The Last ~~Man~~ Woman Standing: Why Protecting and Improving Access to Abortion Medication is Necessary Post-*Dobbs*

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ABSTRACT

To ensure that abortion access remains available for many American women in our post-*Roe* society, it is imperative that lawmakers and regulators protect and improve access to mifepristone, the "abortion pill." Greater access to mifepristone may improve women's health and increase abortion access for marginalized communities. However, contrasting state laws regarding prosecution and prescription of the drug and an overly stringent Risk Evaluation and Mitigation Strategy (REMS) continue to create barriers to access and stifle these potential benefits. This Article outlines proposed solutions to protect and improve medication abortion access and addresses the impending legal battles and attacks against mifepristone.

INTRODUCTION

Originally, mifepristone[1] was heralded as "The Pill That Changes Everything."[2] Now, access to the abortion pill is the "last 'woman' standing" in abortion access for millions of American women.[3] Even still, mifepristone, a U.S. Food and Drug Administration (FDA)-approved drug, is falling short of its full potential to enhance reproductive health in the United States.[4] The Supreme Court's decision to overturn the right to abortion in *Dobbs v. Jackson Women's Health Organization*[5] further

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[1] Mifepristone is the first medication used in the medication abortion process, approved by the U.S. Food and Drug Administration (FDA) in 2000. *Mifeprex (mifepristone) Info.*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information (last visited July 4, 2023).

[2] Cynthia Koons, *The Abortion Pill Is Safer Than Tylenol and Almost Impossible to Get*, BLOOMBERG (May 3, 2022, 8:05am), https://www.bloomberg.com/news/features/2022-02-17/abortion-pill-mifepristone-is-safer-than-tylenol-and-almost-impossible-to-get.

[3] *See* Marielle Kirstein, Joerg Dreweke, Rachel K. Jones & Jesse Philbin, *100 Days Post-Roe: At Least 55 Clinics Across 15 US States Have Stopped Offering Abortion Care*, GUTTMACHER INST. (Oct. 6, 2022), https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care.

[4] *See infra* Part II.

[5] 142 S. Ct. 2228 (2022).

stifled the impact of mifepristone by allowing an onslaught of state restrictions on abortion medication usage and prescription.[6] In the future, it is imperative that federal lawmakers and regulators protect and improve abortion medication access, as for many women in America,[7] mifepristone is the only remaining safeguard of reproductive autonomy.

Part I will address the legal and administrative background leading to approval of mifepristone in the United States, the current restrictions on prescribing the drug, and the status of medication abortion protection in the wake of *Dobbs*.[8] Part II will discuss the current barriers and challenges to continuing and improving access to mifepristone.[9] Section A examines the contrasting state regulations creating unprecedented, ambiguous disparities in jurisdictional protections related to abortion medication, including variations in state laws, the role of virtual clinics, and enforcement against patients and providers.[10] Section B explores how FDA's treatment of mifepristone, in regards to the prescription requirements and in comparison to other drugs, discriminates against and further separates women's reproductive health from traditional health care and regulatory standards.[11] Section C explains how the lack of access to abortion medication creates higher patient health risks and negatively impacts marginalized individuals.[12] Section D reviews current measures for improving and protecting access to abortion medication, as well as additional potential solutions and expected legal challenges.[13] In particular, Section D recommends that the United States invests more in telehealth, increases federal funding of virtual clinic services, asserts a national standard of care and preemption theory to elevate FDA approval of mifepristone, and works toward further removing FDA restrictions on abortion medication.[14] Finally, Part III summarizes the primary reasons as to why it is important to protect and improve mifepristone access through federal action.[15]

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[6] *See generally id.* (overruling *Roe v. Wade* and allowing each state to set its own abortion regulations or protections).

[7] For the scope of this Article, the focus will primarily be on the discrimination and detriment broadly to those identifying as women. However, it is important to note that the impacts and effects discussed are intersectional, affecting low-income and minority women at greater rates, as well as some individuals who do not identify as female, but are nonetheless able to become pregnant. *See infra* Section II.C.

[8] *See infra* Part I.

[9] *See infra* Part II.

[10] *See infra* Section II.A.

[11] *See infra* Section II.B.

[12] *See infra* Section II.C.

[13] *See infra* Section II.D.

[14] *See infra* Section II.D.1.

[15] *See infra* Part III.

I. THE LEGAL AND REGULATORY BACKGROUND LEADING TO THE CURRENT STATE OF ACCESS TO ABORTION MEDICATION

Access to mifepristone is ever-evolving and best understood by looking at the changes to the drug's Risk Evaluation and Mitigation Strategy (REMS), as regulated by FDA. Section I.A outlines FDA's approval of mifepristone for abortion treatment in 2000.[16] This Section also describes the evolving requirements associated with prescribing mifepristone, particularly in the wake of recent Supreme Court jurisprudence and the COVID-19 public health emergency.[17] Section I.B explains how, as FDA relaxes its restrictions on prescribing mifepristone, state policymakers make access to the drug more limited, sometimes in conflict with state constitutions.[18]

A. FDA Approves Mifepristone with a Risk Evaluation and Mitigation Strategy and Continues to Modify the Restrictions Following Dobbs *and the COVID-19 Pandemic*

Before *Dobbs*[19] overturned *Roe v. Wade*,[20] when Americans retained a constitutional right to abortion, mifepristone entered the medical and regulatory scene. Medication abortion, as approved by FDA, involves a course of mifepristone (colloquially, the "abortion pill"), followed by a dose of misoprostol.[21] The FDA-approved label for mifepristone authorizes the drug "for the medical termination of intrauterine pregnancy through 70 days [of] gestation."[22] Since mifepristone's public introduction, the drug has been contentious.[23] Misoprostol is not subject to the same controversy or regulatory restrictions as mifepristone—despite invoking similar risks and side effects—likely due to its other medical uses.[24] While other drug regiments can effectively terminate a pregnancy, 97% of medication abortions are administered

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16 *See infra* Section I.A.

17 *See infra* Section I.A.

18 *See infra* Section I.B.

19 Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2279 (2022).

20 410 U.S. 113, 153–54 (1973).

21 *Mifeprex (mifepristone) Info.*, supra note 1.

22 *Mifepristone Tablets, 200 mg Prescribing Information*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last updated Mar. 23, 2023).

23 This is largely because mifepristone blocks progesterone, the hormone necessary for a pregnancy to progress. Christopher Rowland, Laurie McGinley & Jacob Bogage, *Abortion Pills by Mail Pose Challenge for Officials in Red States*, WASH. POST (May 4, 2022, 5:42 PM), https://www.washingtonpost.com/business/2022/05/04/abortion-pills-online-telemedicine/; Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 635 (2022).

24 Donley, *supra* note 23, at 634. Misoprostol is generally used for stomach ailments. Rowland et al., *supra* note 23; *see also* U.S. FOOD & DRUG ADMIN., MISOPROSTOL PRESCRIBING INFORMATION (2023) (stating that misoprostol "is indicated for reducing the risk of . . . induced gastric ulcers in patients with high risk of complications from gastric ulcer").

with the FDA-approved process of mifepristone and misoprostol.[25] The original approval of mifepristone, the recent modifications to the restrictions of mifepristone distribution, and the state law regulation of abortion medication all greatly impact the accessibility to the drug, which keeps evolving over time.[26]

The legalization process for mifepristone was arduous.[27] Since its initial approval in France in 1988, mifepristone has been used to medically terminate pregnancies.[28] Originally, the mifepristone creator expressed hesitancy to apply for approval in the United States, in fear of boycotts and lawsuits.[29] The company only applied for FDA approval after the Clinton Administration recruited the mifepristone manufacturer to apply.[30] From receiving the initial application in 1996 to approving the drug in 2000, FDA required extensive data and additional clinical trials from the mifepristone manufacturer, despite the original application demonstrating it is a safe and effective drug.[31] FDA approved mifepristone under the Subpart H restricted distribution approval pathway[32] and later, adapted the drug restrictions to follow the Federal Food, Drug, and Cosmetic Act (FDCA) requirements to evaluate the drug for marketing authorizations.[33] This review culminated in a number of restrictions

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[25] Donley, *supra* note 23, at 634 (citing Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2014*, 49 PERSPS. ON SEXUAL & REPROD. HEALTH 1, 6 (2017) (relying on research from Guttmacher Institute, a leading organization for reproductive health data)).

[26] *See infra* Section I.A; Section I.B.

[27] Rowland et al., *supra* note 23.

[28] *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last visited July 4, 2023) [hereinafter *Questions and Answers*]. As of 2022, mifepristone is approved in over eighty countries for abortion-related usage, including in the United States. *Id.*

[29] Donley, *supra* note 23, at 636.

[30] *Id.* at 637.

[31] U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX 15–25 (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf; Megan K. Donovan, *Improving Access to Abortion via Telehealth*, 22 GUTTMACHER POL'Y REV. 23, 24 (2019); *Mifeprex (mifepristone) Info.*, *supra* note 1; Donley, *supra* note 23, at 637–38. Around this same time, the Clinton Administration cooled its support of the drug, as President Clinton recovered from the Monica Lewinsky scandal and needed to protect his image. *Id.* at 638.

[32] FDA may approve drugs through Subpart H authorization by providing accelerated approval or by approving the drug with certain distribution restrictions. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 31, at 10–12; *see also* 21 C.F.R. §§ 314.500, 314.510 (2007). Mifepristone was approved through the latter channel with distribution restrictions. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 31, at 14.

[33] CONG. RSCH. SERV., IF12269, REGULATING REPRODUCTIVE HEALTH SERVICES AFTER DOBBS V. JACKSON WOMEN'S HEALTH ORGANIZATION 2 (2022), https://crsreports.congress.gov/product/pdf/IF/IF12269; *see also* Carter Sherman, *The Fight Over Abortion Is Far From Over. Here's What Will Happen in 2023*, VICE (Dec. 26, 2022, 4:00 AM), https://www.vice.com/en/article/pkg9p7/abortion (explaining that FDA's approval of mifepristone is currently under challenge in a developing lawsuit against FDA in federal court); *Accelerated and Restricted Approvals Under Subpart H (drugs) and Subpart E (biologics)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/accelerated-and-restricted-approvals-under-subpart-h-drugs-and-subpart-e-biologics#NDAs (last visited July 4, 2023) [hereinafter *Accelerated Approvals*] (listing mifepristone as a drug approved per Subpart H authorization); Celine Castronuovo, *FDA Defends Abortion Pill Approval in Response to Texas Lawsuit*, BLOOMBERG LAW (Jan. 18, 2023, 11:58 AM), https://news.bloomberglaw.com/health-law-and-business/fda-defends-abortion-pill-approval-in-response-to-texas-lawsuit (reiterating 2008 Government

imposed on mifepristone's distribution, including allowing only qualified physicians[34] to prescribe and distribute the drug and requiring informed patient consent before prescription.[35]

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA) and eventually, FDA recrafted and maintained the restrictions on mifepristone as a REMS, a drug safety program designed to place limitations on the distribution of certain drugs with serious safety concerns, in order to prevent adverse events and manage potentially serious risks.[36] FDA took the REMS one step further and placed an Elements to Assure Safe Use (ETASU) on mifepristone—a limitation on who can prescribe the drug and under what conditions.[37] Because FDA approved and set restrictions for mifepristone before the REMS system began, it may also be an "accident of history" that the original restrictions, put in place due to FDA's concerns with the clinical trials, converted to a REMS in 2011 and never received re-adjudication.[38] Following a Supplemental New Drug Application (sNDA) from the manufacturer in 2015, with the support of the medical community, FDA modified the REMS to increase the gestational limit on the drug and to allow providers, not just physicians, to prescribe mifepristone.[39]

Many abortion advocates and medical personnel criticized FDA for placing a REMS on mifepristone because of the drug's extensive safety record.[40] Most

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Accountability Office's finding that FDA's mifepristone approval through Subpart H authority was proper).

[34] FDA initially defined "qualified physician" as an individual able to accurately assess the duration of the pregnancy, diagnose ectopic pregnancies, provide surgical intervention, or help a patient get such care through other physicians. Donley, *supra* note 23, at 638–39. By limiting distribution to these physicians, mifepristone stayed out of pharmacies. *Id.*

[35] *Id.* Additionally, FDA placed shipping requirements and a black box warning—a type of warning typically reserved only for drugs that cause death or serious injury—on mifepristone. *Id.* at 639.

[36] *Id.* at 640. Essentially, a REMS is meant to "improve the drug's safety profile at the expense of accessibility." *Id.* at 629.

[37] An ETASU is defined as "requirements or activities" that "support the safe use of the medication . . . [often] undertaken before the medication can be prescribed, dispensed, or received." *What's in a REMS?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems (last updated Jan. 26, 2018) [hereinafter *What's in a REMS?*]; *see also* Donley, *supra* note 23, at 640–41 (2022) (adding that degree of oversight given to mifepristone is akin to restriction on a Schedule II controlled substance, like methadone, despite not qualifying as a narcotic or any akin type of drug).

[38] Donley, *supra* note 23, at 665.

[39] *See id.* at 641 (adding that this update also allowed patients to get drugs in just one visit, rather than in multiple visits).

[40] Mifepristone is proven safe; of the 3.7 million women who took the drug between September 2000 and December 31, 2018, there are only twenty-four reported deaths associated with mifepristone and these "adverse events cannot with certainty be causally attributed to [the drug]." *Id.* at 652; *see also Questions and Answers*, *supra* note 28 (stating that as of 2022, this number is up to twenty-eight, calculated to be the same or lower risk of death as in 2018). This means that the risk of death due to mifepristone is 0.00065%. Donley, *supra* note 23, at 652 (citing *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 (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf (relying on data as of 2018 to determine death rate)); *see also* U.S. FOOD & DRUG ADMIN., MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 06/30/2022, www.fda.gov/media/164331/download (providing that of 5.6 million women to use mifepristone to medically terminate a pregnancy, only twenty-eight died, making the death rate now 0.0005%).

recently, FDA received criticism for taking over a year to remove or relax the in-person prescription requirement for mifepristone as used for abortion, amidst the COVID-19 pandemic.[41] As a result, the American College of Obstetricians and Gynecologists (ACOG) filed a lawsuit in the United States District Court for the District of Maryland[42] to enjoin the in-person dispensing requirement during the pandemic due to the risks posed to patients and providers.[43] The lower court granted the preliminary injunction against FDA and allowed providers to dispense mifepristone through the mail.[44] However, the Supreme Court reinstated the in-person dispensing requirement on January 12, 2021.[45]

In the wake of pandemic data that proved medication abortion is safe to take at home, mifepristone drug applicants proposed an updated REMS; FDA adopted the modified REMS in 2021.[46] FDA formally removed the in-person dispensing restriction in December 2021,[47] improving abortion access by allowing telehealth prescription and at-home use of the drug.[48] After doing so, FDA sent REMS Modification Notification letters to the mifepristone applicants, which ultimately coalesced into adding the pharmacy certification provision, which allows patients to fulfill a mifepristone provision at a certified pharmacy.[49] Prior to this REMS modification, medication abortion made up about 42% of all abortions in the United States.[50] Now, it accounts for over half of U.S. abortions.[51]

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[41] *Update to FDA Risk Evaluation and Mitigation Strategy for Mifepristone on Dec. 16, 2021, Eliminating In-Person Dispensing Requirement*, 135 HARV. L. REV. 2235, 2236 (2022) [hereinafter HARV. L. REV.]. Organizations like the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine advocated for removal of the in-person requirement to limit the unnecessary COVID-19 risk associated with such a time-sensitive health care service. This was due, in part, to FDA quickly removing in-person requirements for other drugs. *Id.* at 2236–37.

[42] Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 189 (D. Md. 2020), *rev'd* FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021).

[43] HARV. L. REV., *supra* note 41, at 2237. ACOG argued that such requirements went against medical advice and demonstrated discriminatory treatment of prescribers and patients, based on abortion bias (with a greater affect on marginalized pregnant individuals). *Id.*

[44] *Id.*; *see generally Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d.

[45] HARV. L. REV., *supra* note 41, at 2237; FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 578 (2021).

[46] Donley, *supra* note 23, at 642; *Questions and Answers*, *supra* note 28 ("The FDA analyzed post-marketing data to determine if there was a difference in adverse events between periods when in person dispensing was and was not enforced. Based on this review, the agency concluded that there did not appear to be a difference in adverse events between periods when in-person dispensing was and was not enforced.").

[47] Donley, *supra* note 23, at 629. In making such decision, FDA said it analyzed data from July 13, 2020, to January 12, 2021, from the injunction on requiring in-person dispensing, to determine that no difference in adverse events existed between the time "when in-person dispensing was enforced and was not enforced." *Questions and Answers*, *supra* note 28.

[48] Donovan, *supra* note 31, at 25; HARV. L. REV., *supra* note 41, at 2235; Justine Coleman, *FDA Broadens Access to Abortion Pills*, THE HILL (Dec. 16, 2021, 5:14 PM), https://thehill.com/homenews/administration/586207-fda-broadens-access-to-abortion-pills/.

[49] *Questions and Answers*, *supra* note 28.

[50] Coleman, *supra* note 48.

[51] Caroline Kitchener, Kevin Schaul & Daniela Santamarina, *The Latest Action on Abortion Legislation Across the States*, WASH. POST (May 2, 2022, 9:48 PM), https://www.washingtonpost.com/nation/interactive/2022/abortion-rights-protections-restrictions-tracker; Sherman, *supra* note 33; *see also* Jeff Diamant & Besheer Mohamed, *What the Data Says About Abortion in the U.S.*, PEW RSCH. CTR. (Jan.

As of January 2023, the certified pharmacy provisions are finally in effect.[52] FDA's altered REMS permits retail pharmacies to provide mifepristone, rather than limiting dispersion to clinics, doctors, and a small number of mail-order pharmacies.[53] The official new REMS came after over a year of negotiations between FDA and mifepristone manufacturers about issues such as the method of prescribing mifepristone and the identity protection measures for prescribing doctors.[54] The new regulation requires a health care provider to seek certification, meet certain qualifications, and complete a Prescriber Agreement Form, or, requires a pharmacy to seek certification, complete the Pharmacy Agreement Form, and ship the medication with a shipping service that provides tracking information before dispensing mifepristone.[55] The patient must also review, sign, and receive a copy of the Patient Agreement Form that explains the risks of mifepristone.[56] There is already criticism that the certification process requires administrative red tape that will dissuade many pharmacies from participating in mifepristone distribution.[57] There is also concern that a future administration may reinstate the in-person requirement, setting back recent progress.[58]

In conclusion, the REMS modifications now allow a patient to receive a prescription for abortion medication through telemedicine services and then get the prescription filled and delivered through the mail—assuming medication abortion by mail is legal in the state where a patient seeks care.[59] The permanent removal of the in-person dispensing requirement was intended to increase patient access to abortion and alleviate the burden on the health care system.[60] Virtual abortion clinics, which have been rising in popularity and existence since the REMS modification, are expanding services to accommodate this increase in demand.[61] Despite twenty states prohibiting telehealth medication abortion treatment, either through an outright ban on telehealth abortion medication prescription or a total abortion ban,[62] the recent

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11, 2023), https://www.pewresearch.org/short-reads/2023/01/11/what-the-data-says-about-abortion-in-the-u-s-2/ (reporting that medication abortion currently accounts for 53% of all legal abortions in the United States, up from "44% in 2019 and 40% in 2018," per CDC data).

52 Pam Belluck, *New Lawsuit Challenges State Bans on Abortion Pills*, N.Y. TIMES (Jan. 25, 2023), https://www.nytimes.com/2023/01/25/health/abortion-pills-ban-genbiopro.html.

53 *Id.* (The enacted regulation "officially removed the in-person requirement from its regulatory rule book.").

54 *Id.*

55 *Questions and Answers*, *supra* note 28.

56 *Id.*

57 Belluck, *supra* note 52.

58 *Id.*; HARV. L. REV., *supra* note 41, at 2239.

59 HARV. L. REV., *supra* note 41, at 2235; Coleman, *supra* note 48.

60 Coleman, *supra* note 48.

61 Heather Landi, *Digital Abortion Providers, Doctors Brace for Complex Legal Landscape After SCOTUS Ruling*, FIERCE HEALTHCARE (June 27, 2022, 7:30 AM), https://www.fiercehealthcare.com/health-tech/digital-abortion-providers-doctors-brace-complex-legal-landscape-after-scotus-ruling; Donley, *supra* note 23, at 631, 690.

62 There are an additional six states that impose some limitation on telehealth abortion services. *The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (June 1, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/. The specific number of states banning abortion or telehealth fluctuates as state policies change over time.

REMS modifications likely severely undercut the expected impact of *Dobbs* in reducing the number of abortions in America by decreasing reliance on procedural abortion and increasing accessibility of abortion for the most vulnerable group.[63] Following these restrictions and bans, Americans in states with restricted access began purchasing abortion medication over the internet at a high rate, both domestically and internationally.[64]

*B. State Constitutions and Regulations Affect and Vary Access to Mifepristone Post-*Dobbs

Just like the overarching right to abortion, post-*Dobbs*, there is no longer a federally protected right to medication abortion. Since the *Dobbs* decision, over "20 million women of childbearing age have lost access to abortion."[65] Leading up to *Dobbs*, America saw more abortion restriction laws passed than in almost five decades.[66] These restrictions greatly affect medication abortion access. Generally, Republican state lawmakers are promulgating legislation to ban medication abortion entirely.[67] In response to the growing use of abortion medication, in 2021, at least eight states enacted legislation to restrict telemedicine for abortion pill use, four states set limits of under ten weeks for using the abortion pill, while other states placed complete bans on mailing abortion medication.[68] Some of these states explicitly prohibit medication abortion, telehealth, or at-home abortion, despite allowing for abortion in other circumstances.[69] *Dobbs* accelerated this process, giving states the power to determine the legality of abortion on a state-by-state basis, rather than upholding *Roe* and *Planned Parenthood v. Casey*, which protected an unenumerated, fundamental constitutional right to abortion for all Americans.[70]

Some state constitutions expressly insulate broad abortion access through protections of privacy, autonomy, self-determination, or other forms of personal

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[63] Not all of these state policies are currently in effect, based on ongoing litigation. *Medication Abortion*, GUTTMACHER INST. (Dec. 1, 2022), https://www.guttmacher.org/state-policy/explore/medication-abortion; Caroline Kitchener, *Conservatives Complain Abortion Bans not Enforced, Want Jail Time for Pill 'Trafficking,'* WASH. POST (Dec. 14, 2022, 7:30 AM), https://www.washingtonpost.com/politics/2022/12/14/abortion-pills-bans-dobbs-roe/; *see also supra* Sections II.A.1, II.C.

[64] Donley, *supra* note 23, at 632 n. 19; Rowland et al., *supra* note 23; Landi, *supra* note 61; *Medication Abortion*, *supra* note 63.

[65] Brendan Pierson, *U.S. Abortion Fight in 2023 to Focus on State Law, Medication*, REUTERS (Dec. 20, 2022, 3:11 AM), https://www.reuters.com/legal/us-abortion-fight-2023-focus-state-laws-medication-2022-12-20/ (citing Guttmacher Institute statistics from October).

[66] *See* Coleman, *supra* note 48 (speculating that passage of these laws is a result of Justice Coney Barrett's nomination to Supreme Court and empowerment of Court's conservative bloc).

[67] This push includes mandating in-person visitation to receive abortion medication or banning the pills from shipment through the mail. *See* Rowland et al., *supra* note 23; Kitchener et al., *supra* note 51.

[68] Rowland et al., *supra* note 23; *see also* Landi, *supra* note 61 (noting a Texas ban on abortion pills sent through mail); Koons, *supra* note 2 (including a fine of jail time and monetary penalty of up to $10,000 for mailing pills in Texas and an attempted similar ban in Georgia).

[69] *See* THOMSON REUTERS, STATE ABORTION LAWS, Westlaw 0100 Surveys 101 (providing chart outlining current state of abortion access in each state).

[70] *Compare* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2279 (2022), *with* Roe v. Wade, 410 U.S. 113, 153–54 (1973), *and* Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 845–46 (1992).

decision making.[71] Fourteen state constitutions expressly include equal rights provisions that prohibit gender-based discrimination.[72] In some jurisdictions, state courts interpret these provisions as barring certain restrictions on abortion access.[73] This process of state-by-state regulation is representative of the general "reverse federalism" approach that activists on both sides of the abortion debate traditionally utilize and part of why abortion regulations are interpreted based on state constitutions and regulations, rather than by federal standards.[74] In some cases, state constitutions and case law protect against state legislation meant to decrease abortion access (including access to medication abortion treatment, directly or indirectly).[75]

The legal challenges to medication abortion are still forthcoming, with some major cases arising with conflicting holdings across the federal courts.[76] Prior case law does not provide answers to many of the key conflicts over mifepristone distribution and use. For example, GenBioPro, a mifepristone seller, sued Mississippi in 2020 over additional requirements that the state imposed solely on abortion medication, including a mandatory waiting period and counseling provisions.[77] However, following *Dobbs*, GenBioPro voluntarily dismissed the case.[78] The legal battleground is shifting to virtual abortion care and the use of telehealth to prescribe abortion medication, as states continually try to restrict abortion access through limiting virtual clinic prescription.[79] Specifically, legislators attempting to limit medication abortion access are expected to advocate for legislation that places restrictions on pharmaceutical companies and organizations providing abortion without a clinic visit or a trip to the pharmacy.[80]

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[71] Scott A. Moss & Douglas M. Raines, *The Intriguing Federalist Future of Reproductive Rights*, 88 B.U. L. REV. 175, 197 (2008).

[72] *Id.* at 205.

[73] *Id.* at 203.

[74] *See id.* at 224 (explaining that, through a theory of reverse federalism, abortion rights advocates originally encouraged "states to reject a federal standard and instead interpret their constitutions differently from the [f]ederal Constitution").

[75] *E.g.*, Planned Parenthood of Mont. v. Knudsen, 515 P.3d 301 (Mont. 2022) (upholding pre-*Dobbs* abortion access based on state constitution, despite legislative attempts to stifle access). *But see* THOMSON REUTERS, *supra* note 69 (charting out current abortion restrictions in Oklahoma, including an abortion pill ban); *Supreme Court Won't Review Ruling Overturning Oklahoma Abortion-Pill Ban*: *Cline v. Oklahoma Coalition for Reproductive Justice*, 21 No. 7 Westlaw Health L. 4 (2013) (describing Oklahoma's complete abortion pill ban as unconstitutional for imposing an undue burden on abortion access).

[76] *See infra* Section II.D.2.

[77] *See* Ann E. Marimow, Laurie McGinley & Caroline Kitchener, *Major Legal Fights Loom Over Abortion Pills, Travel Out of State*, WASH. POST (July 31, 2022, 6:42 PM), https://www.washingtonpost.com/politics/2022/07/31/abortion-medication-lawsuits/ (explaining that GenBioPro attorney argued FDA, rather than individual states, retained power to determine which medications are safe).

[78] Ian Lopez & Celine Castronuovo, *GenBioPro Gives Up Abortion Pill Suit Against Mississippi (2)*, BLOOMBERG LAW (Aug. 19, 2022, 9:14 AM), https://news.bloomberglaw.com/health-law-and-business/genbiopro-gives-up-abortion-pill-suit-against-mississippi.

[79] *E.g.*, Landi, *supra* note 61; Christine Fernando, *Medication Abortion May be the Next Focal Point in the Fight Over Abortion Access. Here's What to Know*, USA TODAY (Dec. 12, 2022, 7:00 AM), https://www.usatoday.com/story/news/nation/2022/12/12/medication-abortion-access-mifepristone-lawsuit/10828265002/.

[80] Fernando, *supra* note 79.

II. ANALYSIS

Over 900,000 abortions occur in the United States every year, with more than half of these abortions occurring by medication abortion treatment since the 2010s.[81] As more and more clinics disappear or lose the ability to provide treatment in abortion-restrictive states, Americans are seeking telehealth more, making access to abortion more dependent on these services and medication abortion.[82] While abortion medication currently serves as the only point of access for many Americans, there is reason to fear for the availability of this vital drug in protecting abortion access.[83]

As regulatory changes allow telehealth and medication abortion to become more mainstream, many barriers to care remain—primarily, ambiguous and varying state laws and the unnecessary and potentially biased restrictions on the prescription of mifepristone.[84] Increasing access is of great import, given the negative health effects that limited access creates.[85] To ameliorate these concerns, this Article concludes by addressing the potential solutions and expected upcoming legal challenges to prepare for the evolving battle over abortion access.[86]

A. Contrasting State Regulations Over Abortion Medication Create Unprecedented Jurisdictional Conflicts and Disparities

The high level of variation between state laws demonstrates fluctuating support for the right to abortion and rejection of a federal standard, in practice, long before the Supreme Court overturned *Roe*.[87] Now, with the formal overruling in *Dobbs*, reverse federalism in state abortion policy is stronger than ever.[88] The REMS modification in December 2021, as well as the *Dobbs* opinion, accelerated the process of polarizing abortion access in individual states.[89] Even if FDA fully removed the REMS, individual state barriers would still create obstacles to full abortion access.[90]

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[81] Kate Knibbs, *What Abortion Pill 'Reversal' Really Accomplishes*, WIRED (Sept. 5, 2022, 9:00 AM), https://www.wired.com/story/abortion-pill-reversal-essay/; Kitchener et al., *supra* note 51.

[82] See Koons, *supra* note 2, for a 2021 study citing a forty-seven-mile increase in distance to the nearest abortion clinic associated with a 41% increase in the use of telemedicine and medication abortion.

[83] *See, e.g.*, Belluck, *supra* note 52 (stating that states increasingly are targeting medication abortion); Landi, *supra* note 61 (expressing that virtual abortion will become new battleground of abortion legality).

[84] *See infra* Sections II.A, II.B.

[85] *See infra* Section II.C.

[86] *See infra* Section II.D.

[87] Moss & Raines, *supra* note 71, at 204.

[88] *See id.* at 204, 224 (mentioning that this strategy of reverse federalism for abortion policies was at one time a tactic used by abortion advocates and focuses on individualized state policy, rather than unified federal standards).

[89] Donley, *supra* note 23, at 694.

[90] Such restrictions are only expected to increase in coming years. *See id.* at 694 ("As a result, removing the mifepristone REMS will accelerate the existing polarization of abortion access across state lines.").

The current political environment threatens to pit states against each other[91] and creates uncertainty about whether states can use criminal laws to prosecute individuals for crimes committed outside that state's borders.[92] Despite low prosecution rates for abortion ban violations, in many Southern and Midwestern states, abortion is now a crime punishable by several years in prison.[93] States enacting laws to punish providers and patients both in and out of a state's boundaries are expected to conflict with jurisdictional laws that protect virtual and in-person abortion providers.[94] This conflict creates an inherent issue of state sovereignty for our judicial systems, which is exacerbated by the variation in state laws, the rise of the virtual clinics, and the emerging prosecution strategies for offenders of these abortion bans.[95]

1. The Variation in State Laws and Barriers to Medication Abortion Access Creates Jurisdictional Conflict and Ambiguity in What Abortion-Related Actions are "Legal"

Emerging state laws take various approaches to the ability to criminalize, seek, or provide care to patients and providers of abortion, in relation to medication abortion access.[96] Unfortunately, the states with the fewest number of in-person abortion clinics are also most likely to prohibit telehealth abortion, making the differences between state abortion access even starker.[97] Reviewing the laws of Missouri, California, and Wisconsin (notably, in different geographic regions) demonstrates just how divisive these laws are.[98] For example, Missouri is attempting to criminalize any and all out-of-state abortions.[99] Conversely, California passed legislation to protect patients and health care providers who receive or offer telehealth abortion services to those in a jurisdiction where abortion services are illegal.[100] In the past

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[91] Rowland et al., *supra* note 23; David Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. (forthcoming Jan. 2023) (manuscript at 1–5) (warning of coming interjurisdictional abortion war).

[92] Typically, such action is not allowed, but there may be enough gaps in the law that prosecution potentially could be allowed for crimes committed in other jurisdictions. *See* Louis Jacobson, *Can States Punish Women for Traveling Out of State to Get an Abortion?*, POYNTER INST. (July 6, 2022), https://www.poynter.org/fact-checking/2022/can-states-punish-women-for-traveling-out-of-state-to-get-an-abortion/.

[93] Kitchener, *supra* note 63.

[94] Donley, *supra* note 23, at 632; Jacobson, *supra* note 92. *E.g.*, Gavin Newsom (@GavinNewsom), TWITTER (Sept. 15, 2022, 10:01 AM), https://twitter.com/gavinnewsom/status/1570457807467708416 (showing billboards from California advertising in abortion-restrictive states about protected abortion access in California).

[95] *See infra* Sections II.A.1, II.A.2, II.A.3.

[96] *See infra* Section II.A.1.

[97] Donley, *supra* note 23, at 694.

[98] *See id.* ("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 [if] 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.").

[99] Rowland et al., *supra* note 23.

[100] *Id.* This legislation is similar to laws in Connecticut, New York, and Massachusetts. Landi, *supra* note 61. Additionally, Washington State considered numerous similar protections in the 2023 legislative session, including H.B. 1340 and companion S.B. 5400, which precluded the possibility of professional

year, California also implemented a bill, passed before the COVID-19 pandemic, that requires all California State University campuses to offer medication abortions, either through on-campus services or transportation to nearby services.[101] Following California's success, other states are looking to implement similar bills.[102] Finally, Wisconsin banned abortion, but did not impose criminal penalties for obtaining an abortion out-of-state.[103] However, Wisconsin does explicitly prohibit citizens from receiving abortion pills in the mail, meaning they must travel to another state to participate in medication abortion through telehealth legally.[104] The state's laws do not prosecute the person receiving the mailed pills, but the shipper could be subject to charges.[105] Concerningly, some argue that precedent would allow a state like Missouri or Wisconsin to punish its citizens for conduct that occurred in another state, *as long as the conduct is criminal in both states*.[106]

At this point, it is unclear if an abortion-restrictive state could initiate a cause of action against another state where its citizen received abortion services, such as for the death of a future citizen.[107] Conversely, such laws may be viewed as a violation of state sovereignty, or perhaps even the right to interstate travel, the dormant commerce clause, or federal abortion law protections.[108] As it is unclear who would win in the judicial system, these conflicting state-level policies are creating an ambiguous, state-against-state, mess.

Other notable differences in state policy greatly affect the level of care women receive. For example, eighteen states allow qualified nonphysician professionals to prescribe mifepristone, which expands abortion access.[109] However, some states require pharmacists to verify that the consumer will not use mifepristone or misoprostol to conduct a medication abortion, potentially limiting access.[110] These

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discipline if a health care provider violates another state's laws prohibiting reproductive health care services. H.B. 1340, 68th Leg., 2023 Reg. Sess. (Wash. 2023); S.B. 5400, 68th Leg., 2023 Reg. Sess. (Wash. 2023). Washington legislators also proposed H.B. 1286 and companion S.B. 5260, which protect any employer who supports reproductive care and allows employers "to recover damages from people who bring action against them when another state allows judgment against an employer." H.B. 1286, 68th Leg., 2023 Reg. Sess. (Wash. 2023); S.B. 5260, 68th Leg., Reg. Sess. (Wash. 2023).

[101] Johanna Alonso, *Abortions on Campus*, INSIDE HIGHER EDUC. (Jan. 24, 2023), https://www.insidehighered.com/news/2023/01/24/california-universities-launch-abortion-services.

[102] *Id.*

[103] Samantha McCabe, *Here's What to Know About Abortion Access in Post-Roe Wisconsin*, WIS. PUB. RADIO (Sept, 9, 2022, 5:00 AM), https://www.wpr.org/heres-what-know-about-abortion-access-post-roe-wisconsin.

[104] *Id.*

[105] *Id.*; *see also* Donley, *supra* note 23, at 699–700 (describing how this policy aligns with historical criminalization of abortion procedures, which traditionally only targeted providers).

[106] Jacobson, *supra* note 92; *see also* McCabe, *supra* note 103 (describing abortion restrictions in Wisconsin); Rowland et al., *supra* note 23 (explaining impact of new and proposed punishments for violations of medication abortion restrictions).

[107] For example, "State A could argue that, unlike traveling to engage in gambling or smoking [cannabis], an abortion has continuing effects in State A, namely, the death of a citizen or future citizen of the state." Jacobson, *supra* note 92.

[108] *Id.*

[109] HARV. L. REV., *supra* note 41, at 2239.

[110] See Annie Burky, *Backlash Against CVS, Walgreens Raises Questions About Role in Post-Dobbs World*, FIERCE HEALTHCARE (Sept. 1, 2022, 8:20 AM), https://www.fiercehealthcare.com/retail/

restrictive state laws serve as a further barrier to care because they create a need for physicians to learn state-specific pharmacy rules.[111] Rather than simply providing abortion medication based on medical education and expert judgment, a physician must learn state rules and variations before legally providing care.[112]

Some states have gone even further, requesting implementation of national safeguards.[113] For example, Illinois Governor J.B. Pritzker (Democrat) asked the Biden Administration to clearly state that an abortion provider in an abortion-accessible state can ship abortion medication to a patient anywhere in the United States, regardless of legality.[114] This would be particularly effective, as 76% of requests for online abortion telemedicine services came from individuals living in states with the most restrictive abortion laws.[115] However, the existing federal guidance on this issue fails to give concrete answers to these ambiguities.[116] For example, on the day of the *Dobbs* decision, Attorney General Merrick B. Garland issued a statement on behalf of the U.S. Department of Justice (DOJ), stating that "[s]tates may not ban [m]ifepristone based on disagreement with FDA's expert judgment about its safety and efficacy."[117] However, in the months since this statement, numerous states banned mifepristone,[118] consequently rejecting federal guidance in the process.

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boycottcvs-draws-reproductive-rights-twitters-regarding-abortion-inducing-medication, for the story of a CVS employee refusing to give a fifty-five-year-old woman her prescription for misoprostol, needed for a non-abortion-related surgery, because she could not verify that the woman wanted the drug for non-abortion purposes.

111 Donley, *supra* note 23, at 648.

112 *Id.* This is a common theme in many of the abortion litigation cases broadly coming about in the latter half of 2022. *E.g.*, *Recent Case Highlights*, CTR. FOR REPROD. RTS., https://reproductiverights.org/our-work/case-highlights/ (last updated Dec. 8, 2022). *See also NATIONAL SURVEY: Intense Concern Over Consequences of Abortion Bans; Sustained Outrage, Half of All Women "Motivated" to Take Action in Support of Abortion Access*, CHANGE RSCH. (Jan. 6, 2023), https://changeresearch.com/wp-content/uploads/2023/01/PPFA-_-Poll-Results-January-2023-1.pdf [hereinafter CHANGE RSCH.] (reporting that 80% of people find it concerning and 74% of people find it likely that health care professionals will face confusion over whether they can provide lifesaving abortion care to a patient due to fear of criminal charges).

113 *See* Marimow et al., *supra* note 77.

114 *Id.*

115 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, 50 (2022).

116 HARV. L. REV., *supra* note 41, at 2241 (stating laws limiting or prohibiting mifepristone functionally overwrite FDA guidance, meaning there is no federal oversight followed); *see also* Jared Gans, *AMA Warns 'Patient Health Is at Risk' Post-Roe, Calls 'Clear Guidance' on State Abortion Laws*, THE HILL (Sept. 8, 2022, 8:01 PM), https://thehill.com/policy/healthcare/3635227-ama-warns-patient-health-is-at-risk-post-roe-calls-for-clear-guidance-on-state-abortion-laws/ (explaining need for clear guidance amidst confusion based on various state laws regarding medication abortion). See the text accompanying *infra* notes 269–71 for recent federal guidance.

117 *Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization*, U.S. DEP'T OF JUST. (June 24, 2022), https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s [hereinafter *AG Garland Statement on Supreme Court Ruling*].

118 GUTTMACHER INST., *supra* note 63; Knibbs, *supra* note 81.

2. The Emergence of Virtual Clinics are Expanding Medication Abortion Access Beyond State Boundaries

Nearly thirty states require physician administration of abortion medication, with some of these states banning medication abortion entirely.[119] Virtual clinics present many workarounds to accessing medication abortion across state lines. A citizen in an abortion-restrictive state can order a mifepristone prescription to an address in an abortion-accessible state, pick it up or have an out-of-state relative or friend mail the pills in-state, so the patient may take the medication at home.[120] As state restrictions on abortion increase, so does demand for services from domestic, virtual medication abortion providers.[121] For example, the number of appointments at Just the Pill, an online medication abortion provider, increased fourfold following the *Dobbs* decision.[122] Additionally, some nonprofits are opening mobile clinics along state borders, with technology to provide telehealth consultations and secure medication delivery to those out-of-state.[123] The hope is that these clinics will alleviate the demand for in-person procedures, saving the resources to provide operations to pregnant women past the ten week gestational mark.[124] Virtual clinics are a big step forward in the fight for abortion access, but many do not offer financial assistance or services to minors, limiting the reach of care.[125] Still, the use of telehealth allows patients to obtain medication abortions sooner and closer to home—increasing the odds of obtaining abortion care within the first trimester.[126]

Some providers are circumventing state restrictions on medication abortion laws, further giving rise to opportunities for prosecution.[127] For example, providers are getting around state law by providing abortion medication without clarifying where the patient lives.[128] Providers are able to get around state laws, bypassing brick and

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[119] Paige Twenter, *'A Legal Gray Area': Abortion Pill Providers Skirt State Law*, BECKER'S HOSP. REV. (Sept. 6, 2022), https://www.beckershospitalreview.com/pharmacy/a-legal-gray-area-abortion-pill-providers-skirt-state-laws.html. The number of states with limitations and bans is constantly in flux, due to pending state legislation. Knibbs, *supra* note 81; *see also State Legislative Tracker: Major Developments in Sexual & Reproductive Health*, GUTTMACHER INST., https://www.guttmacher.org/state-policy (last visited Jan. 30, 2023) [hereinafter *State Legislative Tracker*] (detailing current status of proposed legislation and laws around reproductive health in each state).

[120] Rowland et al., *supra* note 23.

[121] Landi, *supra* note 61.

[122] *Id.*; *Healthcare at Home*, JUST THE PILL, https://www.justthepill.com/video/ (last accessed July 4, 2023).

[123] Landi, *supra* note 61.

[124] *Id.*; Donley, *supra* note 23, at 632; Donovan, *supra* note 31, at 24; *see infra* Section II.B.1 (explaining that another potential barrier is general politicization isolating abortion from other types of health care).

[125] Lauren Rowello, *Where to Get the Abortion Pill Online*, HEALTH (Oct. 28, 2022), https://www.health.com/condition/pregnancy/abortion-pill-resources.

[126] Donovan, *supra* note 31, at 24.

[127] Twenter, *supra* note 119.

[128] *Id.*; *see also* Donley, *supra* note 23, at 696 (giving example of Plan C, a medication abortion resource site, listing process for visiting a virtual clinic and providing a temporary address to send pills, which are forwarded ultimately to patient's own home address).

mortar pharmacies, and evade local restrictions on mailing by avoiding documenting a patient's address.[129]

3. The Variation of State Laws and the Emerging Prominence of Telehealth Medication Abortion Raises Enforcement Challenges in Prosecution of Patients and Providers

One of the biggest gray areas post-*Dobbs* is whether a state can use ordinary criminal laws to prosecute people for crimes committed outside its borders, which historically is not allowed.[130] Since mifepristone is an FDA-approved medication, a mailer cannot be prosecuted for carrying packages containing abortion pills.[131] Additionally, foreign pharmacies typically send abortion medication in unassuming envelopes, making mailing nearly immune from policing.[132]

To counter these challenges, states may start to prosecute patients, not providers, for medication abortions.[133] These policies go against historical trends (and public sentiment),[134] but may become reality as providers are increasingly out-of-state and harder to control.[135] While enforcing bans on abortion pills sent through the mail would prove challenging, perhaps impossible,[136] there is another potential route for prosecutors to gather evidence against individuals illegally receiving telehealth abortion services: digital records.[137]

There is growing concern about the potential use of digital records—whether this includes patient records or online search history—against patients and providers. Patient records could be used to incriminate providers or clinics for providing medication abortion services through electronic health records, employee emails, or even mandatory reporting to state agencies.[138] A woman's online search records, text

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[129] Twenter, *supra* note 119.

[130] Jacobson, *supra* note 92.

[131] Rowland et al., *supra* note 23.

[132] *Id.*

[133] Donley, *supra* note 23, at 699–700; *see also* Poppy Noor, *Onslaught of New Abortion Restrictions Looms in Reddest of States*, THE GUARDIAN (Dec. 13, 2022, 5:00 PM), https://www.theguardian.com/world/2022/dec/13/abortion-restrictions-us-state-legislatures ("States that ban abortion typically impose criminal penalties on providers who violate bans, but exempt—at least formally—the person actually seeking the abortion. Far-right groups have advocated for an end to that exemption, but their efforts have so far proved politically untenable . . . .").

[134] Seventy-four percent of Americans are concerned that "[p]eople in states where abortion is outlawed could go to prison for crossing state lines to get an abortion," with 72% finding it likely that such action may occur. CHANGE RSCH., *supra* note 112. Further, 75% of Americans are concerned about health care requiring health care professionals to report illegal abortions, 75% are both concerned and find it likely that "[p]eople who get an abortion could be charged with a felony or go to prison," and 94% oppose using police power to enforce arresting those who leave the state to get an abortion. *Id.*

[135] For example, Georgia's abortion ban punishes the individual with life imprisonment or the death penalty. Donley, *supra* note 23, at 699, 700 n. 495.

[136] *Id.* at 696.

[137] *See* Ari B. Friedman, Lujo Bauer, Rachel Gonzales & Matthew S. McCoy, *Prevalence of Third-Party Tracking on Abortion Clinic Web Pages*, JAMA INTERNAL MED. (2022) (predicting that abortion-restrictive states may use "digital footprints . . . to identify and prosecute those suspected of having abortions").

[138] Kayte Spector-Bagdady & Michelle M. Mello, *Protecting the Privacy of Reproductive Health Information After the Fall of Roe v Wade*, JAMA FORUM (June 30, 2022).

messages, or other electronic communications have and can be used as evidence against her, if accused of illegally obtaining a medication abortion.[139]

Some companies, including Google, said if a user searches for information regarding abortion-related services, the company will delete the user's location data history; such services are not yet implemented.[140] Another potential source of evidence for prosecutors in abortion-restrictive states is third-party data collection from abortion clinic and virtual clinic websites.[141] Over 99% of abortion clinic websites appear to use code that transfers data to external entities that, in turn, may sell the data or provide it to law enforcement.[142] More concerningly, clinics may not know their sites are sending this data, which suggests that they need to audit their websites and remove third-party trackers to provide safe care and protect the privacy of their patients.[143]

Some legislation and policy pushes are occurring to improve privacy protection. Google, amongst others, supports a federal congressional effort to promote policy and guidance on nationwide data privacy law.[144] Taking charge, some states started to strengthen their own data laws.[145] For example, California expanded its protections over commercially collected personal information, specifically enforcing this protection over reproductive health data.[146] Laws like this increase the variation between jurisdictions.[147] In light of these ever-expanding differences in state law, it is likely that Justice Breyer's *Dobbs* dissent will turn prophetic—the overturning of *Roe* is putting "the court at the center of the coming 'interjurisdictional abortion wars.'"[148]

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[139] Scott Ikeda, *Google Promises to Delete User Location History When Healthcare Clinics Are Visited*, CPO MAGAZINE (July 12, 2022), https://www.cpomagazine.com/data-privacy/google-promises-to-delete-user-location-history-when-healthcare-clinics-are-visited/; *see also* McCabe, *supra* note 103 (noting that patient cell phones could be used in abortion provider investigations).

[140] Ikeda, *supra* note 139.

[141] There are approximately sixty-six unique parent companies tracking abortion clinic data, leading to trackers with unidentifiable parent companies on 73% of clinic websites. Karl Stark, *Abortion Clinic Websites May Unwittingly Aid Patient Prosecutions*, PENN LDI: HEALTH CARE ACCESS & COVERAGE (Sept. 8, 2022), https://ldi.upenn.edu/our-work/research-updates/abortion-clinic-websites-may-unwittingly-aid-patient-prosecutions/.

[142] HIPAA does not extend to cover this information. *Id.*; Spector-Bagdady & Mello, *supra* note 138.

[143] Stark, *supra* note 141. Such data does not fall under the HIPAA Privacy Rule either, as it does not qualify as a protected health information that is shielded by the rule. *See generally* 45 C.F.R. §§ 164.500–164.502 (outlining Privacy Rule and use and disclosure of protected health information).

[144] Ikeda, *supra* note 139.

[145] Spector-Bagdady & Mello, *supra* note 141.

[146] *Id.*

[147] *See id.* (explaining lack of federal standard to provide uniformity over such policies).

[148] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2337 (2022) (Breyer, J., dissenting); Marimow et al., *supra* note 77; *see also* Donley, *supra* note 23, at 694 (stating that *Dobbs* will likely intensify polarization between states as conservative states can now decrease or eliminate abortion access).

B. FDA's Current and Past REMS on Mifepristone Reflects Bias Against Reproductive Health and Unjustifiably Stifles Access to Abortion Medication

The REMS on mifepristone is an outlier, relative to the safety profile of the drug. Mifepristone is one of only sixty drugs actively under the REMS framework, despite the drug's low risk.[149] FDA's decision to keep this rare restriction on abortion medication reflects bias, whether intentional or not, against women's reproductive health and freedom.[150] Despite medication abortion's role as a protector of abortion access, the political and discriminatory history of the REMS requirements and the unusual restrictions on mifepristone compared to other drugs demonstrates that access may be curtailed more than necessary by existing FDA restrictions.[151]

1. The Mifepristone REMS Requirements are Unsubstantiated, as the Current Restrictions on Mifepristone Dispersion are Disproportionate to the Risks of Mifepristone, Reflecting a Bias Against Women's Reproductive Health

While FDA's bias against abortion and women's reproductive health may be implicit, this does not change the fact that, for decades, the restrictions on mifepristone (and many other reproductive-related drugs), have been criticized as politicized and discriminatory.[152] FDA restrictions on abortion medication imply that the drug is more dangerous than statistics show and requires safeguards that are arguably unnecessary.[153] Groups such as ACOG and the American Academy of Family Physicians (AAFP) argue "that the REMS serves no medical purpose."[154] FDA originally subjected mifepristone to these unusual, unwarranted restrictions for the payoff of approval of the drug under Subpart H, which involves placing certain distribution restrictions on approved drugs.[155] However, given the continual proven safety of mifepristone, these REMS and ETASU restrictions actually subject women's health care to unique standards.[156]

The original FDA restrictions on mifepristone, requiring in-person disbursement and physician's certification, are partially responsible for the evolution of abortion

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[149] Belluck, *supra* note 52. (A REMS "has been used for only about 300 other drugs, only 60 of which are currently active[e] . . . .").

[150] *See supra* Section II.B.

[151] *See infra* Section II.B.

[152] HARV. L. REV., *supra* note 41, at 2236.

[153] Donley, *supra* note 23, at 651.

[154] *Id.*

[155] *See infra* Section II.B.1; U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 31; *see also* Donley, *supra* note 23, at 654 (Mifepristone's REMS "does nothing to reduce [the patient's] risk of hemorrhage, infection, or incomplete abortion, all of which would take place at home."); Koons, *supra* note 2 ("Over the past two decades, researchers and medical bodies have built a growing and compelling case that many, if not all, of the regulations are medically unnecessary."); Donovan, *supra* note 31, at 25 ("Given mifepristone's extensive safety record since it was approved for use in the United States in 2000, the REMS restrictions are not justified, which is why leading medical organizations such as the American Medical Association and the American College of Obstetricians and Gynecologists support their removal.").

[156] *See infra* Section II.B.

services as a clinic-based service, segregated from the resources and infrastructure of other health care.[157] Whether intentional or not, mifepristone's REMS effectively ensured that the majority of abortion providers are almost exclusively at abortion clinics, requiring women to travel far distances just to pick up the medication.[158] Up until recently, the prohibition on telehealth exacerbated this problem.[159] Historically, 95% of abortions (including medication abortions) in America occurred at abortion or family planning clinics—outside of traditional health care facilities.[160] This separation perpetuated stigmatization of abortion care and greatly limited societal and individual abortion access, demonstrating the sweeping implications of the REMS restrictions.[161]

The physician (now "provider") certification requirement further separated abortion medication from traditional medicine by requiring doctors to "affirmatively seek certification to prescribe mifepristone, a noncontrolled substance."[162] Segregating abortion care in this way made it easier for anti-abortion advocates to find these clinics and harass both patients and providers, further stigmatizing abortion.[163] Many providers may want and possess the capability to provide abortion care, but decide not to apply for certification based on fear of harm or lack of time and energy to go through the certification barriers.[164] These obstacles decrease abortion access, as only a small number of providers are willing to get certified.[165] This subsequent lack of access is unduly burdensome on patients, particularly those in rural areas.[166]

The new pharmacy certification requirement presents additional concerns regarding access to care. While providers may more likely prescribe mifepristone if the prescription is fillable at a pharmacy, the lack of certified pharmacies may stifle

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[157] Donley, *supra* note 23, at 630; *see generally* Donovan, *supra* note 31 (describing evolution of abortion care).

[158] Donley, *supra* note 23, at 630.

[159] *Id.*

[160] *Id.* at 629–30; *see also* Diamant & Mohamed, *supra* note 51 (stating that while clinics only accounted for 50% of abortion providers, clinics *administered* 96% of all abortion performed in 2020). This was radically disrupted by the pandemic, as at-home use of mifepristone became possible. *See supra* Section I.A.

[161] Donley, *supra* note 23, at 643.

[162] *Id.* at 644.

[163] This is true of providers and pharmacies that provide abortion, as all are required to register with the manufacturer. *Id.* at 638; Landi, *supra* note 61. The fear of harm associated with qualifying as an "abortion provider" is substantiated, as "[i]n 2019, ninety-two abortion providers experienced death threats; 1,507 experienced trespassing; and 3,123 experienced hate mail or harassing phone calls. There have also been eleven murders and six attempted murders of abortion providers since 1977." Donley, *supra* note 23, at 644. Conversely, the rare hospitals that do provide abortion experience nearly zero protests or violence, given that abortion is such a small fraction of the holistic care provided and thus, less stigmatized. *Id.* at 692.

[164] Donley, *supra* note 23, at 643–44, 646 n. 124, 125.

[165] *See id.* (quoting DAVID S. COHEN & CAROLE JOFFE, OBSTACLE COURSE: THE EVERYDAY STRUGGLE TO GET AN ABORTION IN AMERICA 223 (2020)) ("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.'")

[166] *Id.* at 665; *see also infra* Section II.C.

this change to expand care.[167] Additionally, pharmacies considering certification have been dissuaded by concerns of vandalism, arson, threats, or boycotts against their business.[168] The pharmacy certification requirement is another unique restriction imposed on mifepristone, as only forty of the 19,000 FDA-approved drugs require pharmacy certification.[169] This part of the REMS also treats medication abortion as unsafe and segregated from routine health care and medical access.[170]

Beyond the consequences of the REMS, the actual determination that mifepristone needs these strong warnings is puzzling. Typically, FDA will determine that a drug requires a REMS when needed "to ensure that the benefits of the drug outweigh the risks."[171] The additional ETASU is issued when FDA decides a drug "is associated with a serious adverse drug experience" to the point that an ETASU is necessary "to mitigate a specific serious risk listed in the labeling of the drug."[172]

The REMS on mifepristone does not meet the statutory criteria that FDA is supposed to use, because the risks associated with taking mifepristone—serious infection and heavy bleeding—are not substantial enough to warrant a REMS.[173] Based on FDA reports, only a low number of users experienced a serious adverse event associated with mifepristone since the drug's approval in September 2000.[174] FDA states that these reported "adverse events cannot with certainty be causally attributed to mifepristone," given other possible causes such as concurrent use of other drugs, other medical or surgical treatments, coexisting medical conditions, and information gaps related to the patient.[175] Thus, from a medical lens, the health risks associated with mifepristone are not actually directly mitigated by the current restrictions.[176] Specifically, the prerequisite that prescribers and pharmacies meet certain requirements to get certified, while seemingly beneficial, in reality does not mitigate the main risks of the drug, because the patient is using, and in many cases prescribed, the drug at home.[177]

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[167] *See* Donley, *supra* note 23, at 645–46, 658 (predicting that more providers might get certified, because certification will no longer include taking on financial burden of keeping medication in stock).

[168] *Id.* at 646.

[169] Koons, *supra* note 2.

[170] Donley, *supra* note 23, at 643.

[171] 21 U.S.C. § 355-1(a)(2)(A).

[172] *Id.* § 355-1(f)(1).

[173] Donley, *supra* note 23, at 627, 666; *see also infra* Section III.C; What's in a REMS?, *supra* note 36 (detailing risks of mifepristone).

[174] *Questions and Answers*, *supra* note 28.

[175] *Id.*

[176] *See* Donley, *supra* note 23, at 654–55 (explaining that physician and pharmacy certification requirements do not mandate a patient to take mifepristone at a medical facility, so all of the largest risks—hemorrhage, infection, or incomplete abortion—would take place at home without either of these certified entities); *see also* Koons, *supra* note 2 (stating that regulations on mifepristone are increasingly considered medically unnecessary).

[177] *See Questions and Answers*, *supra* note 28 (describing mifepristone's risks and REMS conditions, which seemingly do not correlate); *see also* Section III.B.2 (describing how more deadly and adverse drugs are less regulated and more accessible than mifepristone); Anne Flaherty, *Drug Company and Doctor Sue Over Abortion Pill Access, in Test Cases of Federal Power*, ABC NEWS (Jan. 25, 2023, 1:12 PM), https://abcnews.go.com/Health/north-carolina-doctor-sues-abortion-pill-access-test/story? (explaining that medical risks associated with mifepristone would require immediate medical attention,

Even assuming *arguendo* that the REMS is justifiable, the additional ETASU is not.[178] FDA issues a REMS with an ETASU when a drug is "associated with a serious drug experience," making the additional safeguards necessary to mitigate the specific risk.[179] The ETASU on mifepristone does not match the specific risks in the label or the restrictions on other drugs with similar risks.[180]

More broadly, the regulation of mifepristone, while arguably improper, falls within the federal government's larger history of biased decision making when it comes to reproductive health and abortion care.[181] Previously, scientists accused FDA of biased, politically motivated decision making for the original restrictions on Plan B and initial refusal to approve flibanserin, a drug treatment for sexual desire disorder in women.[182] With mifepristone, FDA faced criticism even before approval, as the drug experienced unusual treatment.[183] For example, during former President George Bush's Administration, rather than allowing Americans to bring mifepristone into the United States under the personal exemption exception, the drug was subjected to automatic detention.[184] This unusual treatment is still prevalent. For example, FDA approved a drug with the exact same chemical composition as mifepristone for usage at a higher, daily dose, without any REMS restrictions.[185] Despite the higher and heavier dosage, the only other notable difference is that this drug treats high cortisol, rather than inducing abortion.[186] Another example of the biased decision making surrounding mifepristone occurred during the pandemic.[187] Despite lifting the in-person dispensing requirement for other drugs, FDA took over a year, in conjunction with an administration change, a lawsuit, and medical lobbying, before removing the same requirement on mifepristone (even though in-person prescription of the drug correlated to a potentially high rate of COVID-19 transmittal between providers and patients).[188]

If FDA is concerned about articulating the risks of abortion medication, the agency should instead put a different kind of REMS on the drug—perhaps a communication plan disclosing the risks of atypical presentation of infection or

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but mifepristone is considered safe enough for prescription and usage without in-person evaluation, creating contradiction in rules).

[178] Donley, *supra* note 23, at 664.

[179] *Id.* at 663.

[180] *Id.* at 664; *see also supra* Section I.A.1.

[181] Donley, *supra* note 23, at 627, 631, 666, 667. While not within the scope of this Article, Donley's article examines in depth FDA's historical stigmatism when approving and regulating drugs connected to female reproductive health. *Id.* at 667–81.

[182] *Id.* at 673.

[183] *Id.* at 670.

[184] "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.'" *Id.* at 671. Congress asked to permit mifepristone under this exemption, but the Bush Administration denied the request. *Id.*

[185] HARV. L. REV., *supra* note 41, at 2236.

[186] *Id.*

[187] *Id.* at 2240.

[188] *Id.* at 2240; Donley, *supra* note 23, at 644 n. 110, 651, 683.

bleeding.[189] There are risks associated with mifepristone use, but provider or pharmacist communication can easily help a patient understand these risks and what to do if experiencing such symptoms, without a need for more stringent restrictions.[190] Unfortunately, the historical separation of abortion care, the arduous certification requirements, and the extreme restrictions on mifepristone all play a role in increasing abortion stigma, increasing reliance on self-managed abortions, and decreasing abortion access.[191] It is time for FDA to alter or remove the REMS and ETASU[192] to reflect the safety and effectiveness of medication abortion and match the risks to the regulation.[193]

2. The Federal and State Restrictions on Mifepristone, as Compared to Other Drugs, Demonstrate a Bias Against Abortion

Mifepristone may be one of the least marketed drugs in the United States, based on the lack of advertisements and low number of prescribing, informed doctors, and pharmacies.[194] For example, since FDA's formal allowance of retail pharmacy certifications in 2023, retail pharmacy giants CVS and Walgreens announced they would seek certification to provide the pill, but only where allowed by state law.[195] Despite limited consumer accessibility, abortion medication is incredibly safe and effective when used as intended; mifepristone sends fewer people to the emergency room than Tylenol or Viagra.[196] The contrast between the availability of mifepristone in comparison to other drugs is further evidenced by the disparate treatment of mifepristone by the states and in comparison to other drugs.

The treatment of mifepristone seems even more bizarre when looking at the state-by-state regulations[197] that essentially make mifepristone an FDA-approved drug that is "unapproved" by the states.[198] This is counter to say, regulation of cannabis (as states are legalizing and actively eliminating restrictions on cannabis, which lacks FDA authorization).[199] At force is what some call "abortion exceptionalism," both at

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[189] Donley, *supra* note 23, at 640; *What's in a REMS?*, *supra* note 36.

[190] Donley, *supra* note 23, at 631.

[191] *Id.* at 651.

[192] Part of the problem regarding the mifepristone REMS is that burden shifting for the original justification, due to the Subpart H approval, keeps occurring, despite the fact that the safety concerns that gave rise to these restrictions no longer exist. *Id.* at 666.

[193] *See supra* note 156.

[194] Koons, *supra* note 2. Mifepristone is not available at most retail pharmacies. *Id.*

[195] Spencer Kimball, *The FDA's Power to Approve Drugs Faces Sweeping Challenge in Lawsuit Seeking to Pull Abortion Pill from U.S. Market*, CNBC (Jan. 24, 2023, 8:36 AM), https://www.cnbc.com/2023/01/24/abortion-pill-fda-challenged-in-lawsuit-seeking-to-pull-mifepristone-from-us.html.

[196] *Id.*; Donley, *supra* note 23, at 631.

[197] *See supra* Sections I.B, II.A.

[198] *See* Marimow et al., *supra* note 77 (discussing issues regarding state laws that conflict with FDA approval of mifepristone); *see also supra* notes 25–31and accompanying text (explaining Subpart H authorization).

[199] *See* Marimow et al., *supra* note 77 (emphasizing importance of a national standard for accessibility of drugs in United States).

the state and federal level.[200] Abortion exceptionalism is "the phenomenon 'in which abortion is singled out for more restrictive government regulation'" and unduly burdensome rules.[201] For example, the FDA-approved treatment of Korlym, a drug for Cushing's Syndrome to treat high levels of cortisol, is drastically different than the restricted approval of medication abortion treatment, despite both treatments using the same drug to accomplish different ends.[202] Even though Korlym is taken in higher doses at a daily regiment at home and is associated with a higher rate of adverse events than mifepristone, which is only taken once, Korlym is treated as a much less "dangerous" drug by FDA.[203]

Federal and state treatment of Viagra further illustrates how abortion exceptionalism affects treatment and access to mifepristone. Viagra is a primary example.[204] Viagra, with the active ingredient sildenafil, is an FDA-approved drug to treat erectile dysfunction in men.[205] Sildenafil is associated with numerous known, serious side effects, including eye, ear, penis, heart, and blood vessel issues, and a possible link to skin cancer.[206] Despite the fact that sildenafil is just as, if not more, dangerous than mifepristone and allowed for daily dosage, FDA declined to put a REMS or any akin restriction on Viagra.[207] The exceptionalism argument is bolstered by the fact that Viagra's fatality rate is four deaths per 100,000—approximately a six times higher fatality rate than mifepristone.[208] Despite dealing with sexual health, albeit men's sexual health, just like mifepristone, this drug does not face the same treatment that abortion medication faces, illustrating potential exceptionalism at work.[209]

Comparing the treatment of opioids with the treatment of mifepristone offers another example. Opioids are highly addictive drugs, responsible for tens of thousands of fatalities in the United States per year.[210] The only REMS on opioids is a requirement that the drug manufacturers offer training to health care providers who

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[200] Donley, *supra* note 23, at 666.

[201] *Id.* at 666 n. 270 (quoting Ian Vandewalker, *Abortion and Informed Consent: How Biased Counseling Laws Mandate Violations of Medical Ethics*, 19 MICH. J. GENDER & L. 1, 3 (2012)).

[202] *Id.* at 653.

[203] *Id.*

[204] *Id.* at 652.

[205] *Viagra*, DRUGWATCH, https://www.drugwatch.com/viagra/ (last updated Nov. 21, 2022).

[206] *Id.*

[207] *See id.* (providing fatality rate of Viagra). *Compare* U.S. FOOD & DRUG ADMIN., VIAGRA MEDICATION GUIDE (2014) (listing risks and requirements for prescribing Viagra), *with What's in a REMS?*, *supra* note 37 (demonstrating much higher restrictions on mifepristone).

[208] Donley, *supra* note 23, at 652. The same is true of penicillin, with a fatality rate of about two deaths per 100,000, making it three times as fatal as mifepristone, despite lacking any REMS. *Id.* This is also the case with anticoagulants (also known as blood thinners) that are available at all pharmacies without an accompanying REMS. *Id.*; *see also supra* notes 225–27 and accompanying text.

[209] *See* Donley, *supra* note 23, at 652–53 (discussing abortion exceptionalism and comparing treatment of mifepristone and Viagra).

[210] *Id.* at 664–65. In comparison, since 2000, there are only twenty-eight cases of mifepristone-related death. *Questions and Answers*, *supra* note 28. While more people presumedly take opioids than mifepristone, it is clear the fatality rate of opioids is much greater. *Id.*

prescribe them.[211] This REMS is much less restrictive than mifepristone's REMS, despite a much higher risk associated with opioid use.[212]

Finally, cannabis provides another foil to the treatment of mifepristone. Cannabis is not an FDA-approved drug.[213] However, only thirteen states outright prohibit cannabis, in line with the federal standard.[214] Notably, the number of states banning cannabis is less than the number of states that prohibit abortion medication, despite mifepristone's federal approval.[215] Even though cannabis is an illegal, mind-altering drug, the states and/or American public deem it safer than FDA-approved, medically supported, and proven safe mifepristone—a clear sign of exceptionalism in the treatment of reproductive health, fueled by a bias against women.[216] By looking at the treatment of mifepristone compared to other drugs, it is clear that access to medication abortion is unjustifiably stymied by unnecessary and unfounded regulations and restrictions, further supporting the need for federal and state laws to alter the restrictions on mifepristone.[217]

C. Limited Access to Mifepristone Leads to Negative Health Effects for Women, Particularly Women in Marginalized Communities

Medication abortion is a safe treatment and does not pose a threat to women's health.[218] In reality, restricting access to medication abortion diminishes the overall quality of women's well-being.[219] Ninety-five percent of medication abortions from May 2016 to September 2020 did not require any additional follow up care.[220] Further, only 6% of mifepristone users required subsequent emergency room visits, and only 0.9% of users recorded serious complications.[221] However, the restrictive federal and state policy governing mifepristone puts the health of women at risk, as evidenced by the health risks associated with a lack of abortion medication access and the disparate negative effect on low-income individuals and communities of color.[222]

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[211] Donley, *supra* note 23, at 664–65; *see infra* Section II.C.

[212] Donley, *supra* note 23, at 664–65.

[213] Nat'l Ctr. for Complementary and Integrative Health, *Cannabis (Marijuana) and Cannabinoids: What You Need To Know*, NAT'L INSTS. OF HEALTH, https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know (last updated Nov. 2019) ("The FDA has not approved the cannabis plant for any medical use."); THOMSON REUTERS, MARIJUANA STATE LEGAL STATUS CHARTS: OVERVIEW (last updated Dec. 8, 2022) [hereinafter THOMSON REUTERS, MARIJUANA].

[214] THOMSON REUTERS, MARIJUANA, *supra* note 213.

[215] *Compare id., with supra* text accompanying notes 64–65, 68–70.

[216] *Compare* Nat'l Inst. on Drug Abuse, *Cannabis (Marijuana) DrugFacts*, NAT'L INSTS. OF HEALTH, https://nida.nih.gov/publications/drugfacts/cannabis-marijuana (last revised Dec. 2019) (explaining effects of cannabis), *with supra* Section II.B.1.

[217] *See supra* Section II.B.

[218] Pam Belluck, *Abortion Pills Take the Spotlight as States Impose Abortion Bans*, N.Y. TIMES (June 27, 2022), https://www.nytimes.com/2022/06/26/health/abortion-medication-pills.html [hereinafter Belluck, *Abortion Pills*].

[219] *See infra* Section II.C.

[220] Belluck, *Abortion Pills*, *supra* note 218.

[221] *Id.*

[222] *See supra* Section II.C.

There are individuals for whom medication abortion is an unsafe procedure, but, as with most medications, these individuals are the outliers.[223] Generally, medication abortion is a low-risk medical procedure, with a fatality rate of 0.0006% and a risk of serious adverse event from 0.01–0.7%.[224] For comparison, the fatality rate for live birth is nearly 0.009%—a fourteen times greater chance of death.[225] The serious adverse events associated with mifepristone are almost always treatable without the user sustaining long-term health issues.[226] In actuality, *not* receiving an abortion, often due to denial of medication abortion or inability to access affordable care in a timely manner, creates arguably greater detriments to a woman's physical and mental well-being.[227] Reduced abortion access is associated with negative health and welfare outcomes, increased financial insecurity, reduced aspirational life plans, and increased incidences of serious pregnancy complications and poor physical health post-pregnancy.[228]

Women of color face generally greater barriers to accessing abortion, including financial and geographical challenges.[229] Barriers like the REMS disproportionately affect those already most marginalized—particularly minority, transgender, and nonbinary pregnant individuals.[230] Eleven of the eighteen states that ban telehealth abortion services are in the South, where BIPOC populations are more represented and access to in-person abortion services are most hampered.[231] Additionally, any woman on Medicaid is unable to obtain an insurance-funded abortion, as the Hyde Amendment *de facto* strips away any Medicaid abortion funding.[232] Most upsettingly, the mental and physical health risks associated with not receiving a

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[223] For example, the following make it unsafe to use abortion medication: an ectopic pregnancy, an adrenal condition, long-term corticosteroid use, an allergy to mifepristone or misoprostol, consumption of blood thinners, experiencing bleeding problems or inherited porphyria, or using an IUD. Rowello, *supra* note 125; *see also Questions and Answers*, *supra* note 28 (describing what conditions and/or medication usages preclude use of mifepristone with misoprostol).

[224] Donley, *supra* note 23, at 634.

[225] *Id.* (quoting Mifeprex REMS Study Grp., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENG. J. MED. 790, 791 (2017)). The pregnancy-related fatality rate is even higher for Black women, at 40 deaths per 100,000 live births, compared with the national average of 18 deaths per 100,000 live births. *Id.*; *see also* Lisa H. Harris & Daniel Grossman, *Complications of Unsafe and Self-Managed Abortion*, NEW ENG. J. MED. 382, 1030 (2020) (explaining that in Latin America, usage of abortion mediation, even when self-managed, is "associated with reduced maternal mortality").

[226] Donley, *supra* note 23, at 634.

[227] *See id.* at 657.

[228] Terri-Ann Thompson, Dana Northcraft & Fabiola Carrion, *Addressing Structural Inequities, a Necessary Step Toward Ensuring Equitable Access to Telehealth for Medication Abortion Care During and Post COVID-19*, FRONTIERS GLOB. WOMEN'S HEALTH, Mar. 17, 2022, at 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8967978/pdf/fgwh-03-805767.pdf. *See also* Donley, *supra* note 23, at 664 (explaining that this is due, in part, to denying women autonomy "to control the number and spacing of their children").

[229] Thompson et al., *supra* note 228, at 1; Donley, *supra* note 23, at 649 (noting that 75% of women seeking abortion are low-income and lack discretionary funds to spend on access to in-person abortion facilities and that women of color, low-income, and rural women "are always disproportionately harmed by disruptions to abortion care").

[230] HARV. L. REV., *supra* note 41, at 2241.

[231] Thompson et al., *supra* note 228, at 3.

[232] *Id.*

wanted abortion disproportionately harm low-income, rural, and BIPOC women the most.[233]

The denial of medication abortion access also affects female patients who need these medications for reasons unrelated to abortion.[234] Women who need mifepristone or misoprostol for other uses are reporting challenges to obtaining the drugs post-*Dobbs*, consequently creating additional medical risks and uncertainties.[235] For example, a woman may want to access these drugs to aid in miscarriage management, as such treatment is often considered best practice.[236] But, she likely may face challenges to actually accessing the medication for a miscarriage, as physicians are often unable to offer this treatment due to the REMS certification requirement.[237]

Finally, restricted access to abortion is also causing an increase in *self-managed* abortions.[238] A self-managed abortion is defined as an attempt to end one's own pregnancy without medical guidance or clinical supervision.[239] Those who face greater barriers to abortion access are more likely to attempt self-managed abortion.[240] While not necessarily associated with high health risks, a self-managed abortion is less safe and poses greater legal risks than a medication abortion with a physician's guidance.[241] Six states subject a woman who engaged in self-managed medication abortion to criminal prosecution.[242]

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[233] *See* Donley, *supra* note 23, at 655.

[234] Gans, *supra* note 116.

[235] See THOMSON REUTERS, IN POST-DOBBS GUIDANCE, HHS ADDRESSES SEX AND DISABILITY DISCRIMINATION RULES FOR PHARMACIES (2022) [hereinafter POST-DOBBS GUIDANCE] (describing how women face uncertainty in accessing these drugs).

[236] Donley, *supra* note 23, at 662.

[237] *Id.*

[238] Lawmakers seemingly fail to account for this fact, as restrictions on abortion do not decrease the number of abortions that take place, but rather, increase the proportion of self-managed abortions. *Id.* at 655; Rowland et al., *supra* note 23. Further, Google search analysis shows "that interest in self-induced abortion . . . was higher in states with restrictive abortion laws than in states without them." Donley, *supra* note 23, at 659; *see also* Lisa B. Haddad & Nawal M. Nour, *Unsafe Abortion: Unnecessary Maternal Mortality*, 2 REVS. OBSTETRICS & GYNECOLOGY 122, 122 (2009) (stating that self-managed abortion is greater in countries, typically third world countries, with heavy abortion restrictions).

[239] Upadhyay et al., *supra* note 115, at 50. Alternatively, self-managed abortion is defined as "when a person ends a pregnancy outside of the medical care setting, typically by ordering abortion pills online." Donley, *supra* note 23, at 658.

[240] Recent evidence suggests that, when inclusively studying abortion-seeking patients beyond just those at abortion clinics, self-managed abortion is higher in places with greater barriers to access. Upadhyay et al., *supra* note 115, at 49–50; *see also* Donley, *supra* note 23, at 659 (noting that self-managed abortion is highest in areas with fewer clinics and greater abortion restrictions, making it highest in the South).

[241] See *id.* at 658–59 for examples of occasions when women faced legal and medical consequences for attempting self-managed abortion and Haddad & Nour, *supra* note 238, for a discussion on the statistical safety of self-managed abortion. Globally, it is estimated that about 68,000 women die per year from self-managed abortion, "making it one of the leading causes of maternal mortality," and of the 20 million women who self-manage, about a quarter "will suffer long-term health complications." *Id.*

[242] HARV. L. REV., *supra* note 41, at 2241. While self-managed medication abortion is inherently illegal in the United Sates, as medication abortion is only authorized through the FDA-approved regiment, these states took extra steps to prohibit the practice. Donley, *supra* note 23, at 659.

In an inclusive study of women seeking abortion, 28% of respondents reported at least one method of attempted self-managed abortion.[243] Disturbingly, of those who attempted self-managed abortion, nearly 40% were still seeking an abortion four weeks later, after unsuccessful self-attempts;[244] in comparison, those who received mifepristone experienced 96% success in ending their pregnancy.[245] Of the study participants, 8% attempted self-managed abortion through ordering abortion pills online without a prescription, and all of these individuals successfully ended their pregnancies.[246] This shows how greater access to medication abortion can increase the safe and effective treatment of abortion, protecting women from harm—a protection many women currently lack in America.[247] Self-managed abortions are likely to continue increasing in abortion-restrictive states, unless in-person requirements are eliminated or FDA further modifies the REMS to increase access to medication abortion for those who otherwise might try to self-manage their abortion.[248]

D. Moving Forward: To Fully Protect and Improve Access to Mifepristone, New Solutions and Preparation for Legal Battles are Necessary

1. To Further Increase Access to and the Positive Impact of Mifepristone, the Federal Government Must Invest in Telehealth Services and Virtual Clinics, Pursue a National Standard of Care under Federal Preemption Theory, and Remove or Modify the REMS

To rectify the unjustified treatment of medication abortion and the barriers to providing abortion access, federal government and private actors are already taking action. Current solutions include establishing virtual clinics, providing advance provision care, laying out federal agency guidance, and asserting a national standard of care through FDA.[249] Building upon these remedies, some additional solutions include increasing telehealth access, reallocating federal funding to virtual clinics that can more easily reach across state boundaries to provide abortion access to those who need it most, and pushing a federal preemption theory to uplift FDA's standard. Finally, FDA can relax or remove the REMS on mifepristone, to ultimately create greater access to the drug in abortion-accessible states (and hopefully, abortion-restrictive states, too).[250]

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[243] Upadhyay et al., *supra* note 115, at 53.

[244] *Id.* at 55.

[245] *Id.* at 53.

[246] *Id.*

[247] Donovan, *supra* note 31, at 26; Donley, *supra* note 23, at 631.

[248] Donley, *supra* note 23, at 700–01 (describing desire to stop particularly unsafe self-managed abortion, such as through physical trauma or taking herbs, as a potential motivator for FDA in further modification of REMS).

[249] *See supra* text accompanying notes 120–30; *see infra* note 273 and accompanying text, text accompanying notes 263–65, 273–88.

[250] *See infra* Section II.D.1.

One way to reduce the disparities in access for marginalized groups is through telehealth access.[251] Improved telehealth and broadband services can help eliminate barriers such as an inability to travel, the need for childcare, lost wages, or loss of privacy.[252] Additionally, remote abortion care generally is less expensive, meeting the needs of low-income abortion patients.[253] However, current state and federal restrictions on mifepristone prescriptions are mitigating telehealth's full potential to help increase medication abortion access.[254] To improve access to mifepristone through telehealth, federal and state governments should increase and invest in broadband access for low-income and BIPOC communities to make telehealth access more equitable.[255] This is a particularly effective solution, as patients living over fifty miles or more from a clinic are more likely to seek an abortion in the second trimester, which eliminates the opportunity for the more affordable medication abortion treatment.[256] Another way to increase access for women of color is to modify the REMS to allow nonphysicians, such as nurses, to dispense mifepristone.[257] This would help increase access for women of color because, as a result of historical medical racism, nurse-centered care can alleviate the medical mistrust between these patients and doctors and improve continuity of care for non-white abortion seekers.[258]

The rise of virtual clinics already increased access to medication abortion through telehealth, especially for those in abortion-restrictive states.[259] These clinics challenge state boundaries as a limitation on affordable, safe abortion access.[260] Virtual clinics are taking their impact even further by providing "advance provision" services.[261] Advance provision occurs when a telehealth service sends a woman abortion pills before they are needed—a measure intended to alleviate stress in the time between the patient finding out she is pregnant, pursuing medical care, and

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[251] Thompson et al., *supra* note 228, at 2; Donovan, *supra* note 31, at 24–27; *see also* Donley, *supra* note 23, at 631 (reminding that "[r]emote abortion care is cheaper, more convenient, and allows patients to avoid the harassment associated with clinics"); *supra* Section II.C (discussing how marginalized groups experience greater negative health impacts associated with lack of access to abortion medication).

[252] Donley, *supra* note 23, at 648.

[253] Thompson et al., *supra* note 228, at 2; Donley, *supra* note 23, at 648, 656, 691.

[254] Thompson et al., *supra* note 228, at 2.

[255] *Id.* at 2, 4.

[256] Donovan, *supra* note 31, at 24; *see also* Donley, *supra* note 23, at 657 (explaining that this problem is exacerbated because 85% of these women reported travel and procedure costs as main reasons they had yet to obtain an abortion elsewhere).

[257] Thompson et al., *supra* note 228, at 3 (noting that currently, this practice is explicitly prohibited in twenty-nine states).

[258] *Id.*

[259] *Id.* at 690–91.

[260] *See id.* at 632 n. 19 (discussing how clinics in Colorado and Nevada began helping Texas women obtain telehealth medication abortions following S.B. 8, decreasing pressure on providers doing surgical abortion procedures); *supra* Section II.A.2.

[261] Megan Cerullo, *Abortion Pill Startup Provides Meds to Women Who Aren't Pregnant Yet*, CBS NEWS (Sept. 8, 2022, 4:43 PM), https://www.cbsnews.com/news/abortion-pill-startup-provides-care-to-people-who-arent-yet-pregnant-stockpile/.

receiving the medication.[262] For example, Choix, a virtual abortion service, will send women abortion pills before they are pregnant in states where abortion is legal.[263]

To expand on the impact of these virtual clinics, a proposed solution is to invest federal funds into virtual clinics and telehealth medication abortion services. The number of brick-and-mortar abortion clinics in the United States is declining, disproportionately so in the South and Midwest, both regions with high numbers of abortion-restrictive states.[264] Increasing virtual clinics eliminates reliance on in-person abortion clinics.[265] Remedying this in-person clinic reliance is becoming a more pressing issue, as numerous states are expected to attempt to prohibit government funding for out-of-state travel to obtain an abortion.[266] As an added benefit, virtual abortion care allows patients to avoid the stigma and violence associated with many in-person clinics.[267] Additionally, investing and promoting virtual care prevents states from utilizing traditional limitations or regulations on abortion clinics.[268]

Federal funds could also support pharmacies that are certified to prescribe mifepristone, bolstering the capacity of such pharmacies to provide abortion medication and serving as an incentive for pharmacies to get certified under the current REMS.[269] Abortion medication is not cheap, so federal subsidization can decrease costs and increase the affordability of the drug for many Americans.[270] By shifting federal funding into virtual medication abortion services, rather than continuing to funnel investment into abortion clinics that are still open in abortion-accessible states (most likely missing those most removed from abortion access already), medication abortion can reach a greater audience and make a bigger impact.

Beyond investment, the federal government should also pursue enforcement of a national standard of access to medication abortion. Thus far, federal guidance does not adequately address or mitigate the variations in state law restrictions on

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[262] *Id.* This is a common challenge for abortion-seekers, exacerbated by legal and logistical barriers for many Americans. *Id.*

[263] *Id.* However, one limitation is that only the person prescribed the pills is (supposed to be) allowed to use them. *Id.*

[264] Even before *Dobbs*, many Americans lived without an abortion clinic within 100 miles of their home. *See* Donley, *supra* note 23, at 646 ("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.").

[265] *Id.* at 702.

[266] Shefali Luthra, *How Some State Legislatures are Preparing to Further Limit Reproductive Rights*, PBS NEWS HOUR (Dec. 6, 2022, 5:02 PM), https://www.pbs.org/newshour/nation/how-some-state-legislatures-are-preparing-to-further-limit-reproductive-rights.

[267] *See* Donley, *supra* note 23, at 691; *supra* Section II.B.1.

[268] *See* Donley, *supra* note 23, at 691, 694 (noting that physical abortion clinics often attract legislative action tied to space, i.e., size of room, distance from hospital, etc., as a means to limit access).

[269] *See id.* at 646 (reiterating that telemedicine is becoming norm of care, thus, implying that funding these services is best use of federal dollars).

[270] *See The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (Dec. 1, 2022), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ (citing abortion medication costs of $250 to $560).

mifepristone.[271] The best solution to achieve this goal is by advancing FDA as the ultimate authority on drug approval through a federal preemption theory.[272] Typically, states complement or supplement federal oversight, with FDA serving as the primary regulator.[273] Federal preemption theory, as applied to the present debacle, says that when compliance with both state and federal law is impossible, state law will be preempted by federal rule if the state law thwarts the purpose of the federal law (here, the approval of mifepristone).[274] Within this role, states may not put forth policy that conflicts with FDA regulations and requirements.[275] After all, the FDA standard is meant to set a national standard for the drugs that consumers can access.[276]

Precedent may support the federal government's preemption argument, based on a case arising from Massachusetts in 2014.[277] Massachusetts tried to ban an FDA-approved opioid, but the federal district court ruled with the manufacturer that FDA approval of the specific opioid preempted state law.[278] However, given the current majority of conservative justices on the Supreme Court, it is unclear if the Court would rule in alignment with this precedent or if, instead, the Court would hold that a state retains authority over the prescription ability of its own licensed medical professionals.[279] If such a ruling occurs, this opens up broader questions: If states can prohibit abortion medication over FDA authorization, what else can states ban?[280] And, how far can state sovereignty be pushed in the medical-legal world?[281]

The preemption lens gives the Biden Administration, or any future administration, the opportunity to urge FDA to adopt a less restrictive REMS on mifepristone and

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[271] *E.g.*, POST-DOBBS GUIDANCE, *supra* note 235 (reporting on HHS guidance issued a few weeks post-*Dobbs*); Mem. Op. for the Gen. Couns. U.S. Postal Serv., 46 Op. O.L.C. (Dec. 2023) (describing proper application of Comstock Act to mailing abortion medication); *AG Garland Statement on Supreme Court Ruling*, *supra* note 117 ("[T]he Constitution continues to restrict states' authority to ban reproductive services provided outside their borders."). Each of these sources is a federal guidance put out in the last year, that is ultimately unenforced, as evidenced by the state laws going against the guidance and standards. *See supra* Section II.A.

[272] Cohen et al., *supra* note 91; Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 NEW ENG. J. OF MED. 705 (2022).

[273] Zettler & Sarpatwari, *supra* note 2722.

[274] *Id.* FDA currently defers to the Department of Justice on matters of preemption over state law regarding mifepristone. *Questions and Answers*, *supra* note 28.

[275] *Id.*

[276] Marimow et al., *supra* note 77. See also *infra* text accompanying notes 326–29, for an example of a current lawsuit utilizing preemption theory.

[277] Marimow et al., *supra* note 77; Belluck, *supra* note 52.

[278] Following the decision, Massachusetts withdrew the regulation, so the case was not appealed and is merely persuasive, not binding. The then-FDA Commissioner warned that a ruling against FDA would set dangerous precedent, allowing other states to ban vital medications, such as birth control or abortion medication. *Id.*

[279] *Id.* This is why many hoped the GenBioPro case would address the question of whether FDA regulation preempts state restrictions, with regards to mifepristone. Lopez, *supra* note 78; *see supra* Section I.B.

[280] *See* Marimow et al., *supra* note 77 (postulating that in such circumstance, states could ban FDA-approved vaccines or implement a state-mandated religion).

[281] *See id.* (suggesting that a decision against FDA on preemption will open door for states to make their own choices in medication approval).

consequently, increase access to abortion.[282] Given that first trimester abortion treatment, the window in which medication abortion takes place, is supported by 60% of Americans, there is a policy rationale supporting a less-restrictive REMS.[283] Such modification could decrease "reliance on the less popular second trimester abortion."[284] Accordingly, this action would realign FDA treatment of mifepristone with its own statutory requirements and bring abortion access back in line with the current view of the American people.[285] While the ultimate goal is removal or extreme modification of the REMS to make the restrictions on mifepristone match the minimal risks of medication abortion, given the emerging legal battle, a prevailing FDA preemption theory is still a considerable win for abortion access.[286]

2. The Emerging Legal Battle Demonstrates that Abortion Medication Access is Under Attack and Lacks Permanency

Ultimately, lasting, expansive access to medication abortion requires agency action bolstered by both federal *and* state law. The fight for abortion access, in large part abortion medication access, is beginning to play out in the judiciary.[287] For example, at the state level, a state court judge in Ohio blocked the jurisdiction's six week abortion ban temporarily after determining that the ban violates the equal protection right from the Ohio state constitution.[288] The county court granted the preliminary injunction, in part, because the ban caused health care detriments, such as a young girl attempting self-managed abortion or a cancer patient forsaking chemotherapy because she was eight weeks pregnant.[289] The court determined this qualifies as discrimination against pregnant women and creates a burden on their health care.[290] This suit in particular provides some hope for the future that if abortion access is seen as a women's health care issue, state constitutions can potentially serve as shields for abortion access and consequently, increase medication abortion access.[291] More recently, in November 2022, a county district court in Kansas struck down a state ban on prescribing medication abortion through

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[282] Donley, *supra* note 23, at 686–87.

[283] *Id.* at 687–88; *see also* Hannah Hartig, *By More Than Two-to-One, Americans Say Medication Abortion Should be Legal in Their State*, PEW RSCH. CTR. (Apr. 11, 2023), https://www.pewresearch.org/short-reads/2023/04/11/by-more-than-two-to-one-americans-say-medication-abortion-should-be-legal-in-their-state/ (relaying that 53% of Americans believe abortion medication "should be legal in their state," compared to only 22% believing medication abortion should be illegal).

[284] Donley, *supra* note 23, at 687.

[285] *See id.* at 684–88 (discussing proper REMS provisions and American perspective on abortion).

[286] The initial thesis and proposed solution of this Article suggested a much stronger call to action. However, as the state-level response to *Dobbs* played out and the hypothesized attack on medication abortion came to fruition, the necessary solution shifted from not just improving medication abortion access, but to *protecting* current access, too.

[287] *See infra* Section II.D.2.

[288] Kate Zernike, *Ohio Judge Temporarily Suspends Abortion Ban*, N.Y. TIMES (Sept. 14, 2022), https://www.nytimes.com/2022/09/14/us/ohio-abortion-ban-suspended.html. This lawsuit is of particular consequence for medication abortion access, as mifepristone can get prescribed for four additional weeks without the ban. *See supra* text accompanying note 22.

[289] Zernike, *supra* note 288.

[290] *Id.*

[291] *Id.*

telehealth services.[292] The decision allows Kansas abortion clinics to legally ship abortion mediation and expand services to rural, underserved areas throughout the state.[293] Notably, in August 2022, Kansas voted to protect a right to an abortion in the state constitution.[294]

However, not all upcoming litigation is as promising or reassuring. Also in November 2022, anti-abortion activists filed a lawsuit in federal court in Texas to revoke FDA approval of mifepristone.[295] The lawsuit alleges that FDA's "fast-track" approval of mifepristone was unlawful, as accelerated approval is only for drugs that treat life threatening illnesses, which pregnancy is not.[296] Plaintiffs also argue to overturn FDA's 2021 decision to allow dispensing of mifepristone by mail.[297] The government argues that any ruling in favor of plaintiffs would greatly harm public health, particularly women's health, as well as undermine the American pharmaceutical drug infrastructure.[298] Further, the government alleges that the six year statute of limitations on bringing such a claim expired, so the claim is time barred.[299] On April 7, 2023, the district court issued a ruling that revoked FDA approval of mifepristone.[300] After a swift appeal, the Court of Appeals for the Fifth Circuit upheld FDA's original approval of the drug, but maintained the rest of the lower court ruling, effectively setting the REMS back to the 2016 version, including prohibiting mail prescription of the pill.[301]

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[292] Rose Conlon, *Judge Blocks Kansas Law That Banned Prescribing Abortion Pills Over Telemedicine*, HIGH PLAINS PUB. RADIO (Nov. 29, 2022, 8:46 AM), https://www.hppr.org/hppr-news/2022-11-29/judge-blocks-kansas-law-that-banned-prescribing-abortion-pills-over-telemedicine; *see also Kansas Telemedicine Ban Blocked, Allowing Expansion of Medication Abortion Services*, CTR. FOR REPROD. RTS. (Nov. 29, 2022), https://reproductiverights.org/kansas-telemedicine-ban-medication-abortion// [hereinafter *Kansas Telemedicine Ban*] (explaining that lower court originally refused to enjoin Kansas ban, but the Kansas Court of Appeals reversed and remanded case after finding no justification for ban, because it delayed care and made medication abortion less accessible, harming patients).

[293] Conlon, *supra* note 292 (noting that medication abortion makes up more than two-thirds of abortions in Kansas).

[294] *Kansas Telemedicine Ban*, *supra* note 292.

[295] Madlin Mekelburg, *Lawsuit Filed Against FDA to Block Access to Abortion Pill*, BLOOMBERG (Nov. 18, 2022, 12:42 PM), https://www.bloomberg.com/news/articles/2022-11-18/lawsuit-filed-against-fda-to-block-access-to-abortion-pill; Susan Rinkunas, *Activists Are Trying to Ban Abortion Pills in Blue States, Forcing Patients to Face Protesters*, YAHOO! (Dec. 12, 2022), https://www.yahoo.com/now/activists-trying-ban-abortion-pills-215500501.html.

[296] Nathaniel Weixel, *Advocates Warily Eye Legal Challenge to Abortion Pills*, THE HILL (Dec. 3, 2022, 4:00pm), https://thehill.com/policy/healthcare/3760312-advocates-warily-eye-legal-challenge-to-abortion-pills/. This contention is refuted by the 2008 Government Accountability Office report, supporting FDA's determination that an unwanted pregnancy qualifies as a "serious condition" and that compared to surgical abortion, mifepristone provides "meaningful therapeutic benefit." Castronuovo, *supra* note 33; *see generally* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 31. Further, classifying the approval as accelerated is an improper designation, given the Subpart H approval pathway used for mifepristone. *See supra* notes 31–35, 155 and accompanying text.

[297] *Id.*

[298] Kimball, *supra* note 195.

[299] *Id.*

[300] Mark Sherman, *Supreme Court Preserves Access to Abortion Pill for Now*, AP NEWS (Apr. 21, 2023), https://apnews.com/article/supreme-court-abortion-pill-mifepristone-access-f781488016640bf571faf36096339ea4.

[301] *Id.*

Following the Fifth Circuit decision in the Texas lawsuit[302] and a case arising out of the Eastern District of Washington on the same day with a conflicting holding,[303] the fight for abortion medication is on a collision course to the Supreme Court. After the Fifth Circuit decision, the Supreme Court determined that mifepristone access should remain as the appeals play out.[304] While the Supreme Court waits for further appeal, the states are taking matters into their own hands, with some jurisdictions purchasing state supplies of mifepristone in anticipation of the worst outcome.[305]

Another emerging legal argument, intended to curtail access to abortion medication, relies on the Comstock Act of 1873.[306] The Act, intended to prohibit sending obscene materials through the mail, was previously enforced broadly against reproductive health-related matters.[307] Some anti-abortion activists argue that the Comstock Act, since never repealed, is still good law, so shipping any abortion medication or abortion-related product across state lines violates the Act.[308] Current Comstock Act advocates also take the leap of claiming that the Act preempts "any state laws to protect abortion rights."[309] The DOJ seemingly responded to such claims by issuing a Memorandum Opinion for the United States Postal Service, General Counsel.[310] The Opinion states that "Section 1461 of title 18 of the U.S. Code does not prohibit" mailing certain drugs used to perform abortion, when "the sender lacks the intent that the recipient of the drugs will use them unlawfully," specifically when mailing, or delivering by mail, mifepristone or misoprostol.[311] The guidance also specifies that entities sending or delivering abortion pills typically lack the complete knowledge of how a recipient intends to use the drug, including unlawful use.[312]

Anti-abortion groups are using other approaches to directly attack abortion medication access. For example, the Students for Life organization filed a citizen

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[302] *See supra* text accompanying notes 297–303; Abbie VanSickle, *Supreme Court Ensures, for Now, Broad Access to Abortion Pill*, N.Y. TIMES (Apr. 21, 2023), https://www.nytimes.com/2023/04/21/us/politics/supreme-court-abortion-pill-access.html.

[303] In Washington, a group of states sued FDA for *limiting* access to mifepristone. Judge Rice issued an opinion precluding FDA from imposing any further limitations on access to abortion medication in those jurisdictions. This created great conflict, as Judge Kacsmaryk in Texas ruled that FDA approval of mifepristone was invalid. Both judges are federal district court judges. VanSickle, *supra* note 302.

[304] *Id.*

[305] Ava Sasani, *The Decision Brought Vows to Keep Fighting From Both Sides of the Abortion Debate*, N.Y. TIMES (Apr. 21, 2023), https://www.nytimes.com/2023/04/21/us/abortion-pill-supreme-court-reactions.html.

[306] Rinkunas, *supra* note 295; Sherman, *supra* note 33.

[307] *Id.*

[308] *Id.* There is also a potential First Amendment argument, as the Comstock Act arguably can curtail discussion of abortion or abortion medication, too. Rinkunas, *supra* note 295.

[309] Sherman, *supra* note 33.

[310] Mem. Op., *supra* note 271.

[311] *Id.* ("Over the course of the last century, the Judiciary, Congress, and USPS have all settled upon an understanding of the reach of section 1461 and the related provisions of the Comstock Act that is narrower than a literal reading might suggest. This construction occurred long before the Supreme Court's decisions in *Griswold v. Connecticut*, 381 U.S. 479 (1965), and *Roe* and thus was not dependent upon the Court's recognition of constitutional rights regarding the prevention or termination of pregnancy.").

[312] *Id.*

petition to FDA asking for the agency to require abortion medication prescribers to accept responsibility for fetal tissue disposal, citing environmental impact as the reason behind the suggested policy reform.[313] In Texas, officials assigned a team to investigate potential incidents of illegal abortion medication distribution.[314] Further, given the difficulty of prosecuting medication abortion through the virtual clinic process, anti-abortion advocates are hopeful that new legislation will create easier routes to prosecute and prohibit mifepristone use.[315] These advances against abortion medication demonstrate both the importance of allowing advance provision of the drug in uncertain times and how the fight against abortion access is shifting to the medication landscape.[316]

The anti-abortion movement is not the only group utilizing the legal system to try to change medication abortion access. Within the first few weeks of 2023, two noteworthy lawsuits attempting to increase medication abortion access were filed.[317] First, in West Virginia, GenBioPro filed a lawsuit challenging the state ban on medication abortion as unconstitutional, alleging preemption theory precludes such restrictive state legislation.[318] GenBioPro alleged that the ban on an FDA-approved drug overreaches state authority, conflicting with the Supremacy Clause and the Commerce Clause.[319] Second, in North Carolina, a practicing obstetrician-gynecologist brought suit and cited similar claims, arguing against North Carolina's restrictions on mifepristone, including mandatory in-person dispersion, mandatory counseling, and a seventy-two hour waiting period, as FDA deems these restrictions unnecessary for patient safety.[320] Both of these lawsuits rely on preemption theory, alleging that the respective states are only allowed to supplement FDA regulations, but "cannot ban or drastically restrict" a federally approved medication, with regulatorily balanced restrictions.[321] Similar to the lawsuit in Texas, if these courts rule with the state government, states across the country may use the decision as an opportunity to ban or restrict other FDA-approved drugs, like the COVID-19 vaccine or morning after pills.[322] Given the sweeping and severe implications of the pending

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313 Environmental experts dismiss the claim from Students for Life, as there is no direct evidence that medication abortion causes contamination in the water supply. Fernando, *supra* note 79; Kitchener, *supra* note 63.

314 *Id.*

315 Activists are optimistic about such legislation without the restrictions of *Roe* and *Casey*. *See id.* ("National advocacy groups are also pivoting to focus on enforcement. Early in the new year, Dannenfelser of Susan B. Anthony Pro-Life America said she plans to strategize with antiabortion governors about how best to deal with the illegal pill networks.").

316 *E.g.*, Cerullo, *supra* note 261 (describing advance provision process); Belluck, *supra* note 52 (explaining how states are increasingly targeting medication abortion).

317 *Id.*

318 *Id.*

319 GenBioPro, one of two mifepristone manufacturers, has an interest in the case as its medical sales have dropped to nil in states with abortion bans or unclear laws. *Id.*; Complaint at 1, GenBioPro, Inc. v. Sorsaia (S.D.W.V. Jan. 25, 2023) (No. 23–11111).

320 Belluck, *supra* note 52; Complaint at 1–5, Bryant v. Stein, (M.D.N.C. Jan. 25, 2023) (No. 23–77) (alleging state requirements place unnecessary costs on doctor and her practice and interfere with her ability to provide medical care aligned with best medical judgment and federal law).

321 Belluck, *supra* note 52.

322 *Id.*

litigation over abortion medication, putting federal resources and time into defending medication abortion access is imperative to keeping the "last woman standing."

III. CONCLUSION

Legal scholars share concern that the Supreme Court's emboldened conservative bloc will ultimately rule against FDA and eliminate or further reduce access to mifepristone when the aforementioned cases reach the highest court.[323] Following the core reasoning of *Dobbs*, such a decision would seem to align with the theme of returning the issue of abortion to "the people."[324] This would greatly undermine FDA's authority and potentially open the door for greater resistance to federal health law policy in other areas (such as vaccination requirements).[325] Additionally, the potential ruling could prompt states to take a cannabis-style approach to approve abortion medication, authorizing mifepristone usage on a state-by-state basis, despite a lack of federal approval.[326] Perhaps the Court will be dissuaded from overruling FDA's approval in fear of "*Lochnerizing*,"[327] but, at this time, it is unclear.

Although abortion medication is currently the best protector of abortion access in the United States, mifepristone is stifled from reaching its full potential. One barrier to achieving greater abortion medication access is the varying, individual state regulations that create disparate care across the country and uncertainty about the legality and penalty of engaging in certain medication abortion services.[328] Additionally, the unjustified, biased FDA REMS on mifepristone further isolates and diminishes abortion medication access and lacks alignment with other drug regulations.[329] These barriers to access create negative health implications for those denied abortion medication, with a greater impact on low-income women and women of color.[330] To improve and protect access to mifepristone, the federal government should invest into greater telehealth services and virtual abortion clinics, promote a theory of federal preemption to enforce a national standard of access, and modify, alter, or eliminate the REMS on mifepristone to better align with the safety profile of abortion medication and make the restrictions on abortion medication match the risks.[331] The government and activists must also allocate energy, time, and

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[323] Weixel, *supra* note 296. It is worth noting that the Alliance Defending Freedom, suing FDA in the federal district court in Texas, also played a role in *Dobbs* and is connected to Supreme Court Justice Amy Coney Barrett. *Id.*

[324] Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2243, 2277 (2022); *see also id.* at 2305 (Kavanaugh, J., concurring) ("On the question of abortion, the Constitution is therefore neither pro-life nor pro-choice. The Constitution is neutral and leaves the issue for the people and their elected representatives to resolve through the democratic process in the States or Congress . . . .").

[325] Weixel, *supra* note 296.

[326] *See* Rinkunas, *supra* note 295 (describing how a ruling against preemption could outlaw mifepristone in entire country); *see also* text accompanying notes 199, 214–18 (explaining how cannabis is approved by individual states, despite lacking FDA authorization).

[327] Cass R. Sunstein, *Lochner's Legacy*, 87 COLUM. L. REV. 873, 874 (1987) ("*Lochner* was wrong because it involved 'judicial activism': an illegitimate intrusion by the courts into a realm properly reserved to the political branches of government.").

[328] *See supra* Section II.A.

[329] *See supra* Section II.B.

[330] *See supra* Section II.C.

[331] *See supra* Section II.D.1.

resources to fight pending and emerging legal battles surrounding abortion medication to maintain the last true safeguard of national abortion access.[332]

[332] *See supra* Section II.D.2.