47).

302 Silverberg, *supra* note 298, at 1551.

303 *Id.*

304 *Benten*, 799 F. Supp. at 283.

305 *Id.* at 289.

306 *Id.* at 286.

dered the FDA to "immediately release the impounded dosage of RU486 to [the] plaintiff."[307]

On appeal, the Second Circuit stayed the injunction. Benten filed an application to vacate the stay, which the Supreme Court denied in a per curium opinion with no analysis.[308] 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 . . . 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."[309] "[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."[310]

On November 19, 1990, the House of Representatives called a hearing to consider the appropriateness of the FDA's decision.[311] There, many scientists testified that they believed the FDA's decision was politically motivated.[312] 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."[313]

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."[314] 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."[315] "[I]f the FDA concludes that RU-486 meets the crite-

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307 *Id.* at 291.

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

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

310 Peter S. Reichertz & Melinda S. Friend, *Hiding Behind Agency Discretion: The Food and Drug Administration's Personal Use Drug Importation Policy*, 9 CORNELL J. L. & PUB. POL'Y 493, 520 (2000).

311 *RU 486: The Import Ban and its Effect on Medical Research: Hearing Before the Subcomm. on Regul., Bus. Opportunities, and Energy of the H. Comm. on Small Bus.*, 101st Cong., 2d Sess. (1990).

312 *Id.* at 31.

313 *Id.* at 33.

314 Noah, *supra* note 59, at 578 (quoting President Clinton).

315 Importation of RU-486, Memorandum for the Secretary of Health and Human Services, 58 Fed. Reg. 7459 (Jan. 22, 1993).

ria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66–47."[316]

C. Female Sex Drugs

The FDA was again accused of bias—this time with regard to women's sexual health—when it refused to approve the female sex drug, flibanserin, which is used to treat hypoactive sexual desire disorder in women.[317] Flibanserin was touted as the "pink pill," which could help women increase their sexual interest.[318] In 2010, the FDA first declined to approve the drug.[319] The agency concluded that the eligibility criteria for the clinical trials were too restrictive, and therefore, the study results were not generalizable to the broader female population; it found that more data was needed to demonstrate the product was effective and safe.[320] The agency also required more data on the drug's interactions with other substances, including alcohol.[321] After the failed FDA review, the pharmaceutical company sponsoring the NDA decided to abandon the drug instead of investing in more clinical trials.[322]

Instead, a small pharmaceutical company, Sprout, bought the rights to the drug and decided to invest in it.[323] 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).[324] 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) compare[d] to those on a placebo."[325] Sprout resubmitted its NDA in 2013, but the FDA again found that more data was needed.[326] This time, the FDA expressed concerns about the marginal benefit of the drug and the drug's safety, especially if used with alcohol.[327]

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316 *Id.*
317 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 [https://perma.cc/SU6X-UXET].
318 *Id.*
319 *Id.*
320 Sanders, *supra* note 271, at 190.
321 *Id.*
322 Leber, *supra* note 317.
323 *Id.*
324 *Id.*
325 *Id.*
326 *Id.*
327 Sanders, *supra* note 271, at 190–91.

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.[328] 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.[329] "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."[330] The FDA rejected claims that gender bias influenced its decision.[331]

Sprout eventually applied for approval a third time, and an advisory committee met in 2015 to review the drug again.[332] 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.[333]

> 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.[334]

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."[335] 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.[336] 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."[337]

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328 Leber, *supra* note 317.
329 *Id.*
330 *Id.*
331 Sanders, *supra* note 271, at 177.
332 *Id.* at 173.
333 *Id.* at 177–78.
334 *Id.* at 184.
335 *Id.* at 186.
336 *Id.* at 187, 189.
337 *Id.* at 189.

This time, the advisory committee voted to approve the drug. Though the advisory committee found the benefits marginal, the benefits were statistically significant and clinically meaningful.[338] However, the FDA remained concerned about the drug's interaction with alcohol.[339] Though Sprout had conducted a study on the interaction of the drug with alcohol, it surprisingly included almost all men.[340] As a result, the committee recommended a REMS.[341] 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.[342] More recent data appears to suggest, however, that the drug is both effective and safe to use with alcohol.[343]

D. Medical Research in Women and Female Animals

In addition to bias in approving products, the FDA has been heavily criticized 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.[344] 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."[345] Women and men are afflicted by different diseases, respond to different treatments, and experience different side effects in response to drugs.[346] The exclusion of women from medical trials has therefore led to a dearth of research on how to treat women most effectively.[347]

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338 *Id.* at 193.
339 *Id.*
340 *Id.*
341 *Id.* at 195.
342 *Flibanserin REMS*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=indvRemsDetails.page&REMS=350 [https://perma.cc/NS66-4LTN] (last updated Oct. 2019).
343 James A. Simon, Anita H. Clayton, Sharon J. Parish, Stuart C. Apfel, & Leah Millheiser, *Effects of Alcohol Administered with Flibanserin in Healthy Premenopausal Women: A Randomized, Double-Blind, Single-Dose Crossover Study*, 17 J. SEXUAL MED. 83, 89–90 (2020).
344 CAROLINE CRIADO PEREZ, INVISIBLE WOMEN: DATA BIAS IN A WORLD DESIGNED FOR MEN 201 (2019).
345 *Id.* at 199; R. Alta Charo, *Protecting Us to Death: Women, Pregnancy, and Clinical Research Trials*, 38 ST. LOUIS U. L.J. 135, 140 (1993).
346 CRIADO PEREZ, *supra* note 344, at 198–99.
347 *Id.* at 200–01.

Women were historically excluded from medical research on the grounds that their menstrual cycles introduced too much variability into the data.[348] Of course, this very difference demonstrates the need to study all sexes; if women's bodies are that different from men's bodies, then their drug response could be too.[349] It also led to the unfortunate reality that diseases affecting women were hardly ever studied.[350] 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.[351] "The vocal pro-life community, galvanized in the wake of the U.S. Supreme Court's 1973 *Roe v. Wade* decision, expressed concern for unborn fetuses by pushing for stringent limits on women's research participation."[352] The FDA's overinclusive and ultimately harmful decision bowed to political pressure and codified the presumption of the male norm in medical research.[353]

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."[354] 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.[355] In 1993, President Clinton signed the NIH Revitalization Act, which required all NIH-funded studies to include wo-

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348 *Id.* at 202.

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

350 CRIADO PEREZ, *supra* note 344, at 198.

351 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 344, at 201.

352 Christine Grady & Colleen Denny, *Research Involving Women*, *in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 407, 409 (Ezekiel J. Emanuel et al. 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 political connotations, had a chilling effect on research involving women of childbearing potential and human fetuses.").

353 Grady & Denny, *supra* note 352, at 416.

354 DUSENBERY, *supra* note 349, at 24.

355 U.S. GOV'T ACCOUNTABILITY OFF., 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 [https://perma.cc/446X-Y4EY].

men and minorities.[356] 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.[357] 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."[358]

By 2001, GAO issued another report, which found significant improvement, but also areas of concern.[359] 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.[360] 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 women but women are still invisible."[361] "[I]nclusion is one thing, analysis is something else[,] [a]nd that's not there yet."[362] 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.[363]

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."[364] 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."[365] Beyond women, the FDA still does not require pre-

356 DUSENBERY, *supra* note 349, at 33.
357 *Id.*
358 *Id.*; Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 51 Fed. Reg. 39406, 39406 (1993).
359 U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 355, at 3–4.
360 *Id.* at 5.
361 DUSENBERY, *supra* note 349, at 36 (quoting Dr. Jan Werbinski, executive director of the Sex and Gender Women's Health Collaborative); Charo, *supra* note 345, at 151.
362 *Id.* at 37 (quoting Phyllis Greenberger, the former president of the Society for Women's Health Research).
363 *Id*; FOOD & DRUG ADMIN., FDA ACTION PLAN TO ENHANCE THE COLLECTION AND AVAILABILITY OF DEMOGRAPHIC SUBGROUP DATA (2014), https://www.fda.gov/media/89307/download [https://perma.cc/WL4X-DJC2].
364 DUSENBERY, *supra* note 349, at 33.
365 *Id.* at 34.

clinical studies to include female animals or cell lines,[366] and many researchers still use exclusively male animals and cell lines in their research.[367] This is despite the fact that sex differences in female animals and cells can also lead to different outcomes in research.[368] 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?"[369] Researchers who focus exclusively on male cells and male animals are missing possible medical breakthroughs for women's health.

E. Labeling Regulations in Pregnancy

Another area where the FDA has shown bias is in its regulations governing the labeling of drugs for use in pregnancy. Medical research in pregnant women has been almost nonexistent, creating a dearth of information about how pregnant women metabolize drugs.[370] 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)."[371] 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.[372]

The FDA's involvement here is related to its labeling regulations, where the agency has historically warned pregnant women about drug risks to their detriment.[373] Before 2015, the FDA required all drugs to be categorized as either A, B, C, D, or

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366 *See Guidance for Industry: 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 [https://perma.cc/A4WU-HKZP].

367 CRIADO PEREZ, *supra* note 344, at 206.

368 *Id.*

369 *Id.* at 207.

370 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. & SOC. CHANGE 45, 55 (2015).

371 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 5, 8 (2008).

372 Frank Hytten, *Blood Volume Changes in Normal Pregnancy*, 14 CLINICS HAEMATOLOGY 601, 601 (1985).

373 *See* Donley, *supra* note 370.

X, which was supposed to help pregnant women understand a drug's safety during pregnancy.[374] Category A was the safest; a drug only received Category A status if there were clinical trials *in pregnant women* that failed to show additional risks.[375] 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."[376] This warning was exclusively required in the pregnancy context; even though the FDA can never rule out drug risks for any population, it does not recommend any other population avoid pharmaceuticals that were shown to be safe in clinical trials.[377] Not only was a similar warning never used for drugs in the general adult population, it was also not required for pediatric use. Pediatric labeling does not contain a similar warning even when there is no available pediatric data showing that the drug is safe for use in kids and even when known risks in that population exist. Thus, "the FDA permit[ed] drugs that are known to be risky to children [ ] contain less precautious labeling than drugs tested in pregnant women without any demonstration of risk."[378]

The pregnancy labeling regulations also "focused exclusively on fetal (as opposed to maternal) risks from drug consumption."[379] This focus led to 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."[380] 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."[381]

And though pregnancy labeling was always required to recommend that pregnant women avoid drugs during pregnancy—which as noted, was an unnecessary, unusual, and paternalistic requirement—the labeling "failed to present infor-

374 *Id.* at 69–70.
375 *Id.*
376 *Id.* at 70 (citation omitted).
377 *Id.* at 70–71.
378 *Id.* at 71–72.
379 *Id.* at 73.
380 *Id.* (citation omitted).
381 *Id.* at 81.

mation on the risks associated with drug avoidance."[382] This is a problem because women and fetuses can experience serious complications when women avoid needed drugs in pregnancy.[383] 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, in addition to the harmful effects for the women's mental health.[384] Thus, pregnant women were not given the information to evaluate the fetal risks of avoiding drug use or the maternal risks associated with either taking drugs or avoiding drugs. 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.[385]

After great criticism and decades of consideration, the FDA finalized a rule that updated its labeling requirements for use in pregnancy, which were phased in from 2015-2020.[386] The new regulations were an improvement: they eliminated the drug categories, required the disclosure of risks affecting 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.[387] Nevertheless, the modified regulations continue to rely on animal data over objections from toxicologists, even low-quality animal data.[388]

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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 when it comes to women's reproductive and sexual health. The agency has allowed the politics of contraception and abortion to override its scientific mission. The mifepristone REMS is another instance where the FDA is failing to follow its own mandate in the context of women's reproductive health. As a result, it should be removed.

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382 Donley, *supra* note 370, at 73.
383 *Id.* at 57.
384 *Id.*
385 *Id.* at 73–75.
386 *Id.* at 49.
387 *Id.* at 76–78.
388 *Id.* at 78–80.

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 sexual and reproductive health. This Section first describes the effort to remove the REMS, which started as a legal challenge under the Trump administration but evolved into a direct request to the FDA under the Biden administration. As this Article was coming to press, the FDA announced that it will maintain the REMS, but remove the in-person dispensing requirement, suggesting that litigation may still be necessary to fully dismantle the REMS. This Section then explores how early abortion care is already being transformed by the removal of the in-person dispensing requirement, and how it can be further improved if the rest of the REMS were also relinquished.

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*,[389] 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, violating the Administrative Procedures Act. I briefly explain the merits and weaknesses of these theories below. I then explore how the Biden administration could remove the mifepristone REMS on its own.

1. *Constitutional Challenge*

Historically, the most common challenge to abortion laws was under the Due Process Clause—specifically, litigants argue that the law constitutes an undue burden under *Planned Parenthood v. Casey*.[390] 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

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389 Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment at 11–12, Chelius v. Azar, No. 17-cv-493 (D. Haw. Nov. 27, 2019).

390 505 U.S. 833, 836–38 (1992).

abortion of a nonviable fetus."[391] In *Whole Woman's Health v. Hellerstedt*, the Court strengthened the undue burden standard by requiring that the law's benefits outweigh its burdens.[392] Thus, if the law has no benefits for women's health, then it would be unconstitutional because any burdens would outweigh the nonexistent benefits. Relying on *Whole Woman's Health* or similar balancing tests, some lower courts have found 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 unconstitutional under the state constitution, using a balancing test.[393] 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, even though off-label use is permitted and common for other drugs,[394] relying on a balancing test.[395]

But in *June Medical v. Russo*—the first abortion case after Justice Kennedy retired—a majority of the Court did not sign onto the balancing test from *Whole Woman's Health*. Chief Justice Roberts cast the fifth vote to overturn a restrictive Louisiana abortion regulation, but penned a separate concurrence that effectively overruled the balancing test.[396] He argued that the balancing test was inconsistent with *Planned Parenthood v. Casey* and that he would instead utilize a less rigorous version of the undue burden standard in future cases.[397] 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.[398] In this view, it is irrelevant if the law benefits women's health. Because Justice Roberts's vote is now necessary

391 *Id.* at 877.

392 136 S. Ct. 2292, 2309 (2016).

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

394 "Laws prohibiting the 'off-label' use of abortion-inducing medication offer a paradigm case of abortion exceptionalism." Greenhouse & Siegel, *supra* note 270, at 1447.

395 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 Tex. Surgical Health Servs. v. Abbott, 951 F. Supp. 2d 891, 905 (W.D. Tex. 2013).

396 June Med. Servs. v. Russo, 140 S. Ct. 2103, 2133-2142 (2020) (C.J. Roberts, concurring).

397 *Id.*

398 *Id.*

to invalidate any abortion restriction, the reasoning in these earlier cases, which relied on a balancing test, is inconsistent with how a majority of the Supreme Court understands its abortion precedent.

Since *June Medical*, the composition of the Supreme Court has changed again. Justice Barrett replaced Justice Ginsburg, moving the Court even further to the right. The impact of this change was on display in *ACOG v. FDA*—a 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* was the first abortion case with Justice Barrett and was largely thought to signal the Court's receptivity to both the *Chelius* case and abortion rights generally. 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.[399] The district court, relying on *Whole Woman's Health*'s balancing test, 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 seeking care: needless exposure to the severe risks of illness and death associated with COVID-19.[400]

Thus, the court found the in-person dispensing requirement to create an unconstitutional undue burden.

The Supreme Court reversed this preliminary injunction.[401] 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.[402] In light of this outcome in *ACOG v. FDA*, it is hard to imagine the Court reaching a different result in the *Chelius* case, where the urgency of the pandemic is not at issue. "[B]y allowing the FDA to enforce in-person requirements for mifepristone during the pandemic, the Court heavy-handedly insinuates that these same requirements would be acceptable

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399 Order for Preliminary Injunction, ACOG v. FDA, No. 8:20-cv-01320-TDC 80 (D. Md. Jul. 13, 2020).

400 *Id.* at 25.

401 FDA v. ACOG, 141 S. Ct. 578 (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).

402 *Id.*

in a non-pandemic world."[403] Perhaps more importantly, at a time where the Supreme Court is expected to overturn or significantly limit the constitutional right to abortion in the near future, a strategy that relies on this doctrine is not likely to be successful, at least not before the Supreme Court.

2. *Arbitrary and Capricious Challenge*

Given the current Supreme Court and the expected hostility it will have to future constitutional challenges to abortion regulation, 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 [sic] may in the end offer the greatest protection against regulations that single out abortion for disfavored treatment."[404]

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."[405] 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)."[406] 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 was treating Plan B exception-

403 Jareb A. Gleckel & Sheryl L. Wulkan, *Abortion and Telemedicine: Beyond COVID-19 and the Shadow Docket*, 55 UC DAVIS L. REV. ONLINE (forthcoming 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3801124&dgcid=EJournal_htmlemail_women,:gender:the:law:ejournal_abstractlink [https://perma.cc/JLV2-LYZJ].

404 Metzger, *supra* note 309, at 869.

405 *Id.* at 899 (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)).

406 INS v. Yang, 519 U.S. 26, 32 (1996).

ally and not following its typical practices.[407] 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."[408] As Metzger noted, "[o]ften what triggers greater scrutiny is judicial perceptions of perceived agency arbitrariness, expansion of power, or improper influences."[409] 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 motivating its actions."[410]

This Article highlights the evidence that the FDA irrationally departed from its standards when it issued the mifepristone REMS.[411] There is a strong case to be made, therefore, that the agency acted arbitrarily and capriciously. 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 involve 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 overrule the same decision under non-exigent circumstances. 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.[412] 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.'"[413] This position may not be

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407 Tummino v. Hamburg, 936 F. Supp. 2d 162, 197–98 (E.D.N.Y. 2013).

408 Nat'l Res. Defense Council, Inc. v. SEC, 606 F.2d 1031, 1049 n.23 (D.C. Cir. 1979).

409 Metzger, *supra* note 309, at 900.

410 *Id.*

411 *See supra* Part II.

412 Metzger, *supra* note 309, 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.").

413 FDA v. ACOG, 141 S. Ct. 578 (2021) (Roberts, C.J., concurring).

popular with the rest of the conservative wing of the Court, which has spent years attempting to weaken deference to administrative agencies,[414] but it could nevertheless provide an easy justification to allow the Court to maintain the mifepristone REMS while simultaneously appearing politically neutral.

Nevertheless, 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. *Reconsideration Within 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 keep the REMS in place during the middle of a deadly pandemic when it was otherwise temporarily suspending REMS requirements for other medications.[415] But with Biden's 2020 victory, activists shifted their approach to working directly with the agency to reevaluate the REMS.

The president has historically 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."[416] 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.[417] Moreover, first-trimester abortion is supported by a majority of Americans (sixty percent), and he could reasonably argue that

414 Joshua Matz, *The Imminent Demise of Chevron Deference*?, TAKE CARE (June 21, 2018), https://takecareblog.com/blog/the-imminent-demise-of-chevron-deference [https://perma.cc/7BSH-XZKM].

415 POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY, *supra* note 110, at 7 n.13.

416 Noah, *supra* note 59, at 573.

417 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 [https://perma.cc/X6FG-8KXT].

loosening the mifepristone REMS will reduce reliance on the less popular second-trimester abortion.[418]

The Biden administration clearly had some of this in mind when it announced on December 16, 2021 that it would permanently remove the in-person dispensing requirement. Though the announcement on the website was bare bones,[419] the agency sent a letter to the American Association of Pro-Life Obstetricians and Gynecologists outlining the reasons for its decision.[420] (That group had asked the agency to strengthen the mifepristone REMS and make medication abortion more difficult to access.) As noted above, the agency justified its decision by relying on recent evidence and published data clearly establishing the safety and efficacy of remote provision of medication abortion.[421] With that safety established, the agency concluded that it *must* remove the requirement because doing so "will render the REMS less burdensome to healthcare providers and patients, and . . . the REMS will continue to ensure that the benefits of mifepristone for medical abortion outweigh the risks."[422] Nevertheless, the agency refused to remove the provider certification requirement or the patient agreement form because no new data proved they were unnecessary;[423] it similarly added a pharmacy certification requirement because it concluded that there was insufficient data to suggest its safety and efficacy at retail pharmacies.[424]

Though the FDA's decision to remove the in-person dispensing requirement was a step in the right direction, advocates should continue to put pressure on the agency to remove the other REMS requirements. They can do this in a few ways: First, reproductive health scholars can conduct research demonstrating that the other REMS requirements are unnecessary for safety and efficacy and then ask the FDA to modify the REMS based on that research. Though certainly worth the investment, this research is time consuming and expensive, meaning that this approach will likely take years. Second, ad-

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418 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 [https://perma.cc/DFG8-RDYW].

419 Mifeprex (mifepristone) Information, Food & Drug Admin (last updated Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information [https://perma.cc/2VK8-5Z64].

420 FDA Letter, *supra* note 14.

421 *Id.* at 6-7.

422 *Id.* at 35.

423 *Id.* at 23-24.

424 *Id.* at 34-35.

vocates can also continue the *Chelius* lawsuit and argue that mifepristone does not meet the statutory criteria of a REMS. If advocates win at the district court or circuit court level, the FDA may decide not to appeal the decision and simply remove the REMS in compliance with the lower court's order, thereby never asking the Supreme Court to weigh in.

It's important to note that if the FDA does conclude that the evidence supports removing 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 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 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. Anti-abortion activists have argued since the FDA approved mifepristone in 2000 that the drug is dangerous and should not only be restricted, but entirely removed from the market.[425] 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.[426] These arguments will likely get recycled in litigation about the mifepristone REMS.[427]

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425 *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 [https://perma.cc/U6J7-CAKY]; Letter from Ted Cruz, Senator, and Nineteen Other Senators to Stephen Hahn, Commissioner, FDA (Sept. 1 2020), https://www.cruz.senate.gov/files/documents/Letters/2020.09.01%20--%20Pro-Life%20Mifeprex%20Letter%20to%20FDA%20-%20FSV.pdf [https://perma.cc/L6Q9-87K6].

426 Letter to FDA Commissioner, *supra* note 425, at 2–3.

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

But just as precedent on judicial deference to administrative agencies would harm abortion rights activists in the *Chelius* lawsuit, it would similarly harm anti-abortion activists in a lawsuit challenging the removal or modification of the REMS.[428] 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 judge would recognize that such a scientific 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*.[429] 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 reissue the decision, correcting the flaws identified by the court.

B. The Future of Abortion Care Without the Mifepristone REMS

Removing the mifepristone REMS has the power to transform early abortion care. Already, the removal of the in-person dispensing requirement has created possibilities that were unimaginable five years ago—namely, an early abortion through telehealth without ever leaving one's home. And these innovations led to medication abortion becoming, for the first time, the majority (54%) of all abortions in 2020.[430] But these benefits will not be felt everywhere. Some states have their own laws that will continue to burden medication abortion provision even if the federal policy disappears. Nineteen states, for instance, either require medication abortion to be distributed in the presence of a physician or ban the use of telemedicine for

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428 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, 163 (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.

429 141 S. Ct. 578, 578–79 (2021) (Roberts, C.J., concurring).

430 Rachel K. Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions* (Feb. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

abortion.[431] More states are likely to pass similar laws in the next few years.[432] As a result, the FDA's removal of the in-person dispensing requirement will not help patients in these states.

In the remaining thirty-one states, however, removing the in-person dispensing requirement will lead to an enormous expansion of access. Many of these changes have already begun.[433] The COVID-19 pandemic transformed remote abortion care from a distant dream to a current reality.[434] After the District of Maryland temporarily suspended the in-person dispensing requirement, a variety of start-ups launched, including Abortion on Demand, Hey Jane, Choix, and Just the Pill, which created "virtual clinics" that provide remote abortion care.[435] Some of these organizations are innovating abortion care, like sending the abortion medication in a care package that includes herbal tea and anti-nausea medication, and most have significantly cut the cost of early abortion by hundreds of dollars.[436] More traditional abortion clinics also began mailing abortion medication after meeting with patients via telemedicine.[437] As a result, telemedicine is quickly becoming

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431 *Medication Abortion*, GUTTMACHER INST. (May 1, 2021), https://www.guttmacher.org/state-policy/explore/medication-abortion [https://perma.cc/4JRF-NNT5].

432 *See* Alice Miranda Ollstein & Darius Tahir, *Will At-Home Abortions Make Roe V. Wade Obsolete?*, POLITICO (updated March 21, 2021), https://www.politico.com/news/2021/03/20/abortion-pills-telemedicine-477234 [https://perma.cc/6QJX-GPQV].

433 *See* Chong et al., *supra* note 189, at 2 (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 [https://perma.cc/WE8K-G74W]; Carrie N. Baker, *How Telemedicine Startups Are Revolutionizing Abortion Health Care in the U.S.*, MS. MAG. (Nov. 16, 2020), https://msmagazine.com/2020/11/16/just-the-pill-choix-carafem-honeybee-health-how-telemedicine-startups-are-revolutionizing-abortion-health-care-in-the-u-s/ [https://perma.cc/ZGE8-8L5Q].

434 *See* Reader, *supra* note 433 (noting that these start-ups started offering remote abortions after the District of Maryland suspended the in-person dispensing requirements); Baker, *supra* note 433.

435 Reader, *supra* note 433.

436 Susan Rinkunas, *A Bitter Pill*, MARIE CLAIRE (Jan. 13, 2021), https://www.marieclaire.com/politics/a35203155/pandemic-abortion-telemedicine/ [https://perma.cc/MXZ6-T9XW].

437 *See id.* (noting that Whole Woman's Health is offering remote appointments); *see also PPMW Now Offering Medication Abortion At-Home Services*, PLANNEDPARENTHOOD.ORG. (Sept. 10, 2021), https://www.plannedparenthood.org/planned-parenthood-metropolitan-washington-dc/press-room/ppmw-now-offering-medication-abortion-at-home-services [https://perma.cc/3NQT-5T38] (noting that Planned Parenthood of Metropolitan Washington, DC started offering telemedicine).

the norm for early abortion care in states that allow it.[438] This trend is unlikely to change once the pandemic ends: "[t]he 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 patients would no longer need to travel to clinics to end a pregnancy in the first ten weeks.[440] As noted in subpart I.C, this would immediately improve access by reducing the cost and logistical burdens associated with travel, especially for those who live hundreds of miles from the nearest clinic.[441] This will especially benefit rural women, who must travel the farthest, and poor women, who are least able to afford the costs associated with travel.[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 patients pay for abortion out of pocket[444] and half of those needing an abortion live in poverty,[445] this benefit will be very impactful for all abortion patients.

Another huge advantage of telemedicine is that patients 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]

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438 Baker, *supra* note 433 (describing remote abortion as the new standard of care).

439 Rinkunas, *supra* note 436.

440 Mounting evidence suggests that medication abortion is safe and effective through twelve weeks, and the mifepristone label may eventually be changed to extend the timing of its use. 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, https://www.womenonweb.org/en/page/573/what-will-happen-if-you-do-an-abortion-with-pills-after-the-first-12 [https://perma.cc/FG6F-4EWV] (last visited Mar. 23, 2021).

441 *See supra* subpart I.C.

442 *See supra* subpart II.B.

443 Rinkunas, *supra* note 436.

444 *How do Women Pay for Abortions*, GUTTMACHER INST. (2013),https://www.guttmacher.org/sites/default/files/graphics/infographics/HowDoWomenPay-740.pdf [https://perma.cc/EP7F-9LBF].

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 [https://perma.cc/4273-Q5GQ].

446 COHEN & JOFFE, *supra* note 123, at 114.

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 3,387 incidents of obstructing facilities (up from 3,038 in 2018), and 123,228 incidents of picketing (up from 99,409 in 2018)."[447] In addition to traditional harassment, 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 abortions and shame them online; protesters 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 public stigma associated with 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] Concentrating all abortion care in certain locations like clinics makes it easy for protesters and extremists to target providers and patients. For instance, 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 abortions.[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 care. And by making it safer and less stigmatizing for providers to offer early abortion care, more physicians would likely be willing to provide it.[452]

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447 Chong et al., *supra* note 189, at 2.

448 COHEN & JOFFE, *supra* note 123, at 119.

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

450 *Anti-Abortion Violence*, NARAL PRO-CHOICE AM., https://www.prochoiceamerica.org/issue/anti-abortion-violence/ [https://perma.cc/XT6Q-32ET].

451 COHEN & JOFFE, *supra* note 123, at 114–15.

452 *See* Cohen & Connon, *supra* note 130, at ix–x (noting that "partly because abortion providers are not safe, there are very few abortion providers in the United States").

Though this de-linking of early abortion from physical spaces has many positive implications for early abortion care, clinics would still be necessary for surgical abortions after ten weeks.[453] 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.[454] 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 are also expected to struggle financially if new, virtual clinics reduce demand for their services, which could lead to more clinic closures, even in states with abortion friendly laws.[455] This is a serious concern given that it is already difficult for women to find a clinic that offers second-trimester abortion care.[456] In other words, the removal of the REMS will improve the experience and availability of early abortion but could have the opposite effect on abortion after ten weeks.

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."[457] This perspective ignores the reality that abortion is segregated into clinics because of laws like the mifepristone REMS that have isolated abortion outside of traditional healthcare. Nevertheless, states have historically attempted to regulate the physical space within abortion clinics to the extent that compliance is difficult or

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453 Rinkunas, *supra* note 436.

454 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 [https://perma.cc/M62M-UK9R], when all abortion care occurred in clinics, the majority of clinic-based care was in the first trimester. However, this would change if telemedicine "skim[s] off all of the early abortions" from clinics. Rinkunas, *supra* note 436.

455 Rinkunas, *supra* note 436.

456 *See Later Abortion*, GUTTMACHER INST. (Nov. 13, 2019), https://www.guttmacher.org/evidence-you-can-use/later-abortion [https://perma.cc/JPR6-4YTP].

457 Lindgren, *supra* note 449.

impossible.[458] 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."[459] When abortion is happening entirely online and in the privacy of one's home, there are no physical spaces to regulate.[460] This is not to say that antiabortion legislatures will be unable to regulate abortion provided online—or simply ban it as many states have done—but it does undercut one of their common strategies over the past few decades.

Unfortunately, the states with the fewest brick-and-mortar clinics are also those most 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 harassment 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 and won't see much change in their legal abortion model after the REMS is removed; northern and coastal states, on the other hand, which have recently sought to codify and expand abortion protections, will see dramatic improvement in early abortion access without the in-person dispensing requirements.[461]

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 *Casey*.[462] The case, *Dobbs v. Jackson Women's Health Organization*, concerns

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458 *See Targeted Regulation of Abortion Providers*, GUTTMACHER INST. (May 1, 2021), https://www.guttmacher.org/state-policy/explore/targeted-regulation-abortion-providers# [https://perma.cc/D3SK-XLG6].

459 *Id.*

460 *See* Lindgren, *supra* note 449, at 358–64 (describing the privacy benefits associated with medication abortion in the home).

461 *See* Elizabeth Nash, *Unprecedented Wave of Abortion Bans is an Urgent Call to Action*, GUTTMACHER INST., https://www.guttmacher.org/article/2019/05/unprecedented-wave-abortion-bans-urgent-call-action [https://perma.cc/GS5Q-R38V] (updated May 31, 2019); Elizabeth Nash et al., *State Policy Trends 2019: A Wave of Abortion Bans, But Some States Are Fighting Back*, GUTTMACHER INST. (Dec. 12, 2019), https://www.guttmacher.org/article/2019/12/state-policy-trends-2019-wave-abortion-bans-some-states-are-fighting-back [https://perma.cc/JS43-LK4D].

462 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 [https://perma.cc/688L-PRSS].

whether a state can ban abortion starting at fifteen weeks, long before a fetus is viable.[463] With Justices Barrett and Kavanaugh replacing Justices Ginsburg and Kennedy, there is a genuine fear that the constitutional right to abortion may become a relic of a different era.[464] 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 nearly half are expected to ban all or most abortions.[465] These bans would disproportionately and significantly harm poor women, rural women, and women of color living in antiabortion states, who would struggle to afford the high cost of interstate travel to access care.[466] Nevertheless, women living in the remaining states will continue to enjoy all the benefits of expanded access to early abortion that came from removing the in-person dispensing requirement. As a result, the removal of the mifepristone REMS has the power to transform and improve abortion access in parts of the country even if the constitutional right to abortion falls.

The states that have their own limits on medication abortion—or, if *Dobbs* allows, even ban abortion completely—will still see ripple effects associated with greater abortion access in other parts of the country. One of these effects is an increase in illegal, self-managed abortion everywhere. Though illegal abortion conjures up images of the back-alley abortions from generations ago, self-managed abortion in today's world is very different. It essentially involves women taking the same FDA-approved medications, but purchased outside of the traditional healthcare setting, and often without the help of a physician.[467]

Many abortion rights activists believe self-managed abortion will become the future of abortion care, especially if *Roe* is overturned or dramatically weakened.[468] Already, self-man-

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463 *Id.*

464 *Id.*

465 Elizabeth Nash & Lauren Cross, *26 States Are Certain or Likely to Ban Abortion Without Roe: Here's Which Ones and Why*, GUTTMACHER INST. (Oct. 2021), https://www.guttmacher.org/article/2021/10/26-states-are-certain-or-likely-ban-abortion-without-roe-heres-which-ones-and-why [https://perma.cc/YAV6-P9EX].

466 Megan K. Donovan, *In Real Life: Federal Restrictions on Abortion Coverage and the Women They Impact*, 20 GUTTMACHER POL. REV. 1, 5–6 (2017).

467 *See Donovan*, *supra* note 466, at 44.

468 *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/ [https://perma.cc/785J-2Y5L] (describing how medication abortion has been used in other countries where abortion is criminalized). In

aged abortion has grown as abortion became increasingly difficult to access in parts of the country,[469] with a greater incidence in states with harsher abortion restrictions.[470] But as mifepristone becomes easier to access in a majority of states because the FDA has loosened its unnecessary restrictions, women in conservative states will likely be able to obtain the drug more easily, albeit, illegally, from other states (instead of relying on international pharmacies, as they do now). Women in these 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 because the abortion would occur in a private setting, but it might also be legally difficult to restrict.[471]

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 that provider's state lines, who would then ship the out-of-state patient the drug once it arrives.[472] Plan C, an organization that helps women find abortion medication, has detailed instructions on its website for creating a temporary address in a state that allows remote abortion access so that a patient in an abortion-restricting state could visit a virtual clinic, provide that temporary address, and then have the pills forwarded to their home address without ever leaving their house.[473] Furthermore, remote abortion care makes traveling out of state for abortion

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2021, the Supreme Court agreed to hear a case that would directly challenge *Roe v. Wade*. *See* Ziegler, *supra* note 462.

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

470 *Id.* at 92, 94.

471 *See* David S. Cohen, Greer Donley, & Rachel Rebouche, *The New Abortion Battleground* (draft manuscript on file with author) (describing the complex legal issues that will challenge state enforcement of abortions laws related to out-of-state conduct); Rachel Rebouche, *The Public Health Turn in Reproductive Rights*, *78* WASH. & LEE L. REV. 1355, 1400, n.220 (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").

472 Rebouche, *supra* note 471, at 40; Gleckel & Wulkan, *supra* note 403, at 15–16.

473 The Plan C Guide to Abortion Pills, Plan C (last visited Nov. 7, 2021), https://www.plancpills.org/guide-how-to-get-abortion-pills#find-pills [https://perma.cc/FXR2-RZRG].

easier because women can have the medication mailed to a post office near the state line instead of needing to travel to a clinic within that state.[474]

Though a healthcare provider's involvement is still the gold standard for abortion care, self-managed abortion can be done safely. According to the World Health Organization, there are three components to self-managed abortion without the involvement of a provider (sometimes 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."[475] Evidence endorsed by the WHO suggests that the latter two components can be done safely.[476] Even under the REMS, most women already take the abortion medication drugs at home and assess the abortion's completion on their own with pregnancy tests; 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."[477]

However, until very recently, researchers have had questions about the safety of 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 most women can accurately do.[478] 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.[479] Many abortion patients, however, will not be certain of their last missed period, and for them, self-assessment will be more challenging. As noted, there have been incidences of self-managed abortion well into the second trimester that led to medical emergencies.[480] Furthermore, there are other eligibility questions related to risk factors, like whether a woman could have a rare ectopic pregnancy, which is contraindicated for mifepristone, or a negative blood type, which might require an addi-

474 *Id.*
475 *Self-Managed Medication Abortion*, *supra* note 216, at 44.
476 *Id.*
477 *Id.*
478 *Id.*
479 Raymond et al., *supra* note 135, at 363.
480 *See* the notes and discussion, *supra* notes 256-58 and 261-64.

tional medication to protect her future fertility.[481] Fewer women know their blood type and only an ultrasound can diagnose an ectopic pregnancy.[482]

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.[483] 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 had been used for decades.[484] The zeitgeist now prefers "no touch abortions," where most women can obtain abortion care without any in-person testing, unless it is medically indicated.[485] Not only does this model remove even more logistical burdens associated with care, but it also reduces the cost of the abortion, making abortion even more accessible.[486]

More recent data suggests that these extra tests are unnecessary. For instance, recent studies have shown that for women who are Rh negative, antibodies may not develop to a pregnancy in the first ten weeks and therefore the additional medication would not be necessary.[487] And because ectopic pregnancy often comes with symptoms like bleeding or pain, ultrasound could be reserved for women experiencing those symptoms.[488] The virtual clinics described above are already offering no-touch abortions, and even traditional clinics are

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481 *See* Raymond et al., *supra* note 135, at 363.

482 *Id.* at 364.

483 *Id.* at 361.

484 *Id.* ("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 time sensitive treatment while limiting transmission of infection by maintaining distance between and among patients and providers."); Chong et al., *supra* note 189, 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).

485 *See Telehealth Care for Medication Abortion Protocol*, REPROD. ACCESS (May 2021), https://www.reproductiveaccess.org/wp-content/uploads/2020/03/03-2020-no-touch-MAB.pdf [https://perma.cc/X5W6-CA38].

486 Baker, *supra* note 433; *see* Chong et al., *supra* note 189, at 4 (noting that "[m]onths with high enrollment were also months in which large percentages of abortions occurred without screening ultrasounds").

487 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, 266 (2019).

488 Raymond et al., *supra* note 135, at 363–34.

moving in this direction by altering their protocols so that women never need to set foot in a healthcare facility to receive an abortion.[489] Two very recent studies, one in England[490] and one in the United States,[491] show that no touch medication abortions are safe and effective. As a result, it appears that even when it comes to self-assessment of eligibility, a physician's involvement may not be required except when women are unsure of their last period or experiencing symptoms of ectopic pregnancy. 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 Part 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-induce an abortion.[493]

> [T]here 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 those 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 *patients* for abortions, and laws typically prefer to criminalize providers, this might change if providers

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489 Baker, *supra* note 433 (describing remote abortion as the new standard of care); Carrie N. Baker, *No-Test Medication Abortion Increases Safety and Access During COVID-19*, MS. MAG. (May 13, 2020), https://msmagazine.com/2020/05/13/no-test-medication-abortion-increases-safety-and-access-during-covid-19/ [https://perma.cc/9N7Q-EHDY] (interviewing a provider who is already using the new protocol).

490 A.R.A. Aiken, P.A. Lohr, J. Lord, N. Ghosh & J Starling, *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 INT'L J. OBSTET. & GYNAECOL. 1464, 1470 (2021).

491 Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study*, JAMA INTERNAL MEDICINE (March 2022), file:///Users/DONLEY/Downloads/jamainternal_upadhyay_2022_oi_220007_1647267379.10073.pdf.

492 *See* Lindgren, *supra* note 457, at 3.

493 *See supra* Part II.

494 *Self-Managed Medication Abortion*, *supra* note 216, at 45.

are out of state and harder to control.[495] On the other hand, as self-management becomes more commonplace and organized, women can be counseled about how to avoid detection, even when experiencing side-effects and risks that require medical care.[496] Because there is no discernable difference between an abortion by medication and miscarriage, women who need medical care can simply show up to a hospital claiming to be experiencing natural fetal loss.[497]

Though self-managed abortion is likely to increase in antiabortion states, removing the in-person dispensing requirement will likely reduce self-management in abortion-supportive states. Self-management will become less desirable when it is easy to access medication abortion from a U.S. provider while still ending the pregnancy in the privacy of one's home, avoiding the harassment, travel, and obstacles associated with clinic-based care, and the legal risks associated with self-management.[498] And as argued above, the very possibility of self-management with abortion care should encourage the FDA to release the REMS in its entirety to encourage women to obtain care through a doctor given that self-management is already an option for American women.[499] And the FDA may be worried about the fact that many women attempt to self-

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495 *See* Cohen, Donley & Rebouche, *supra* note 471. 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 [https://perma.cc/PSK2-PJ86].

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 433.

497 Though this pretense will protect many women, it is becoming more common for zealous prosecutors to prosecute women experiencing pregnancy loss due to the perception that the woman was attempting to terminate the pregnancy. *See, e.g.*, The Editorial Board, *When Prosecutors Jail a Mother for a Miscarriage*, N.Y. TIMES (Dec. 28, 2018), https://www.nytimes.com/interactive/2018/12/28/opinion/abortion-pregnancy-pro-life.html [https://perma.cc/TY69-LHJA]. I suspect these instances will continue to grow as illegal abortion becomes more common, harming women—especially poor women and women of color—experiencing abortion, miscarriage, and stillbirth.

498 *See* Aiken et al., *supra* note 469, 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 1 (Aug. 2018), https://ibisreproductivehealth.org/sites/default/files/files/publications/US%20research%20roadmap%20self%20managed%20abortion.pdf [https://perma.cc/G6S3-8L4U]; Daniel Grossman, et al., *Self-Induction of Abortion Among Women in the United States*, 18 REPROD. HEALTH MATTERS 136, 144 (2010).

499 *See supra* Part II.

manage in less safe ways—with physical trauma or ineffective supplements and herbs.[500]

Beyond the in-person dispensing requirement, if the FDA removed the rest of the REMS, the agency's abortion exceptionalism would cease, and patients would see additional benefits in accessing early abortion. Patients in states without their own prohibitions could obtain a prescription for medication abortion from any willing doctor and pick up the medication in any pharmacy.[501] 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,[502] but abortion would immediately become less siloed. And the more integrated abortion becomes in traditional healthcare, the more normal and less stigmatized it will be.

Primarily, removing the provider certification requirement will lead to an increase in physicians offering medication abortion.[503] No longer would providers need to opt into a prescribing system or identify as an abortion provider—they would simply provide early abortions to their patients when they need them. This would reduce the fear that the certified provider list could be leaked after a data breach, exposing all the providers on the list to harassment and violence.[504] Similarly, now that physicians can provide early abortion care from their home offices or via telemedicine (i.e., not always at clinics), they might similarly feel safer.[505] 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 or establishing a relationship with a "certified pharmacy."[506] 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

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500 Ushma D Upadhyay, Alice F. Cartwright, Daniel Grossman, Barriers to abortion care and incidence of attempted self-managed abortion among individuals searching Google for abortion care: A national prospective study, 106 Contraception, 49, 49 (2022).

501 *Medication Abortion, supra* note 431.

502 *Self-Managed Medication Abortion*, *supra* note 216, at 43–44.

503 COHEN & JOFFE, *supra* note 123, at 223.

504 Mifeprex REMS Study Group, *supra* note 35, at 792.

505 *See* Cohen & Connon, *supra* note 130, at ix–x (noting that "partly because abortion providers are not safe, there are very few abortion providers in the United States").

506 *Self-Managed Medication Abortion*, *supra* note 216, at 43; Mifeprex REMS Study Group, *supra* note 35, at 792.

provider,[507] increasing the number of providers could reduce the burden on existing abortion providers and improve access to abortion generally.

If the Supreme Court overrules *Roe v. Wade*, and roughly half the states ban abortion, increasing the number of abortion providers in abortion-supportive states will be urgently important.[508] In this scenario, abortion providers in half the country will be responsible for providing all U.S. abortions. Already, SB8—a Texas law that essentially bans abortions after six weeks in our country's second most populous state—have pushed providers to the brink of their capacity, even in distant states like Minnesota.[509] If half the country bans abortion, the entire system will experience immense strain, delaying care for everyone. To the extent the remaining states can increase the number of providers offering early abortion care, it will free up surgical abortion providers to focus their expertise on those needing abortions past ten weeks.

Removing the mifepristone REMS will also have an impact on miscarriage management. As mentioned above, recent research has suggested that the same combination of medications used for abortion (mifepristone and misoprostol) is more effective at treating a missed or incomplete miscarriage than the current protocol, which only involves misoprostol.[510] Without the mifepristone REMS, any provider could start prescribing the same protocol for missed or incomplete miscarriage as they do for abortion.[511] Not only does this benefit women who are experiencing a missed or incomplete miscarriage, but it would also help to reduce mifepristone's stigma. 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—even in abortion-restrictive

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507 *Data Center*, GUTTMACHER INST., https://data.guttmacher.org/states/table?state=US&topics=71+72+73&dataset=data [https://perma.cc/HV8J-JFJT].

508 Nash & Cross, *supra* note 465.

509 Ashely Hacket, After Texas' abortion ban, some groups have seen increased demand for abortions in Minnesota, Minn Post (Nov. 19, 2021), https://www.minnpost.com/health/2021/11/texas-abortion-ban-has-increased-demand-for-legal-abortions-in-minnesota-and-it-might-just-be-the-beginning/ [https://perma.cc/2EW8-GCMQ](""However," Rierson said, "We're overwhelmed now. And if Roe falls, the combination of state level restrictions [in other states] and the lack of providers here means that we're not going to be able to meet the need if it's federally overturned.")

510 Schreiber et al., *supra* note 29, at 2161.

511 *Id.*

states—as state laws limiting the provision of mifepristone are often tied to 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. Already, the FDA's decision to remove the in-person dispensing requirement means that patients will no longer need to travel long distances to clinics for early abortion, nor will they need to deal with the harassment of protesters. Patients will be able to terminate an early pregnancy at home, entirely through telemedicine. If the FDA removed the rest of the unnecessary and burdensome requirements, more providers would offer early abortion care, and there will be less of an incentive for patients to rely on self-managed abortion to end a pregnancy. Mifepristone could 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—banning it completely if the Supreme Court allows. Self-managed, illegal 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 prefer to have a doctor oversee their abortion.

CONCLUSION

Medication abortion is an effective and safe way to end a pregnancy in the first ten weeks. Nevertheless, the FDA has dramatically limited its distribution by imposing a REMS—a tool intended to protect the public from particularly risky drugs. The REMS has segregated medication abortion outside of traditional healthcare settings and into abortion and family planning clinics. Before December 2021, the REMS also banned remote abortion through telehealth, dramatically reducing access to abortion across the country.

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. Patients in those states will be able to receive abortion care entirely from the comfort of their own homes at lower cost 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 harassment and violence. None of these benefits will be felt by those in states that continue to limit medication abortion, and as a result, the FDA's decision to remove or modify the mifepristone REMS, as it began to do in December, will accelerate 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 patients in the remaining states will continue to experience the benefits associated with easier access to medication abortion.