COMMENT

NO LONGER VIABLE: THE PUSH FOR THE FDA'S REMOVAL OF MIFEPRISTONE FROM THE REMS PROGRAM UNDER *DOBBS*

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INTRODUCTION

On September 28, 2000, the landscape of reproductive rights and abortion access was forever altered by the Food and Drug Administration's (FDA's) approval of mifepristone (RU-486) for use as an abortifacient.[1] Two months after FDA approved mifepristone, it became available to the general public under the brand name Mifeprex.[2] French researchers created the drug, and France was the first country to approve it; China, the United Kingdom, Sweden, and a dozen European countries followed—all before the United States.[3]

Mifepristone spurred controversy in the United States, as it had around the world, even before the first dose became available.[4] Protestors and extremists around the world, particularly those affiliated with certain political and religious groups, vehemently opposed the drug, believing it posed serious threats to human health and personal values. These threats were so severe that one of the drug's early shareholders pulled it from the market after already approving its supply to several countries.[5] The creator of the drug, Émile Baulieu, described its early introduction to the United States as "arriv[ing] like a splash of gasoline on a blazing fire."[6] In addition to mifepristone being a designated banned substance, both Presidents Reagan and H.W. Bush prohibited research into the drug.[7] Although politicians and anti-abortion activists objected to its approval, FDA finally approved the use of mifepristone in the United States, where Baulieu claimed the drug's "eventual destiny would be shaped" due to the country's invention of "oral contraception" and "high

1. *See* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 571–73, 603 (2001) (explaining the history and official approval of mifepristone in the United States); *Abortifacient*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/abortifacient (last visited Feb. 7, 2023) (defining "abortifacient" as "an agent (such as a drug) that induces abortion").

2. *See* Noah, *supra* note 1, at 571–72.

3. *Id.* at 574–76.

4. *See* Lauren Collins, *The Complicated Life of the Abortion Pill*, NEW YORKER, (July 5, 2022), https://www.newyorker.com/science/annals-of-medicine/emile-baulieu-the-complicated-life-of-the-abortion-pill.

5. *Id.* (explaining that Roussel-Uclaf, the French company that developed mifepristone, was heavily influenced to pull the drug from the market by the Catholic Church's opposition and threats of a boycott).

6. *Id.* (outlining attempts by opponents of mifepristone to thwart its approval and research in the United States).

7. *Id.* The President Reagan and President H.W. Bush-era bans were accompanied by other pro-life sentiments in the United States aimed at prohibiting the development and distribution of abortion medication. *Id.*

rates of [teenage] pregnancy."[8] While the drug's safety and scientific efficacy have become far more clear, much of the controversy, charged feelings, and unsupported claims regarding its safety and morality remain.[9]

Mifepristone is combined with another drug, misoprostol, in a two-step regimen to initiate the process of a "medication abortion."[10] First, a patient must ingest mifepristone, a 200-milligram tablet that "blocks the body's receptors for the hormone necessary to sustain pregnancy," causing "the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall."[11] Next, twenty-four to forty-eight hours after taking mifepristone, the patient must orally take the second drug, misoprostol.[12] Misoprostol induces "uterine contractions that expel the contents of the uterus."[13] During this process, patients typically experience cramping and bleeding between two and twenty-four hours after taking misoprostol, which denotes that the pregnancy is terminating.[14]

As medication abortion has become increasingly safe and common, the restrictions on mifepristone, the primary drug used to administer medication abortions, have barely loosened over the last twenty years.[15] Although research shows that mifepristone (colloquially known as "the abortion pill," along with its companion drug misoprostol) is safe, the drug remains heavily regulated by FDA under the Risk Evaluation and Mitigation Strategies (REMS) program.[16] This limits access to healthcare

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8. *Id.* (highlighting how oral abortion medication serves as a transformative medical treatment for many in the United States who seek a safe and less physically traumatic pregnancy termination).

9. *See* Joshua Cohen, *Politicizing Safety of the Abortion Pill Mifeprex*, FORBES (Sept. 6, 2020, 2:40 PM), https://www.forbes.com/sites/joshuacohen/2020/09/06/politicizing-safety-of-the-abortion-pill-mifeprex/?sh=28ea73a944c5 (illustrating attempts to spread misinformation despite the proven safety and effectiveness of medication abortion).

10. *See* Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 189–90 (D. Md. 2020) (discussing the steps individuals take to administer a medication-induced abortion). A medication abortion differs from other types of abortion in that it terminates a pregnancy without physical intervention. *See also* Collins, *supra* note 4 (noting that medication-induced abortions are less physically traumatic and less risky to health).

11. *See Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 190.

12. *Id.*

13. *Id.*

14. *Id.*

15. *See generally The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (Jan. 4, 2023), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ (explaining how state restrictions and requirements have historically impeded access to medication abortions).

16. *See* Scripps News, *Prescription Denied: Accessing the Abortion Pill*, YOUTUBE, at 5:30–6:47 (July 9, 2020), https://www.youtube.com/watch?v=wDwQIW56uwo; *see also* discussion *infra* Part I.

for many pregnant individuals across the country, often forcing them to obtain less safe and reliable care, or no care at all.[17]

While medical professionals, health advocates, and legal scholars have been pushing for years to remove mifepristone from the REMS program,[18] the complexity of accessing the drug and the severity of possible consequences became ever-present in June 2022 when the Supreme Court struck down the constitutional right to an abortion.[19] This decision imperiled the autonomy of several million people with the capacity for pregnancy in terms of making their own healthcare decisions.[20] The ability to access safe and effective abortion is life determining for some pregnant individuals, as many people live in states with "maternity care deserts," which lack hospitals that offer obstetric care, birth centers, and obstetric providers.[21] Specifically, research from the Journal of the American Medical Association "shows that bans and

17. *Abortion*, WORLD HEALTH ORGANIZATION [WHO] (2021), https://www.who.int/news-room/fact-sheets/detail/abortion (emphasizing that the lack of access to safe, timely, affordable, and respectful abortion care is a critical public health and human rights issue).

18. *See* Letter from Michael L. Munger, Board Chair, Am. Acad. of Fam. Physicians (AAFP), to Norman Sharpless, Acting Comm'r, U.S. Food & Drug Admin. (June 20, 2019) [hereinafter AAFP Letter] https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf; Petition from Am. Coll. of Obstetricians & Gynecologists (ACOG) et. al to Lauren Roth, Assoc. Comm'r for Policy, U.S. Food & Drug Admin. (Oct. 4, 2022) [hereinafter ACOG Petition], https://reproductiverights.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22.pdf.

19. *See* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2240–43, 2252–53, 2261, 2265–66, 2279, 2284 (2022) (explaining that states historically determined their own laws and regulations regarding abortions independently, and holding that *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), were uncalled-for judicial usurpations of state legislative authority); *see also* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 979 (1992) (Scalia, J., dissenting) ("The States may, if they wish, permit abortion on demand, but the Constitution does not *require* them to do so."); Thornburgh v. Am. Coll. of Obstetricians & Gynecologists, 476 U.S. 747, 787 (1986) (White, J., dissenting) ("[D]ecisions that find in the Constitution principles or values that cannot fairly be read into that document usurp the people's authority . . . ."); Doe v. Bolton, 410 U.S. 179, 221–22 (1973) (White, J., dissenting) ("I find nothing in the language or history of the Constitution to support the Court's judgment.").

20. *See* Oriana Gonzalez, *Health Experts See Rise in Maternal Mortality Post-Roe*, AXIOS, (July 5, 2022), https://www.axios.com/2022/07/05/maternal-mortality-death-abortion-ban-roe; *see also State Legislation Tracker*, GUTTMACHER INST. https://www.guttmacher.org/state-policy (last visited Feb. 7, 2023) (presenting abortion availability data on a state-by-state basis).

21. *See* Gonzalez, *supra* note 20 (demonstrating how "trigger laws" and abortion bans can result in insufficient care, which could lead to higher maternal mortality rates in the United States).

restrictions are decreasing access" particularly for "those living in the South," as well as "those who are poor, Black, or Native American."[22]

Mifepristone continues to be a lifeline for Americans—one that is arguably more vital now than ever—but constant legal threats and battles in the post-*Roe* world makes its place in the U.S. healthcare system uncertain.[23] This is the first time in history that mifepristone exists without the corresponding protections provided by *Roe v. Wade*.[24] FDA's mission is "protecting the public health by ensuring the safety, efficacy, and security of . . . drugs, biological products, and medical devices" and "advancing the public health" by expediting the innovation of effective, safe, and affordable medical products, and by providing the public with accurate information grounded in science.[25] FDA is thus obligated to reconsider the REMS restrictions on mifepristone.

The scientific evidence indicates that mifepristone is highly effective and low-risk, and, therefore, FDA can create a safer, more effective reproductive healthcare system by removing mifepristone from the REMS program.[26] FDA can modify or remove REMS regulations in two ways.[27] First, FDA can update REMS regulations in response to a petition with an "adequate rationale" from a party who holds an approved application for a medication subject to REMS.[28] Second, FDA can update REMS regulations on its own, subject to regulatory requirements.[29] Although the government removed regulations requiring in-person visits to obtain mifepristone during the COVID-19 pandemic, many states are looking to further roll back access to the medication.[30] Leading scientific experts and organizations agree that the

22. Aatish Bhatia, Claire Cain Miller & Margot Sanger-Katz, *A Surge of Overseas Abortion Pills Blunted the Effects of State Abortion Bans*, N.Y. TIMES (Nov. 1, 2022), https://www.nytimes.com/2022/11/01/upshot/abortion-pills-mail-overseas.html.

23. *See id.* (discussing how some individuals may require follow-up care after using mifepristone or misoprostol, and how people managing their own abortions can be legally liable, which may increase as abortion accessibility is further restricted within certain states post-*Roe*).

24. 410 U.S. 113 (1973); *see also* Noah, *supra* note 1, at 571 (stating that mifepristone (RU-486) was approved in 2000 and that the drug was created after the *Roe v. Wade* decision in 1973).

25. *What We Do: FDA Mission*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/what-we-do#mission (Mar. 18, 2018).

26. *See* AAFP Letter, *supra* note 18 (noting that since 2000 over three million women have used mifepristone and misoprostol, and the drug is more than ninety-seven percent effective, with less than one percent of users experiencing complications).

27. Julie Dohm & Mingham Ji, *An Introduction to Risk Evaluation and Mitigation Strategies*, 104 CONTRACEPTION 4, 5 (2021), https://doi.org/10.1016/j.contraception.2021.04.018.

28. *Id.*

29. *Id.*

30. Jane Marcellus, *Tennessee Republicans Turn to Mail Regulation to Restrict Abortion*, WASH.

current REMS program classification of mifepristone is too restrictive and unnecessary, but FDA has yet to alter its course.[31]

This Comment addresses why and how FDA so severely regulates mifepristone through REMS, what its regulation means for the future of reproductive healthcare access, and why removing the drug from the REMS program will benefit the overall health of the American people. Part I explains the history and scope of the authority of FDA's REMS programs, including what the REMS restrictions entail, how FDA can modify or eliminate these restrictions, and examples of drugs that have adhered to these restrictions and since been released from them.[32] Part II discusses the scientific research on mifepristone, which demonstrates why FDA can and should remove the drug from the REMS program.[33] Part III analyzes the effect of the Court's recent overturning of *Roe v. Wade* in *Dobbs v. Jackson Women's Health Organization*[34] on mifepristone distribution and why this makes the drug's removal from the REMS program even more urgent.[35] Part IV recommends that FDA remove mifepristone from the REMS program because scientific evidence demonstrates the drug is safe and beneficial to the health of people with the capacity for pregnancy. Additionally, Part IV recommends that FDA more closely consider the opinions of medical groups and experts when developing its regulations and practices, particularly in instances that impact reproductive care.[36]

POST (May 25, 2022, 6:00 AM), https://www.washingtonpost.com/outlook/2022/05/25/tennessee-republicans-turn-mail-regulation-restrict-abortion/ (discussing a Tennessee law that would restrict medication abortion through mail regulation).

31. *See* AAFP Letter, *supra* note 18 (indicating that in 2019, AAFP, a medical association representing over 134 thousand family physicians and medical students across the country, recommended that FDA remove mifepristone from REMS drug regulations); *see also* ACOG Petition, *supra* note 18, at 19–20 (indicating that nearly fifty additional associations, including the American College of Obstetricians and Gynecologists and the Association of Women's Health, Obstetric and Neonatal Nurses, also support the removal or modification of mifepristone's REMS drug regulations in 2022).

32. *Infra* Part I.

33. *See* discussion *infra* Part II.

34. *See* Dobbs v. Jackson Women's Health Org., 142 S. Ct 2228, 2284–85 (2022) (overturning *Roe v. Wade*, 410 U.S. 113 (1973), and holding that the Constitution does not prohibit states from "regulating or prohibiting abortion").

35. *See* discussion *infra* Part III.

36. *See* discussion *infra* Part IV.

I. THE REMS PROGRAM: ITS LIMITATIONS AND RESTRICTIONS

A. The History of Mifepristone and Its Context Within the REMS Program

Mifepristone is regulated under FDA's REMS program, reserved "for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks."[37] REMS applies to a very limited set of medications: currently only sixty medications that are regulated under the REMS program.[38] REMS focuses on "preventing, monitoring, and/or managing a specific serious risk by informing, educating, and/or reinforcing actions to reduce the frequency and/or severity of the event."[39] Although the program intends to reduce harm, REMS is "not designed to mitigate all the adverse [effects] of a medication."[40] However, all foreseeable adverse effects are included in the medication's prescribing information, which is communicated to healthcare providers so that they are aware of all possible effects.[41]

In categorizing mifepristone under the REMS program, FDA has three main goals: a specific certification in the Mifepristone REMS Program for prescribing healthcare providers; distribution of the medication in settings supervised by a certified prescriber; and patient education regarding the risks and potential complications of mifepristone.[42]

While a review of scientific evidence has proved that medication is a safe and effective way to end an early pregnancy—with a safety record of over ninety-nine percent[43]—FDA has barely altered the regulations affecting mifepristone.[44] Although twenty years of information and studies demonstrate that mifepristone is not as high-risk as it was once thought to be

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37. *Risk Evaluation and Mitigation Strategies*, U.S. FOOD & DRUG ADMIN. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (Dec. 17, 2021) (providing FDA's reasoning for imposing REMS restrictions on certain drugs).

38. *Id.* (showing that REMS programs are only necessary for only a small number of drugs including mifepristone, antipsychotic drugs, leukemia treatments, and immunosuppressant medications).

39. *See id.*

40. *Id.*

41. *Id.* (explaining that health risks are possible even when following REMS guidelines).

42. *See id.*

43. PLANNED PARENTHOOD, THE FACTS ON MIFEPRISTONE 1 (2019) [hereinafter FACTS ON MIFEPRISTONE], https://www.plannedparenthood.org/uploads/filer_public/42/8a/428ab2ad-3798-4e3d-8a9f-213203f0af65/191011-the-facts-on-mifepristone-d01.pdf.

44. *See* Rachel Rebouché, David S. Cohen & Greer Donley, *The Coming Legal Battles Over Abortion Pills*, POLITICO (May 24, 2022, 2:45 PM), https://www.politico.com/news/magazine/2022/05/24/coming-legal-battles-abortion-pills-00034558 (outlining the objectives of FDA's REMS programs).

in the United States, little has changed regarding the original restrictions placed on mifepristone.[45] In fact, FDA has been criticized for a "history of bias and political involvement in reproductive health decisions . . . ."[46] There has been inconsistent FDA action surrounding the use of mifepristone, and more generally, in the regulation of reproductive rights overall.[47] FDA deviates from its own standards without clearly explaining specific exceptions to the general rule, like classifying mifepristone under REMS.[48] Legal scholar and professor Greer Donley note that there is "a strong case to be made . . . that the agency acted arbitrarily and capriciously" in including mifepristone under the narrow umbrella of REMS drugs.[49]

Today, approximately one in four abortions that take place in the United States are medication abortions.[50] More than three million individuals have used mifepristone since FDA approved it and it has been proven to be safer than childbirth.[51] Currently, "FDA has approved [mifepristone] for use only within the first ten weeks of pregnancy."[52] Because abortion pills are often obtained through online pharmacies or international providers, they can sometimes take weeks to arrive.[53]

Much of the early backlash toward mifepristone was not only due to concerns about health risks, but also clouded by a mix of complicated business and political issues that seeped into the drug's approval process throughout the 1980s

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45. *See* Claudia Wallis, *Abortion Pills Are Very Safe and Effective, Yet Government Rules Still Hinder Access*, SCI. AM. (Mar. 1, 2022), https://www.scientificamerican.com/article/abortion-pills-are-very-safe-and-effective-yet-government-rules-still-hinder-access/ (highlighting the dissonance between the available scientific and safety information about mifepristone and the lack of action taken to make the drug more accessible).

46. Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 685 (2022) (highlighting the advantages of abortion alternatives that improve the safety of patients).

47. *Id.*

48. *Id.*

49. *Id.*

50. *A Call to End the Excessive Regulation of Mifepristone*, BIXBY CTR. FOR GLOB. REPROD. HEALTH, https://bixbycenter.ucsf.edu/news/call-end-excessive-regulation-mifepristone (last visited Feb. 7, 2023) (showing that medication abortions are common).

51. *See id.* (noting the widespread use of mifepristone in the United States and its proven safety).

52. *See* Collins, *supra* note 4. In January 2023, FDA finalized a rule change granting certified retail pharmacies the authority to offer abortion pills, where permitted by law. *See Information about 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/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (Jan. 24, 2023).

53. *See* Collins, *supra* note 4 (highlighting the inaccessibility and long wait times for abortion pills by mail).

and 1990s.[54] Like the initial resistance toward the approval of the drug, many groups and individuals are either skeptical or deeply opposed to the removal of mifepristone from the REMS program.[55] This opposition is due, in part, to concern about reproductive health and safety, but also fueled by political and personal beliefs and control of the medical market.[56]

Like all drugs, mifepristone does come with potential risks and a wide range of possible reactions.[57] Severe reactions could include anaphylactic reactions and toxic epidermal necrolysis, while more moderate reactions could include hypertension, dyspnea, constipation, hot flashes, anemia, and vaginal bleeding.[58] Milder side effects could include headache, diarrhea, dizziness, insomnia, and

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54. *Brief History of the Abortion Pill in the U.S.*, WEBMD (Sept. 28, 2000), https://www.webmd.com/women/news/20000928/brief-history-of-abortion-pill-in-us (discussing how business and political issues intertwine with healthcare issues regarding mifepristone); *see also* R. Alta Charo, *A Political History of RU-486*, *in* BIOMEDICAL POLITICS, 43, 43 (Kathi E. Hanna ed., 1991) (noting issues related to the drug's approval process).

55. *See Brief History of the Abortion Pill*, *supra* note 54. *See also* David C Reardon, Donna J. Harrison, Ingrid Skop, Maka Tsulukidze, Christina A. Cirucci & James Studnicki, *Overlooked Dangers of Mifepristone, the FDA's Reduced REMS, and Self-Managed Abortion Policies: Unwanted Abortions, Unnecessary Abortions, Unsafe Abortions*, CHARLOTTE LOZIER INST. (Dec. 16, 2021) https://lozierinstitute.org/overlooked-dangers-of-mifepristone-the-fdas-reduced-rems-and-self-managed-abortion-policies-unwanted-abortions-unnecessary-abortions-unsafe-abortions/ (discussing why some think it is harmful to remove mifepristone from the REMS program).

56. *Brief History of the Abortion Pill*, *supra* note 54. *See also* Ahmed Aboulenein, *Analysis: Abortion Pills over the Counter? Experts See Big Hurdles in Widening U.S. Access*, REUTERS (June 24, 2022, 6:17 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/abortion-pills-over-counter-experts-see-major-hurdles-widening-us-access-2022-06-23/ (highlighting the competing beliefs about the safety medication abortions).

57. Blake M. Autry & Roopma Wadhwa, *Mifepristone*, NAT'L LIBR. OF MED., https://www.ncbi.nlm.nih.gov/books/NBK557612/ (May 8, 2022) (stating the process of administering mifepristone and the potential side effects of the drug).

58. *Id.* Dsypnea is a tight feeling in your chest where you may not be able to take a deep breath and is also referred to as "shortness of breath." *Dyspnea*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/symptoms/16942-shortness-of-breath-dyspnea (last visited Feb. 7, 2023). Anemia "occurs when there are not enough healthy red blood cells to carry oxygen to your body's organs. As a result, it's common to feel cold and symptoms of tiredness or weakness." *Anemia*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/diseases/3929-anemia (last visited Feb. 7, 2023). Anaphylaxis is a "potentially life-threatening allergic reaction" which, "causes the immune system to release a flood of chemicals that can cause you to go into shock." *Anaphylaxis*, MAYO CLINIC (Oct. 2, 2021), https://www.mayoclinic.org/diseases-conditions/anaphylaxis/symptoms-causes/syc-20351468. Toxic epidermal necrolysis (TEN) is, "a rare, life-threatening skin reaction, usually caused by a medication." *TEN*, MAYO CLINIC (Aug. 9, 2020), https://www.mayoclinic.org/diseases-conditions/toxic-epidermal-necrolysis/symptoms-causes/syc-20491903.

menstrual irregularity.[59] While these adverse effects do occur, they are highly unlikely, as evidenced by the number of individuals who have successfully used the drug over the years to end a pregnancy.[60] While many drugs have the potential for serious side effects, some with particularly severe side effects are readily available over the counter and heavily advertised.[61]

B. The FDA's Authority to Regulate Mifepristone and Implement REMS Restrictions

Section 505-1 of the Federal Food, Drug, and Cosmetic Act (FDCA) establishes FDA's REMS authority.[62] The Food and Drug Administration Amendments Act of 2007 added § 505-1 to the FDCA.[63]

FDA created another division of the FDCA, which recognizes that some drugs may require "elements to assure safe use" (ETASU) as part of REMS.[64] In 2011, "FDA approved the existing mifepristone REMS with additional [ETASU], a special category of REMS."[65] FDA can impose ETASU on drugs "shown to be effective" but "associated with a serious adverse drug experience" such that the drugs can be approved only when the designated elements are satisfied.[66] ETASU may include one or any combination of six elements:

> The [ETASU] under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug, and to mitigate such risk, may require that–
>
> (A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via

59. Autry & Wadhwa, *supra* note 57.

60. FACTS ON MIFEPRISTONE, *supra* note 43, at 1.

61. *See* Julia Belluz, *Why Prescription Drug Ads Always Have That Absurd List of Side Effects at the End*, VOX (Sept. 29, 2015, 11:00 AM), https://www.vox.com/2015/9/29/9414145/direct-consumer-advertising-pharmaceutical-regulation (describing how prescription drugs are advertised and discussing why serious side effects are included in those advertisements).

62. U.S. FOOD & DRUG ADMIN., REMS: FDA'S APPLICATION OF STATUTORY FACTORS IN DETERMINING WHEN A REMS IS NECESSARY 2 (2019) [hereinafter FDA STATUTORY FACTORS], https://www.fda.gov/media/100307/download (outlining the sections of the Food and Drug Amendments Act of 2007 that give FDA the authority to create REMS).

63. *Id.*

64. *Id.* (explaining the meaning and importance of elements to assure safe use (ETASU)).

65. Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 190 (D. Md. 2020) (discussing the additional REMS restrictions imposed on mifepristone).

66. 21 U.S.C. § 355(f)(1)(A).

> mail) as approved by the Secretary at reasonable cost to the provider);
>
> (B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);
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> (C) the drug be dispensed to patients only in certain health care settings, such as hospitals;
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> (D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;
>
> (E) each patient using the drug be subject to monitoring; or
>
> (F) each patient using the drug be enrolled in a registry.[67]

"All REMS programs should include one or more overall goals; and if the REMS [includes] ETASU, the REMS must [also contain] one or more goals to mitigate a specific serious risk listed in the labeling of the drug . . . ."[68] REMS generally must also include a timetable for assessment submissions.[69] Assessments are required eighteen months after the REMS is initially approved, three years after the REMS is initially approved, and seven years after the REMS is initially approved, or at another frequency specified in the program.[70]

FDA has the authority to add, modify, or remove any goal or element of an approved REMS.[71] A person with an approved application for a REMS drug can submit an "adequate rationale" in addition to a suggested revision. Alternatively, FDA can impose a modification if they deem that an adjustment should be made to accomplish one of three things: to confirm that "the drug's benefits outweigh its risks"; to lessen healthcare providers' burden in distribution; or to update the new drug application's ETASU.[72]

In addition to altering the goals and elements of an approved REMS, FDA can also "release a REMS entirely and has done so for a number of drugs."[73] "Consistent with the statutory language for when a REMS may be required, the FDA has explained that it will release a REMS if [it] determines that the measures 'are no longer necessary to ensure a medication's benefits outweigh its

67. *Id.* § 355(f)(3).

68. *See* FDA STATUTORY FACTORS, *supra* note 62, at 3.

69. *Id.* The submission of assessments serves as a periodic check-in for the effectiveness and necessity of a REMS. *Id.*

70. *Id.*

71. *See* Dohm & Ji, *supra* note 27 (showing that it is well within FDA's authority to remove mifepristone's REMS restrictions).

72. *Id.* (explaining the second method by which FDA could modify REMS).

73. *Id.* (highlighting FDA's authority to eliminate REMS restrictions from drugs if the agency deems them no longer necessary, such as the REMS for Vivitrol, Stelara, and Testim).

risks.'"[74] For example, the REMS with ETASU for Tikosyn (dofetilide)[75] was released after determining that ETASU were no longer necessary for Tikosyn and that solely maintaining the Medication Guide as part of the drug's approved labeling was adequate.[76] Based on the REMS assessments submitted for Tikosyn, FDA determined that "healthcare providers, including non-certified prescribers, demonstrated acceptable knowledge of the product's risks" and its safe use conditions, which could "be conveyed appropriately via the current product labeling."[77]

In 2013, FDA eliminated REMS for "rosiglitazone-containing type [two] diabetes medicines, which are approved as Avandia, Avandamet, Avandaryl, and generics."[78] FDA determined that the prescribing and dispensing regulations were no longer needed because the rosiglitazone medications "did not demonstrate an increased risk of heart attack" as opposed to "the standard type [two] diabetes medicines metformin and sulfonylurea."[79] FDA also "required the drug manufacturers to provide educational training to healthcare professionals" about the latest knowledge and updated status of the heart risks of rosiglitazone medicines.[80] The tracking and oversight of these medications continue, but FDA found that the data determined the REMS was "no longer necessary to ensure that the benefits of rosiglitazone medicines outweigh their risks" and has since sustained their removal from REMS.[81]

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74. *Id.* (quoting U.S. FOOD & DRUG ADMIN., NDA 022526/S-009, SUPPLEMENT APPROVAL FOR FLIBANSERIN (2019) https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/022526Orig1s009ltr.pdf).

75. Tikosyn is a drug used to maintain a "normal sinus rhythm (a delay in time in time to recurrence of atrial fibrillation/atrial flutter) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm." *Risk Information for Tikosyn (dofetilide)*, U.S. FOOD & DRUG ADMIN. (Mar. 09, 2016), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-tikosyn-dofetilide.

76. *Id.*

77. *See* U.S. FOOD & DRUG ADMIN., NDA 020931/S-012; S-013, SUPPLEMENT APPROVAL FOR TIKOSYN (2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/020931Orig1s012,s013ltr.pdf (showing that like Tikosyn, mifepristone could also be distributed safely with its risks listed on its label in lieu of its inclusion in the REMS program).

78. Press Release, U.S. Food & Drug Admin., FDA Drug Safety Communication: FDA Eliminates the Risk Evaluation and Mitigation Strategy (REMS) for Rosiglitazone-Containing Diabetes Medicines (Dec. 16, 2015), https://www.fda.gov/media/94871/download (providing an example of the success of eliminating certain drugs from the REMS program over the last decade).

79. *Id.*

80. *Id.*

81. *Id.* (showing the development and success of the rosiglitazone-containing type 2 diabetes medicines that led to their removal from the REMS program).

II. RECENT SCIENTIFIC RESEARCH AND DATA CREATE A DISSONANCE BETWEEN REMS REQUIREMENTS AND THE RISKS OF MIFEPRISTONE

A. The FDA's Safety Data and Restrictions on Mifepristone

Since its initial approval of mifepristone, FDA has administered strict "requirements on the drug that are not imposed on drugs with similar safety records."[82] In December 2021, FDA took a step in the right direction by removing the restriction that required patients to collect mifepristone in person at a healthcare facility.[83] Instead, FDA allowed patients to obtain mifepristone through the mail after a virtual appointment.[84] FDA stated that these changes were made to comply with required COVID-19 pandemic procedures.[85] FDA also indicated that the travel necessary to undergo these procedures "can put patients and others at risk transmission of the coronavirus."[86]

According to FDA, Mifeprex, the brand name for mifepristone, has posed no new safety concerns in the last several years, and the known risks seldom occur.[87] A National Academies of Sciences, Engineering, and Medicine report found that infection, hospitalization, or hemorrhage requiring transfusion "occur in fewer than one percent of patients."[88] Additionally, "[o]f more than 20,000 FDA-approved drugs, Mifeprex is the *only* one" that FDA permits patients to take unsupervised—but still requires them to pick

82. *See* Rebouché et al., *supra* note 44 (highlighting the incongruity between which regulations are necessary and which are actually being used for mifepristone); *see also* Donley, *supra* note 46, at 652 (demonstrating that all drugs can pose serious health risks, but most are not subjected to REMS, like Viagra and Penicillin).

83. *See* Donley, *supra* note 46, at 703 (demonstrating that FDA is capable of loosening the REMS restrictions and that it is one step closer to removing the mifepristone REMS entirely).

84. *Id.* (noting FDA made access to mifepristone safer and easier during the COVID-19 pandemic).

85. Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183, 213 (D. Md. 2020) (noting a clear reason for the change in REMS restrictions during the COVID-19 Pandemic).

86. *Id.* The REMS requirements for mifepristone are unduly burdensome on patients trying to access the drugs, especially those in medically underserved and rural areas. *See The Availability and Use of Medication Abortion*, *supra* note 15 (explaining that the REMS requirements are burdensome for patients, particularly those in rural or medically underserved areas while drugs with more complications are easily accessible); Press Release, ACLU, ACLU Challenges Federal Restrictions on Abortion Pill (Oct. 3, 2017, 2:00 PM), https://www.aclu.org/press-releases/aclu-challenges-federal-restrictions-abortion-pill (highlighting patients' hurdles in traveling to obtain an abortion).

87. *See* Scripps News, *supra* note 16.

88. *Id.*

up in a clinical setting.[89] "Fewer than [three percent] of FDA-regulated drugs have a REMS, and three-quarters of those with a REMS are opioids . . . ."[90] Although the heavy regulation of mifepristone continues, it has proved safer than significantly less restricted drugs, including a number of drugs that can be obtained over the counter.[91] For example, erectile dysfunction drugs cause deaths at a rate "four times greater than" Mifeprex.[92] These stark statistics do not align with the restrictive requirements of the mifepristone REMS regulations.

FDA claims that these REMS restrictions are vital to the health of individuals, but the American Medical Association, the American College of Obstetricians and Gynecologists, and other leading medical groups oppose these restrictions.[93] FDA's own scientific reviewers also unanimously recommended that Mifeprex's special counseling form be eliminated because it does not make use conditions any safer.[94] Despite this overwhelming opinion by the reviewers, the FDA Commissioner overruled the recommendation.[95] International practice is also at odds with the regulations; in some European countries, ninety percent of abortions are performed using pills.[96]

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89. Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgement at 5, Chelius v. Becerra, No. 1:17-CV-00493-JAO-RT, 2021 WL 2492965 (D. Haw. Apr. 16, 2021) [hereinafter Plaintiffs' Memorandum of Law]; Case Profile of *Chelius v. Becerra*, ACLU (Oct. 3, 2017) [hereinafter ACLU Case Profile], https://www.aclu.org/cases/chelius-v-becerra.

90. Plaintiffs' Memorandum of Law, *supra* note 89, at 5.

91. *See* Angela Hill & Karen Rodriguez, *Abortion Pill Restricted by FDA for Decades Has Better Safety Record Than Penicillin and Viagra*, USA TODAY (July 10, 2020, 4:12 PM), https://www.usatoday.com/story/news/2020/07/10/abortion-pill-restricted-fda-record-safer-than-penicillin-viagra/5412810002/.

92. Scripps News, *supra* note 16 (showing that the REMS restrictions on mifepristone do not match up with their health risks, especially when compared to riskier drugs that lack REMS restrictions). Drugs for erectile dysfunction, like Viagra, are phosphodiesterase type five inhibitors and can be "associated with death in up to 0.004% of users," but do not have REMS programs. *See* Elizabeth G. Raymond, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENG. J. MED. 790, 792 (2017).

93. *See* Wallis, *supra* note 45 (noting the disapproval of FDA's REMS restrictions by highly regarded medical professionals and organizations).

94. Plaintiffs' Memorandum of Law, *supra* note 89, at 2 (demonstrating that even officials within FDA think that the mifepristone REMS restrictions are unnecessary and burdensome).

95. *Id.*

96. *See* Kelly Tyko, *Abortion Pill Online Orders Expected to Grow Post Roe*, AXIOS (June 24, 2022), https://www.axios.com/2022/06/24/abortion-pills-order-online-roe-wade-decision (explaining that mifepristone is considered safe and more accessible in several other countries).

B. The Power of the FDA Commissioner

With such an extensive range of food and drug-related authority, the FDA Commissioner has substantial power to alter the way we regulate both everyday items and specific drugs, like mifepristone.[97] The Commissioner "oversees the full breadth of the FDA portfolio and execution of the [FDCA] and other applicable laws," which includes "assuring the safety, effectiveness, and security" of various medicals products such as drugs, vaccines, and medical devices, as well as the nation's food supply, cosmetics, dietary supplements, any items that emit electronic radiation, and tobacco regulations.[98]

Since assuming the position in February 2022, several medical and healthcare leaders have urged FDA Commissioner Robert Califf to remove mifepristone from the REMS program.[99] State leaders like Michigan Governor Gretchen Whitmer, as well as top medical organizations like the American College of Obstetricians and Gynecologists and the American Medical Association, wrote letters imploring Commissioner Califf to remove the mifepristone REMS restrictions "to eliminate yet another burdensome requirement that threatens timely and essential reproductive health care."[100] The Commissioner has the authority to change the rules and follow the opinions of medical and scientific experts.[101] Despite these calls for change, Commissioner Califf has not moved on the issue.[102]

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97. *See Profile of FDA Commissioner*, U.S. FOOD & DRUG ADMIN. (Feb. 17, 2022), https://www.fda.gov/about-fda/fda-commissioner (highlighting the broad range of power enjoyed by FDA Commissioner).

98. *Id.*

99. *See* Letter from the American College of Obstetricians & Gynecologists (ACOG) & American Medical Association (AMA), to Robert Califf, Comm'r, U.S. Food & Drug Admin. (June 22, 2022) [hereinafter ACOG & AMA Letter], https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfdr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf; *see also* Letter from Governor Gretchen Witmer, to Robert Califf, Comm'r, U.S. Food & Drug Admin. (July 21, 2022) [hereinafter Whitmer Letter to FDA Commissioner], https://content.govdelivery.com/attachments/MIEOG/2022/07/21/file_attachments/2223974/220721%20-%20FDA%20letter%20%28with%20signature%29.pdf (requesting the FDA Commissioner remove mifepristone from the REMS program).

100. Whitmer Letter to FDA Commissioner, *supra* note 99 (asking for changes to mifepristone's REMS restrictions in order to make essential healthcare more accessible); ACOG & AMA Letter, *supra* note 99.

101. *See* Whitmer Letter to FDA Commissioner, *supra* note 99.

102. *See* ACOG & AMA Letter, *supra* note 99.

In 2016, despite recognizing that Mifeprex is safe, FDA reauthorized three restrictions on mifepristone under the REMS program.[103] The first restriction required a patient to pick up their prescription at a health center, instead of by mail or at a pharmacy.[104] This restriction was lifted in December 2021.[105] The second restriction requires providers prescribing Mifeprex to fax a form to the drug distributor attesting to their basic qualifications and confirming that they are equipped to distribute the drug.[106] The third restriction requires patients to complete a special counseling form.[107]

C. Current Litigation and the FDA's Refusal to Remove Mifepristone from REMS

Some groups have already initiated lawsuits challenging the regulations on mifepristone.[108] In *Chelius v. Becerra*,[109] plaintiff Dr. Graham Chelius argued on behalf of his patients—who live on the Hawaiian island of Kaua'i—because their only option for abortion access is a 300-mile round-trip flight.[110] Chelius argued that FDA violated the Administrative Procedure Act (APA) when it reauthorized the 2016 mifepristone REMS, "act[ing] arbitrarily and exceed[ing] its authority under a statute strictly limiting when such restrictions may be imposed."[111] "Congress authorized the FDA to require a REMS only when 'necessary to ensure that the benefits of [a] drug outweigh [its] risks' . . . ."[112] *Chelius* addresses "the six statutory factors [found in] 21 U.S.C. § 355-1(a)(1), none of which FDA addressed in maintaining the Mifprex REMS, except to acknowledge the *rarity* of serious complications."[113] Chelius also argued that FDA's REMS for

103. Plaintiffs' Memorandum of Law, *supra* note 89, at 13(continuing to place a burden on those seeking to obtain mifepristone with needless restrictions).

104. *Id.* at 1.

105. *See* Rebouché et al., *supra* note 44; *see also* Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html.

106. Plaintiffs' Memorandum of Law, *supra* note 89, at 8 (explaining the obstacles set out by mifepristone's REMS restrictions).

107. *Id.*

108. Chelius v. Becerra, No. 1:17-CV-00493-JAO-RT, 2021 WL 2492965 (D. Haw. filed Nov. 27, 2019).

109. *Id.*

110. *See generally id.*

111. Plaintiffs' Memorandum of Law, *supra* note 89, at 2 (providing a key argument in the case that shows FDA's reauthorization of mifepristone's REMS restrictions was not legal).

112. *Id.* (alteration in original).

113. *Id.* at 2–3 (demonstrating that FDA has not given a legitimate basis for maintaining the REMS restrictions on mifepristone). The six statutory factors include "(A) [t]he estimated size of the population likely to use the drug involved, (B) [t]he seriousness of the disease or

mifepristone is unconstitutional, under both substantive due process and equal protection analyses, because it severely restricts access to abortion care with no medical basis, imposing significant burdens on low-income patients, people of color, and people living in rural areas.[114] While FDA has since the in-person distribution requirement, *Chelius* remains unresolved by the U.S. District Court for the District of Hawaii.[115]

Years before lawsuits challenging these restrictions started cropping up, FDA recognized that mifepristone does not impose serious health and safety risks.[116] "In 2013, the FDA reviewed the existing REMS and reaffirmed the elements already in place."[117] In that review, FDA determined that "no new safety concerns [had] arisen in recent years and that the known serious risks occur rarely." FDA also found that because the number of adverse events appear to stabilize or decrease over time, "it is likely that . . . serious adverse events will remain acceptably low."[118] FDA's review would be supporting evidence in current and future cases calling for the removal of mifepristone from the REMS program, helping discredit the myths surrounding mifepristone's continued danger.

III. THE OVERTURNING OF *ROE V. WADE* SEVERELY COMPLICATES THE PROCESS

A. The Immediate Effects of Dobbs v. Jackson Women's Health Organization

With the Supreme Court's recent decision in *Dobbs*, many states have moved to curtail access to safe, effective abortions.[119] The *Dobbs* decision

condition that is to be treated with the drug, (C) [t]he expected benefit of the drug with respect to such disease or condition, (D) [t]he expected or actual duration of treatment with the drug, (E) [t]he seriousness of any known or potential adverse events that may be related to the drug, and the background incidence of such events in the population likely to use the drug, [and] (F) [w]hether the drug is a new molecular entity." *Id.* at 4; *see also* 21 U.S.C. § 355-1(a)(1).

114. Plaintiffs' Memorandum of Law, *supra* note 89, at 35–42 (adding another layer to the legal arguments made against REMS restrictions for mifepristone).

115. *See id.* at 190; *see also* Plaintiffs' Memorandum of Law, *supra* note 89, at 1–2 (demonstrating that while the suspension of the in-person distribution requirement is a win for healthcare, the rest of the REMS restrictions remain unchanged); Joint Motion to Stay Case Pending Agency Review, Chelius v. Becerra, No. 1:17-00493-JAO-RT, 2021 WL 3725625 (D. Haw. May 7, 2021).

116. *See Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 191 (supporting the position that it would be safe to get rid of the restrictions).

117. *Id.* at 190–91 (showing that despite FDA's recognition that mifepristone does not pose serious health and safety risks, it reauthorized harsh regulations).

118. *Id.*

119. *See* Sarah Knight, Carmel Wroth, Haidee Chu, Wynne Davis, Kristin Gourlay & Katie

has also emboldened political leaders to suggest and support a nationwide abortion ban.[120] In states, such as Arkansas, Missouri, and Tennessee, governor certification activates "trigger laws" preventing access to abortion; other states are following suit.[121] With abortion all but banned in these states, the states may move to reduce or prevent access to medication abortion—meaning, access to the pills themselves.[122] State-initiated abortion bans implicate the legality of interstate telehealth and potentially inhibit patients from crossing state lines to obtain an abortion.[123]

Daugert, *Here's Where Abortions Are Now Banned or Strictly Limited, and Where They May Be Soon*, NPR, https://www.npr.org/sections/health-shots/2022/06/24/1107126432/abortion-bans-supreme-court-roe-v-wade (Jan. 6, 2023, 5:26 PM) (highlighting the states that have rolled back abortion access since the overturning of *Roe v. Wade*). While many states are moving to ban abortion, some have considered adding abortion to the ballot and voting against the bans, indicating that there is widespread interest in permitting abortion access. *See* Dylan Lysen, Laura Ziegler & Blaise Mesa, *Voters in Kansas Decided to Keep Abortion Legal in the State, Rejecting an Amendment*, NPR, https://www.npr.org/sections/2022-live-primary-election-race-results/2022/08/02/1115317596/kansas-voters-abortion-legal-reject-constitutional-amendment (last updated Aug. 3, 2022, 2:18 AM). In August 2022, Kansas was the first state to vote on abortion rights since the Supreme Court ruled on the *Dobbs* decision, and voters rejected a proposed state constitutional amendment that would have erased the right to an abortion in the state. *Id.*

120. *See* Kelsey Snell, *GOP Sen. Lindsey Graham Introduces 15-Week Abortion Ban in the Senate*, NPR (Sept. 13, 2022, 1:49 PM), https://www.npr.org/2022/09/13/1122700975/gop-sen-lindsey-graham-introduces-15-week-abortion-ban-in-the-senate; *see also* Taurean Small & Eden Harris, *Wisconsin Law Makers Signal Support for Sen. Graham's Abortion Ban*, SPECTRUM NEWS NY1 (Sept. 29, 2022, 4:26PM), https://www.ny1.com/nyc/all-boroughs/politics/2022/09/29/wisconsin-lawmakers-signal-support-for-graham-s-abortion-ban (mentioning Sen. Graham's plan to enact a federal abortion ban).

121. Elizabeth Nash & Isabel Guarnieri, *13 States Have Abortion Trigger Bans—Here's What Happens When Roe Is Overturned*, GUTTMACHER INST. (June 6, 2022), https://www.guttmacher.org/article/2022/06/13-states-have-abortion-trigger-bans-heres-what-happens-when-roe-overturned (demonstrating the severe impacts of the *Dobbs* decision on states).

122. *See* Knight et. al, *supra* note 119; *see also* Christine Vestal, *As Abortion Pills Take Off, Some States Move to Curb Them*, PEW (Mar. 16, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/03/16/as-abortion-pills-take-off-some-states-move-to-curb-them (highlighting states that have moved to ban FDA abortion pills including Alabama, Arizona, and Iowa).

123. *See* Evan Kolsof, *With Roe Overturned, Can You Order Abortion Pills Online?*, WUSA9, https://www.wusa9.com/article/news/verify/what-is-medication-abortion-aka-abortion-pills-if-roe-is-overturned-can-you-order-these-pills-online-mifepristone-misoprostol/65-2a413e44-ea27-4612-9883-89d7dd2bdd0d (June 24, 2022, 10:34 AM) (discussing the legal implications of mail abortion services in a post-*Roe* world).

As telehealth has become more commonplace, the issue of where and by whom mifepristone is administered has become more complicated.[124] Thirty-two states currently require a physician to prescribe the pills needed for a medication abortion and at least eighteen states restrict telehealth for medication abortions.[125] The jurisdiction in which a patient is located during the telehealth visit determines which law applies, but how these laws would be enforced remains unclear.[126] For example, if a doctor from Maryland prescribes the abortion pill to someone in Texas, it would be difficult for law enforcement in Texas to trace and penalize the doctor in Maryland.[127] The larger concern is that states will look to pass laws that penalize the patient, rather than the medical professional.[128] In states where abortion is illegal, retaliatory legal action is possible against anyone who aids an individual in obtaining an abortion, regardless of their location.[129] As state abortion laws continue to change, conflict between interstate abortion laws and commerce will continue to arise.[130]

B. Federal Regulations Versus State Laws: The Battle Over Preemption

Since the Court's decision in *Dobbs*,[131] legal fights over abortion bans and restrictive state laws that limit abortion procedures are already being filed in courts.[132] For example, in West Virginia, Attorney General Patrick Morissey said that the state could regulate the prescription of mifepristone as a result of the *Dobbs* decision.[133] While this would likely cause a legal fight between West Virginia and the federal government, the West Virginia Attorney General insists that "the State retains the police power to regulate how drugs

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124. *Id.*

125. *Id.* (highlighting the differences in abortion laws from state to state); *see also Medication Abortion*, GUTTMACHER INST. (Nov. 1, 2022), https://www.guttmacher.org/state-policy/explore/medication-abortion.

126. Kolsof, *supra* note 123 (discussing potential legal issues that would arise from interstate telehealth visits).

127. *Id.*

128. *Id.* (increasing the possibility of harm to the patient and making reproductive healthcare even more difficult to access).

129. *Id.* (highlighting potential legal battles that could arise from interstate abortion access).

130. *Id.*

131. 142 U.S. 2228 (2022).

132. *See* Jen Christensen, *Biden Administration Says Federal Law Preempts State Abortion Bans When Emergency Care Is Needed*, CNN, https://www.cnn.com/2022/07/11/health/federal-abortion-law-preempts-state-law/index.html (July 11, 2022, 4:41 PM) (noting a high number of states dealing with abortion-related legal battles).

133. *See* Brad McElhinny, *Abortion Drugs Could be a Battleground in States like West Virginia*, W. VA. METRONEWS (July 4, 2022, 2:38 PM), https://wvmetronews.com/2022/07/04/abortion-drugs-could-be-a-battleground-in-states-like-west-virginia/ (demonstrating the immediate effect of *Dobbs*).

may be used by medical professionals."[134] Additionally, since *Dobbs*, West Virginia can reinstate an 1800s law that applies criminal penalties to abortion, including through the use of drugs.[135] The law would impose felony penalties for any person convicted of administering or receiving an abortion, including three to ten years in prison.[136] Also, any individual performing an abortion, by drug or other means, which results in a woman's death, will be tried for murder.[137] West Virginia is just one state of many likely to take action that will conflict with FDA's mifepristone policies.[138]

The availability of medication abortion through the mail adds another layer to the state law issue.[139] While FDA allows people to access the necessary drugs for a medication abortion via the mail, states are pushing back.[140] Tennessee Governor Bill Lee signed a law that "prohibits anyone, including a manufacturer or physician, from distributing 'an abortion-inducing drug via courier, delivery, or mail service.'"[141] If someone violates this law, a felony offense punishable by up to twenty years in prison and a fine of up to $50,000 is possible.[142] While federal law typically preempts state law, no lawsuit has yet been filed challenging the state's newly enacted law and its severe penalties.[143]

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134. *Id.*

135. *Id.* (creating an extremely tough barrier for women to obtain medication abortions). West Virginia's criminal abortion law states:

> Any person who shall administer to, or cause to be taken by, a woman, any drug or other thing, or use any means, with intent to destroy her unborn child, or to produce abortion or miscarriage, shall be guilty of a felony, and, upon conviction, shall be confined in the penitentiary no less than three nor more than ten years; and if such woman die by reason of such abortion performed upon her, such person shall be guilty of murder. No person, by reason of any act mentioned in this section, shall be punishable where such act is done in good faith, with the intention of saving the life of such woman or child.

W. VA. CODE § 61-2-8 (2020).

136. § 61-2-8.

137. *Id.*

138. *See* McElhinny, *supra* note 133.

139. Marcellus, *supra* note 30 (noting three states that restricted mailing medication abortion prior to the *Dobbs* decision).

140. *Id.* (highlighting a Tennessee law that would make it illegal to receive any abortion services via mail).

141. *Id.* (quoting Tennessee Abortion-Inducing Drug Risk Protocol Act, 2022 Tenn. Pub. Acts 1001 (codified as amended at TENN. CODE ANN. § 63-6-1103(b))).

142. *Id.*

143. *See* Kimberlee Kruesi, *Tenn. Governor Signs Bill Regulating Medication Abortions*, ASSOCIATED PRESS (May 6, 2022), https://apnews.com/article/abortion-business-health-tennessee-medication-4de8afa5d6d2923c41d13f16b103155b (showing that the Tennessee law is new territory post-*Dobbs*).

A question remains of whether this law would hold up against the U.S. Postal Service's (USPS's) rules and regulations. Though states have sued the USPS for a variety of issues in recent years, no abortion-related case exists as a roadmap for possible actions regarding the conflict of state laws and federal postal regulations.[144] The USPS has advised that it is up to the mailer to comply with state laws surrounding abortion pills.[145] However, the enforcement process to prevent abortion pills from entering certain jurisdictions seems minimally effective without assistance from the USPS.[146] An individual's mail cannot be pointlessly ransacked, therefore, even in states that ban telehealth providers, they can use a third party to gain healthcare access.[147] Nonetheless, if the law is challenged, Tennessee could fight back fervently. Once again, the line between what is and is not legal is blurred in the post-*Roe* world.

The battle between federal preemption and states' rights has created a messy landscape for governments, doctors, and patients.[148] In July 2022, the Biden Administration announced that federal law will preempt state laws banning abortions when emergency care is needed.[149] The announcement noted that "the federal government can penalize institutions or providers that fail to provide abortions [necessary] to treat medical emergencies."[150] The Secretary of the Department of Health and Human Services (HHS), Xavier Becerra, clarified in a letter to the nation's healthcare providers that the Emergency Medical Treatment and Active Labor Act (EMTALA) "protects providers' clinical judgment and the actions they take to provide stabilizing treatment to pregnant patients who are under emergency medical conditions, regardless of restrictions in any given state."[151] The EMTALA protects providers in using abortion as a stabilizing treatment for various medical conditions, including ectopic pregnancy and miscarriages.[152]

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144. *See* Eric Katz, *USPS: It's Up to Mailers to Comply with State Laws on Abortion Pills*, GOV'T EXEC. (June 29, 2022), https://www.govexec.com/management/2022/06/usps-its-mailers-comply-state-laws-abortion-pills/368799/ (describing the uncertainty regarding abortion-related lawsuits with the United States Postal Service).

145. *Id.*

146. *Id.*

147. *Id.*

148. *See* Christensen, *supra* note 132 (demonstrating the intricacies and potential legal issues of interstate abortion services).

149. *Id.* (reinforcing that, regardless of state law, federal law requires providers to treat medical emergencies with abortions when deemed necessary).

150. *Id.*

151. *Id.* (offering another solution to state laws restricting abortions).

152. *Id.* (showing the federal government's attempt to find a life-saving solution amidst state abortion bans).

In addition to facing interstate legal issues, some people are looking to international providers to order abortion pills online.[153] According to the Journal of the American Medical Association, there was a nearly 120% increase in overseas online abortion pill orders in July and August 2022.[154] Individuals placed these orders through Aid Access, an organization that operates outside of the United States, circumventing state abortion bans.[155] However, there is no way to track whether these ordered medications have been received or taken, which is essential to understanding the overall picture.[156] While it is illegal to sell prescription medicine to Americans without a prescription from a licensed U.S. doctor, many individuals have found this to be their best, if not only, option.[157]

While legal challenges continue to sprout up in states across the country, finding other innovative avenues through the collaboration of FDA and other Executive Branch agencies will be vital to protect the existing safeguards against abortion bans and to ensure the health and safety of pregnant individuals everywhere. Without scrupulous attention to the intricacies of how state and federal law interact at every step of the medication abortion process, draconian laws will continue to resurface in anti-abortion states. This is especially important for cases involving mail delivery of abortion pills because the more options people have that do not require going to a specified, physical location, the fewer abortion providers, clinics, and individuals seeking an abortion have to worry about threats and attacks.[158] Until more lawsuits arise to establish precedent, the lines between state versus federal law remain ambiguous.

C. The Ultimate Ruler: A Debate Over the Supremacy Clause

Several cases argue that the Supremacy Clause of the U.S. Constitution provides a clear answer,[159] with courts in a handful of states striking down attempts to get rid of access to certain types of drugs.[160] In Massachusetts,

153. Aatish Bhatia, Claire Cain Miller & Margot Sanger-Katz, *A Surge of Overseas Abortion Pills Blunted the Effects of State Abortion Bans*, N.Y. TIMES (Nov. 1, 2022), https://www.nytimes.com/2022/11/01/upshot/abortion-pills-mail-overseas.html.

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.*

158. *See* Donley, *supra* note 46, at 692 (arguing that attacks against providers and their clinics will decrease as abortions are less tied to physical locations).

159. U.S. CONST. art. 6, cl. 2.

160. *See* Celine Castronuovo, *Abortion Pill Lawsuit Offers Guide to Challenging State Limits*,

a district court granted a partial preliminary injunction against state measures that denied access to the FDA-approved opioid Zohydro.[161] The U.S. District Court for the District of Massachusetts determined that Zogenix, Zohydro's manufacturer, "had a plausible case that the state restrictions infringed on the FDA's authority under the [FDCA] to ensure that safe and effective drugs are available to the public."[162] The following year, the U.S. District Court for the District of Maine rejected a state law that permitted Maine residents to secure prescription drugs from retail pharmacies located in Canada, the United Kingdom, Australia, or New Zealand.[163] Ultimately, the court decided that the FDCA preempted Maine's law, pursuant to the Supremacy Clause.[164] While there have been multiple examples of federal drug law preemption, some health and legal experts have expressed concern that the path for mifepristone will be a bit more obfuscated.[165]

In particular, states that intend to block mifepristone through state laws will focus on the Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corporation*.[166] That decision, regarding FDA's authority to regulate tobacco products, announced that that "Congress has not given FDA the authority to regulate [those] products as customarily marketed."[167] The Court noted that Congress failed to explicitly designate such regulatory power to FDA.[168] The key difference between the arguments in this case and the arguments that states could make regarding mifepristone is that *Brown & Williamson* does not specifically address an FDA-approved drug.[169] Mifepristone's FDA approval is a factor that would likely negate the states'

BLOOMBERG L. (May 25, 2022, 5:35 AM), https://news.bloomberglaw.com/health-law-and-business/abortion-pill-lawsuit-offers-guide-to-challenging-state-limits (exemplifying that federal law has been successful in overruling state law).

161. *Id.* (offering an example of courts striking down state law and favoring FDA's regulations); Zogenix, Inc. v. Patrick, No. 14-11689, WL 1454696, at *3 (D. Mass. Apr. 15, 2014).

162. Castronuovo, *supra* note 160 (granting a preliminary injunction against the state).

163. *Id.* Ouellette v. Mills, 91 F. Supp. 3d 1, 12 (D. Me. 2015).

164. Castronuovo, *supra* note 160. *Mills*, 91 F. Supp. 3d at 12.

165. Castronuovo, *supra* note 160 (discussing the arguments states banning abortion, and more specifically medication abortion, are likely to make).

166. *Id.* (giving an example where the states won a legal battle regarding the regulation of drugs). FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 (2000).

167. *Brown & Williamson*, 529 U.S. at 120, 161.

168. *Id.* at 148.

169. Castronuovo, *supra* note 160 (showing that this case may not support the states' arguments enough to win a legal battle over medication abortion); *Brown & Williamson*, 529 U.S. at 120 (interpreting the scope of the Food, Drug and Cosmetic Act to read that Congress has not permitted FDA to regulate tobacco products as customarily marked).

argument that FDA should not regulate the drug, even though relying on *Brown & Williamson*'s holding may otherwise bolster the argument.[170]

While the discussion regarding abortion has been addressed in terms of emergency care and procedures, federal officials have also addressed the use of mifepristone in non-emergency situations.[171] Attorney General Merrick Garland made it evident that mifepristone will remain a resource.[172] In a statement released shortly after the *Dobbs* decision, he clarified, "[s]tates may not ban [m]ifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy."[173] He also directed states not to interfere with the duties of federal employees and agencies that will "continue to provide reproductive health services to the extent authorized by federal law," asserting that "[i]t is the Department's longstanding position that [s]tates generally may not impose criminal or civil liability on federal employees who perform their duties in a manner authorized by federal law."[174]

Many medical associations and legal experts agree that removing mifepristone from the REMS program would offer a clearer path for medication abortions and reduce burdens placed on patients; others do not believe that completely removing the drug from REMS will be enough.[175] Those in the latter camp worry that even if FDA removes REMS restrictions for mifepristone, state laws will still prevent access to the drug.[176] No matter what FDA decides for the future of mifepristone and the REMS program, courts must still decide that state restrictions are preempted because they conflict with FDA oversight.[177] Due to the

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170. Castronuovo, *supra* note 160 (providing a potential answer to legal battles between states and FDA).

171. *See* Press Release, Off. of Pub. Affs., U.S. Dep't of Just., Attorney General Merrick B. Garland Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022) [hereinafter DOJ Press Release], https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s (strongly disagreeing with the Court's decision).

172. *Id.* (specifying in his statement that mifepristone is protected by the power of the federal government).

173. *Id.*

174. *Id.*

175. *See* Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705, 706 (2022), https://www.nejm.org/doi/full/10.1056/NEJMp2118696 (explaining that there is a possibility that state laws could override federal laws even with the removal of mifepristone's REMS restrictions); *see also* Collins, *supra* note 4.

176. Zettler & Sarpatmari, *supra* note 175.

177. *Id.* (giving the courts the ultimate power as to whether state or federal law controls abortion laws).

persistent division among relevant experts on what the future may hold, the prospect of continued access to mifepristone and other medical abortions and their legal repercussions remains uncertain.

IV. RECOMMENDATIONS

Even with the concerns around the validity of federal preemption, removing mifepristone from the REMS program will mitigate the heart of this issue. While it is just one piece of the larger puzzle of abortion access and healthcare, it is a significant one. Mifepristone can also be self-administered[178] and is now offered in some retail pharmacies, certain rules permitting. Patients are still required to have a prescription from a certified health prescriber, but the pills can be dispensed in stores and by mail via any pharmacy that agrees to accept those prescriptions and follow additional criteria.[179] Although removing the drug completely from the REMS program would be a stronger solution, this is a step in the right direction to foster more accessible, affordable healthcare that is safe and effective.

"Numerous studies and more than twenty years of clinical data confirm that mifepristone is a safe, effective prescription medication."[180] Patients have used it "for decades to end an early pregnancy in the privacy and comfort of home."[181] Now, with more updated, accurate, and robust scientific knowledge than existed two decades ago when the drug was just emerging in the United States, the harsh restrictions surrounding mifepristone no longer make sense for the utmost health and safety of people with the capacity for pregnancy and their reproductive health in the United States.[182] Additionally, making medication abortion more widely known as an option should be a priority. Eighty percent of American adults, including two-thirds of women between the ages of eighteen to forty-nine, are unaware that medication abortion exists.[183] Abortion healthcare options are not effectively communicated to the majority of Americans, including those who need it most.

To achieve national success for reproductive healthcare and the safety of those with the capacity for pregnancy, the solution is two-fold. First, FDA must remove mifepristone from the REMS program because dozens of anecdotes, studies, and statistics over the last two decades have pointed to its

178. *See Risk Evaluation and Mitigation Strategies*, *supra* note 37.

179. Pam Belluck, *Abortion Pills Can Now Be Offered at Retail Pharmacies, F.D.A. Says*, N.Y. Times (Jan. 3, 2023), https://www.nytimes.com/2023/01/03/health/abortion-pill-cvs-walgreens-pharmacies.html.

180. ACLU Case Profile, *supra* note 89.

181. *Id.* (showing the history of safe use of mifepristone to end pregnancy).

182. *Id.*

183. *See* Collins, *supra* note 4 (referencing a Kaiser Family Foundation study).

safe use and minimal harmful effects.[184] FDA has the power to modify or eliminate REMS, including the restrictions on mifepristone, as long as the risks no longer outweigh the benefits.[185] Second, FDA should be required to implement a more collaborative process with medical groups, legal experts, and researchers in its assessment of drugs, particularly those highly scrutinized drugs within the REMS program, and its rulemaking. Incorporating expertise from multiple relevant disciplines will result in a fairer, more comprehensive distribution strategy that will bolster safe and effective healthcare, rather than limit it.

Decades of studies and data prove mifepristone not only to be a safe and effective drug, but FDA itself has recognized the significant burden that REMS restrictions place on those individuals seeking to obtain mifepristone.[186] FDA knows that mifepristone's REMS classification continues to inhibit abortion access, and if it truly wishes to make safety regulations the least burdensome they can be, the Agency should remove the drug from the program.[187] FDA is able to do so without compromising the health and safety of those receiving the drug, while also providing more comprehensive and widespread healthcare to people across the country.[188] While FDA concludes that its REMS requirements for mifepristone are critical to assure patient privacy and safety, some healthcare groups and medical professionals claim that, by restricting mifepristone through REMS, FDA arbitrarily disregarded evidence of the drug's safe use and made it needlessly difficult for patients to access.[189] Much like the removal of Tikosyn from the REMS program, mifepristone could be removed from the program so long as FDA creates an adequate, approved labeling scheme for the drug that specifies its use methods and safety risks.[190]

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184. *See A Call to End the Excessive Regulation of Mifepristone*, *supra* note 50 (supporting the notion that mifepristone is clinically proven to be a safe drug to use without the extra REMS restrictions).

185. *See* Dohm & Ji, *supra* note 27, at 5.

186. *See* Scripps News, *supra* note 16.

187. *See* JENNIFER A. STATMAN & JON O. SHIMABUKURO, CONG. RSCH. SERV., LSB10706, MEDICATION ABORTION: A CHANGING LEGAL LANDSCAPE (2022), https://crsreports.congress.gov/product/pdf/LSB/LSB10706 (highlighting FDA's knowledge that REMS is burdensome on those trying to obtain reproductive healthcare and its ignorance in remedying the issue).

188. *See* ACLU Case Profile *supra* note 89.

189. *Id.;* Shannon Connolly, *FDA Repeals Mifepristone Dispensing Restriction*, CAL. ACAD. OF FAM. PHYSICIANS (Jan. 5, 2022), https://www.familydocs.org/news-fda-repeals-mifepristone-dispensing-restriction/ (highlighting FDA's REMS categorization is not evidence-based, which ignores a possible remedy to the issue and places a heavy burden on those trying to obtain reproductive healthcare).

190. *See* Dohm & Ji, *supra* note 27, at 5 (providing an easy and effective alternative to the REMS restrictions on mifepristone).

Many clinicians across the country are unable to satisfy all of the current requirements, leaving many patients scrambling to find alternative care or with no care at all.[191] Removing REMS barriers would give many more people the freedom to make choices concerning their own health and bodily autonomy. They would have greater access to safe and reliable abortion care. Without having to jump through the additional REMS hoops, patients will also be able to retain more privacy by avoiding public areas that sometimes cause danger for those seeking an abortion.[192] It is essential that medical professionals, healthcare organizations, and the American people keep the courts privy to the most up-to-date scientific findings, research, and real-life experiences, allowing courts to make fair, informed decisions moving forward. These key players can help uphold the integrity and legality of FDA's authority and federal preemption over state laws.

With healthcare groups, medical professionals, scholars, and researchers supporting the relaxation of the mifepristone restrictions,[193] FDA should work with different groups and experts to formulate its rules and standards to provide a more balanced rulemaking framework. In collaborating with these groups, FDA may have a better chance of avoiding bias or inconsistency in its standard practices.[194] For example, the Agency could work with the Attorney General, who has already shared his commitment to protecting critical access to reproductive healthcare,[195] to bar wrongful prosecutions and protect interstate travel in states where abortion is still legal.

These priorities have also been highlighted by an Executive Order, in which the Biden Administration assembled the "Task Force on Reproductive Healthcare Access."[196] The Order also calls for protecting data and patient privacy, creating a reproductive rights task force specifically within the Department of Justice, and preserving emergency medical care through the EMTALA, which states are required to offer stabilizing treatment, including abortion services, in emergency situations, where state law will be preempted.[197] This coalition of political leaders, government organizations, and medical and legal experts must work together to build accountability and promote proper

191. *See* Gonzalez, *supra* note 20.

192. *See* Donley, *supra* note 46, at 692.

193. *See* ACOG & AMA Letter, *supra* note 99.

194. *See* Donley, *supra* note 46, at 684–85.

195. *See* DOJ Press Release, *supra* note 171.

196. *See* Press Release, White House, Fact Sheet: President Biden Issues Executive Order at the First Meeting of the Task Force on Reproductive Healthcare Access (Aug. 3, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/03/fact-sheet-president-biden-issues-executive-order-at-the-first-meeting-of-the-task-force-on-reproductive-healthcare-access-2/.

197. *Id.*

enforcement of life-saving laws and standards. With reproductive rights in a fragile state, our nation must piecemeal together the laws and protections that are available and use them to their utmost potential.

Legal experts have emphasized the fact that the American Medical Association has advised FDA to make oral contraceptives completely available over the counter, which is commonplace in other countries.[198] Legal scholar and FDA expert Lewis Grossman suggests that until such a change has been seriously considered and adopted at the federal level, pro-choice states could themselves create laws relaxing and prescribing procedures as close as possible to an over-the-counter status. [199] These recommendations would be further enhanced by FDA staff andCommissioner meeting with medical groups and associations to update the practices around mifepristone and how they can function within state regulations. While rulemaking is not as strong an approach as solidifying the constitutional right to an abortion,[200] it is a careful, balanced approach. Thus, these recommendations are vital.

CONCLUSION

Since its approval in 2000, mifepristone has been a safe and effective drug for people seeking an abortion, and the need for it only continues to grow.[201] As mifepristone's safety and efficacy proves successful year after year, the top drug and medical agencies in the nation should be advocating for it, not rejecting it.[202] FDA has the power to advance this essential medication.[203] Without these safeguards in place, people with the capacity for pregnancy will continue to face mental and emotional trauma, severe physical complications, and even death.[204]

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198. *See* Lewis A. Grossman, *Pushing Back with Pills—Enhancing Access to Reproductive Health Drugs After* Dobbs, 387 NEW ENG. J. MED. 1056, 1058 (2022), https://www.nejm.org/doi/full/10.1056/NEJMp2209377?query=featured_secondary.

199. *Id.*

200. *See* Donley, *supra* note 46, at 684.

201. *See A Call to End the Excessive Regulation of Mifepristone*, *supra* note 50.

202. *Id.*

203. *See* STATMAN & SHIMABUKURO, *supra* note 187; *see also Chelius v. Becerra*, Am. Civ. Liberties Union (Oct. 3, 2017), https://www.aclu.org/cases/chelius-v-becerra.

204. *See* Gonzalez, *supra* note 20; *see also* Tori Rodriguez, *The Mental Health Impact of Abortion Restrictions*, PSYCHIATRY ADVISOR (July 29, 2022), https://www.psychiatryadvisor.com/home/topics/general-psychiatry/myriad-of-mental-health-ramifications-stemming-from-the-loss-of-abortion-access/. Furthermore, "compared with having an abortion, being denied an abortion may be associated with greater risk of initially experiencing adverse psychological outcomes." M. Antonia Biggs, Ushma D. Upadhyay, Charles E. McCulloch & Diana G. Foster, *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA PSYCHIATRY 169, 169 (2017), doi:10.1001/jamapsychiatry.2016.3478.

The controversial fight over the use of mifepristone is no longer a scientific debate, but a political one. With lives at stake, science and the law must dictate the necessary action. If decisionmakers choose not to follow either, the remaining access to reproductive healthcare for many Americans will be severely diminished—and for many it already is.[205]

205. *See* Gonzalez, *supra* note 20.