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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; and STATE OF VERMONT, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES	NO. COMPLAINT

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DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

I. INTRODUCTION

1. The availability of medication abortion has never been more important. As states across the country have moved to criminalize and civilly penalize abortion, the Plaintiff States have preserved the right to access abortion care, and have welcomed people from other states who need abortion care. The extremely limited availability of abortion in other states, and the growing threat to abortion access nationwide, makes patients' access to medication abortion paramount. Medication abortion through a combination of mifepristone and misoprostol is the "gold standard" for early termination of pregnancy, used by the majority of people in the U.S. who choose to have an abortion.

2. More than 22 years ago, the United States Food and Drug Administration (FDA) approved mifepristone (under the brand name Mifeprex) to be used with the drug misoprostol, in a two-drug medication regimen to end an early pregnancy. Approval was based on a thorough and comprehensive review of the scientific evidence, which established that mifepristone is safe and effective.

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3. Since this regimen was approved in 2000, mifepristone has been used approximately 5.6 million times in the United States.[1] As FDA acknowledged in 2016, mifepristone "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[2] Mifepristone is safer than many other common drugs FDA regulates, such as Viagra and Tylenol.

4. Medication abortion is now the most common method of abortion in the United States. For example, almost 60% of abortions in Washington State are medication abortions.

5. But FDA has continued to hamper access by singling out mifepristone—and the people in the Plaintiff States who rely on it for their reproductive health care—for a unique set of restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). The restrictions on mifepristone are a particularly burdensome type of REMS known as Elements to

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[1]FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, https://www.fda.gov/media/164331/download ("Mifepristone U.S. Post-Marketing Adverse Events"), attached hereto as Ex. A.

[2]FDA, Ctr. for Drug Evaluation & Research, No. 020687Orig1s020, Mifeprex Medical Review(s) at 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf ("FDA 2016 Medical Review"), attached hereto as Ex. B.

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Assure Safe Use (ETASU), which strictly limit who can prescribe and dispense the drug. FDA's decision to continue these burdensome restrictions in January 2023 on a drug that has been on the market for more than two decades with only "exceedingly rare" adverse events has no basis in science. It only serves to make mifepristone harder for doctors to prescribe, harder for pharmacies to fill, harder for patients to access, and more burdensome for the Plaintiff States and their health care providers to dispense.[3] Not only that, but the REMS require burdensome documentation of the patient's use of mifepristone for the purpose of abortion, making telehealth less accessible and creating a paper trail that puts both patients and providers in danger of violence, harassment, and threats of liability amid the growing criminalization and outlawing of abortion in other states.

6. FDA has imposed REMS for only 60 of the more than 20,000[4] FDA-approved prescription drug products marketed in the U.S. These cover dangerous drugs such as fentanyl and other opioids, certain risky cancer drugs, and high-dose sedatives used for patients with psychosis.[5]

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[3]Ex. B (FDA 2016 Medical Review) at 47.

[4]Office of the Commissioner, *FDA at a Glance: FDA Regulated Products and Facilities*, FDA (Nov. 2021), https://www.fda.gov/media/154548/download.

[5]*Id.*

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7. This case is about whether it is improper and discriminatory for FDA to relegate mifepristone—a medication that has been used over 5 million times with very low rates of complications, very high rates of efficacy, and which is critical to the reproductive rights of the Plaintiff States' residents, as well as visitors who travel to the Plaintiff States to seek abortion care—to the very limited class of dangerous drugs that are subject to a REMS.

8. The Plaintiff States seek an order directing FDA to follow the science and the law. The Court should order FDA to remove the unnecessary January 2023 REMS restrictions that impede and burden patients' access to a safe, proven drug that is a core element of reproductive health care in the Plaintiff States.

II. JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, as this is a civil action arising under federal law, and under 5 U.S.C. § 702, as this is a civil action seeking judicial review of a final agency action.

10. This action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202, by Federal Rules of Civil Procedure 57 and 65, and by the inherent equitable powers of this Court.

11. The Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1391(e) because Defendants are agencies and officers of the United States.

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12. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because this is a judicial district in which Plaintiff State of Washington resides. Defendants' policies adversely affect the health and welfare of residents in the Plaintiff States, including in this district, and harm the financial interests of the Plaintiff States, including Washington. Abortion access is far more limited in Eastern Washington than in Western Washington, with the State's clinics concentrated in urban areas and the I-5 corridor.

III. PARTIES

Washington

13. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

14. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

15. Washington also has standing because the 2023 REMS creates and maintains substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

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16. Washington additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Washington residents.

Oregon

17. Plaintiff State of Oregon is represented by its Attorney General, who is the chief law officer for the State. Oregon has a strong interest in the proper provision of health care within the state, particularly at public hospitals, and joins in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Oregon residents.

Arizona

18. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

19. As the operator of facilities that provide reproductive health care and pharmaceutical services, Arizona is directly subject to the January 2023 REMS and has standing to vindicate it proprietary interests in delivering high-quality patient care.

20. Arizona also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens for health care and pharmaceutical services provided in state owned or operated facilities.

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21. Arizona additionally brings this suit in it capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Arizona residents.

Colorado

22. Plaintiff the State of Colorado is a sovereign state of the United States of America. This action is brought on behalf of the State of Colorado by Attorney General Phillip J. Weiser, who is the chief legal representative of the State of Colorado, empowered to prosecute and defend all actions in which the state is a party. Colo. Rev. Stat. § 24-31-101(1)(a).

Connecticut

23. The State of Connecticut is a sovereign state. The Attorney General is Connecticut's chief civil legal officer, responsible for supervising and litigating all civil legal matters in which Connecticut is an interested party, including federal court matters.

24. Medication abortion is indispensable to reproductive health care in Connecticut. According to the Centers for Disease Control, more than 65% of Connecticut abortions are medication abortions using mifepristone.

25. Access to mifepristone for medicated abortions is increasingly critical in Connecticut. An ongoing wave of hospital closures and consolidations threaten to leave swaths of the state without access to on-site reproductive

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healthcare, even as demand for abortion care has increased in the aftermath of *Dobbs*.

26. Connecticut is directly subject to the January 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care. Connecticut funds and operates the John Dempsey Hospital of the University of Connecticut Health Center (UConn Health) and its associated pharmacy. The Hospital provides reproductive health services, including prescribing mifepristone for medication abortions. The pharmacy dispenses mifepristone to patients.

27. Connecticut also has standing because the 2023 REMS create and maintain substantial and costly administrative burdens, including burdens to UConn Health and its associated pharmacy.

28. Connecticut additionally brings this suit in its capacity as parens patriae to protect is quasi-sovereign interest in the health and well-being of Connecticut residents.

Delaware

29. Plaintiff the State of Delaware is a sovereign state of the United States of America. This action is brought on behalf of the State of Delaware by Attorney General Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941).

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Attorney General Jennings also brings this action on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

Illinois

30. Plaintiff the State of Illinois is a sovereign state of the United States of America. This action is brought on behalf of the State of Illinois by Attorney General Kwame Raoul, the State's chief legal officer. *See* Ill. Const. art. V, § 15; 15 ILCS 205/4.

31. Illinois has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care costs, including emergency care, some of which is borne by the state through Medicaid expenditures.

32. Illinois additionally brings this suit in its capacity as *parens patriae* to protect its quasi-sovereign interest in the health and well-being of Illinois residents.

Attorney General of Michigan

33. Attorney General Dana Nessel is the chief legal adviser to the State of Michigan. The Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

34. The Attorney General brings this suit in her capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Michigan residents.

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Nevada

35. Plaintiff State of Nevada is represented by its Attorney General. The Attorney General is the chief legal officer of the State.

36. The Nevada Attorney General may commence or defend a suit in state or federal court when in his opinion a suit is necessary to protect and secure the interest of the State.

37. Nevada provides reproductive healthcare services including medication abortions using mifepristone.

38. As a provider of reproductive healthcare services, Nevada is subject to the January 2023 REMS program.

39. Nevada has standing to challenge the REMS because it imposes financial and administrative burdens on Nevada reproductive healthcare service providers seeking to prescribe and distribute mifepristone for medication abortions.

40. Nevada also has standing to challenge the program because the program interferes with its inherent authority to provide for the health and welfare of its residents. It imposes medically unnecessary barriers to Nevada's provision of reproductive healthcare using the least intrusive and most cost-effective means.

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New Mexico

41. Plaintiff State of New Mexico, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Raúl Torrez is the chief legal officer of the State of New Mexico. He is authorized to prosecute all actions and proceedings on behalf of New Mexico when, in his judgment, the interest of the State requires such action. N.M. Stat. Ann. § 8-5-2(B). Likewise, he shall appear before federal courts to represent New Mexico when, in his judgment, the public interest of the state requires such action. N.M. Stat. Ann. § 8-5-2(J). This challenge is brought pursuant to Attorney General Torrez's statutory authority.

42. As an operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, New Mexico is directly subject to the 2023 REMS and has standing to vindicate its proprietary interests in delivering high-quality patient care.

43. New Mexico also has standing because the 2023 REMS will impose substantial and costly administrative burdens for State-operated hospitals, clinics, and pharmacies.

44. New Mexico additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of New Mexico residents.

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Rhode Island

45. The Rhode Island Attorney General is the chief legal officer for the State of Rhode Island. The Rhode Island Attorney General's powers and duties include acting in federal court on behalf of the State on matters of public concern.

46. Rhode Island has standing because the 2023 REMS create barriers to accessing medically necessary abortion and miscarriage care, leading to subsequent health care utilization, including emergency care, some cost of which is borne by the state through Medicaid expenditures.

47. Rhode Island additionally brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Rhode Island residents.

Vermont

48. The Attorney General is the chief legal adviser to the State. The Attorney General's powers and duties include representing the State in civil causes when, in her judgment, the interests of the State so require.

49. Vermont brings this suit in its capacity as parens patriae to protect its quasi-sovereign interest in the health and well-being of Vermont residents.

Plaintiff States

50. The Plaintiff States collectively represent more than 59 million Americans with protected rights to abortion care.

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Defendants

51. Defendant United States Food and Drug Administration (FDA) is an agency of the federal government within the United States Department of Health and Human Services (HHS). FDA is responsible for administering the provisions of the federal Food, Drug, and Cosmetic Act that are relevant to this Complaint.

52. Robert M. Califf is the Commissioner of the United States Food and Drug Administration and is sued in his official capacity. He is responsible for administering FDA and its duties under the federal Food, Drug, and Cosmetic Act.

53. Defendant HHS is a federal agency within the executive branch of the federal government.

54. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity. He is responsible for the overall operations of HHS, including FDA.

IV. ALLEGATIONS

A. Statutory Background

55. Under the Food, Drug and Cosmetic Act (FDCA), a new drug cannot be marketed and prescribed until it undergoes a rigorous approval process to determine that it is safe and effective. *See generally* 21 U.S.C. § 355. An approved prescription medication is subject to robust safeguards to ensure that it is used safely and appropriately, including the requirement of a prescription by a

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licensed medical provider, patient informed-consent laws, scope of practice laws, professional and ethical guidelines, and state disciplinary laws regulating the practice of medicine and pharmacy, as well as additional warnings, indications, and instructions that FDA may impose specific to the medication.

56. FDA relies on this set of safeguards to ensure the safe and effective use of the *vast* majority of prescription drugs.

57. A "Risk Evaluation and Mitigation Strategy" (REMS) is an additional set of requirements, beyond the usual network of safeguards, that FDA may impose in the rare case when—and only when—"necessary to ensure that the benefits of the drug outweigh the risks of the drug[.]" 21 U.S.C. § 355-1(a)(1).

58. The most burdensome type of REMS are "Elements to Assure Safe Use" (ETASU), which FDA may impose only when necessary because of a drug's "inherent toxicity or potential harmfulness." *Id.* § 355-1(f)(1).

59. By statute, FDA may impose ETASU only for medications that demonstrate risks of serious side effects such as death, incapacity, or birth defects, and only where the risk of side effects is sufficiently severe that FDA could not approve, or would have to withdraw approval of, the medication, absent the ETASU. *Id.* §§ 355-1(b)(5), (f)(1)(A).

60. ETASU must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved

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areas," and must "minimize the burden on the health care delivery system[.]" *Id.* §§ 355-1(f)(2)(C)–(D).

61. In light of these stringent statutory limitations, REMS, and in particular an ETASU, are exceptionally rare: of the more than 20,000 prescription drug products approved by FDA and marketed in the U.S.,[6] there are only 60 REMS in place, 56 of which include an ETASU, covering dangerous drugs like fentanyl and other opioids.[7]

B. FDA's Approval of Mifepristone and the History of the Mifepristone REMS Program

62. The current FDA-approved regimen for the medical termination of early pregnancy involves two drugs: (1) *mifepristone*, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) *misoprostol*, which causes uterine contractions that expel the pregnancy from the uterus. Shortly after taking mifepristone and then misoprostol, a patient will experience a miscarriage.[8]

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[6] *Supra* n.5.

[7] Ex. C (FDA Approved REMS).

[8] Taken alone, misoprostol also acts as an abortifacient—but it is less effective and causes more negative side effects than the mifepristone/misoprostol regimen. Misoprostol, however, it is not subject to a REMS; patients may obtain it from any provider and have it filled at retail or mail-order pharmacies.

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63. Mifepristone was first approved for medical termination of early pregnancy in France in 1988 and its approval expanded to the United Kingdom and European countries throughout the 1990s.

64. In 1996, the Population Council, a non-profit organization based in the United States, sponsored a New Drug Application (NDA) for Mifeprex for use in combination with misoprostol for the medical termination of early pregnancy. In 1999, the Population Council contracted with Danco Laboratories, L.L.C. (Danco) to manufacture and market the medication.

65. FDA approved the marketing of mifepristone under the brand name Mifeprex in September 2000,[9] concluding that mifepristone is safe and effective for medical termination of intrauterine pregnancy through 49 days' gestation when used in a regimen with the already-approved drug, misoprostol. In granting its approval, FDA extensively reviewed the scientific evidence and determined that mifepristone's benefits outweigh any risks.[10]

66. FDA's review included three clinical trials that together involved 4,000 women: two French trials that were complete at the time of the application, and one then-ongoing trial in the United States for which summary data on

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[9]FDA NDA 20-687 Approval Memo, Sept. 28, 2000, attached hereto as Ex. D.

[10]Food and Drug Administration Approval and Oversight of the Drug Mifeprex, https://www.gao.gov/assets/gao-08-751.pdf, attached hereto as Ex. E.

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serious adverse events were available.[11] FDA has explained that "[t]he data from these three clinical trials . . . constitute substantial evidence that Mifeprex is safe and effective for its approved indication in accordance with the [FDCA]."[12] FDA also considered: (1) results from other European trials from the 1980s and 1990s in which mifepristone was studied alone or in combination with misoprostol or similar drugs; (2) a European postmarket safety database of over 620,000 women who used medication to terminate a pregnancy, approximately 415,000 of whom had received a mifepristone/misoprostol regimen[13]; and (3) data on the drug's chemistry and manufacturing.[14]

67. Despite the strong findings on the safety and efficacy of Mifeprex from clinical trials and European post-market experience, FDA originally approved Mifeprex under Subpart H of the FDCA regulations (the predecessor to the REMS statute) and imposed "restrictions to assure safe use"—a restricted

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[11] *Id.* at 5.

[12] 2016 FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Christian Medical & Dental Ass'ns, and Concerned Women for Am. denying 2002 Citizen Petition, Docket No. FDA-2002-P0364 (Mar. 29, 2016) (Citizen Petition Denial) at 8, Mar. 29, 2016, attached hereto as Ex. F.

[13] *Id.* at 8.

[14] Ex. E, supra n.11.

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distribution system—as a condition of approval.[15] For example, FDA imposed an in-person dispensing requirement (later "ETASU C," pursuant to 21 U.S.C. § 355-1(f)(3)(C)) and permitted the drug to be dispensed only in a hospital, clinic, or medical office, by or under the supervision of a "certified provider" (discussed more below), who at that time could only be a physician. FDA also imposed a prescriber-certification ETASU (later "ETASU A," pursuant to 21 U.S.C. § 355-1(f)(3)(A)), which prohibited health care providers from prescribing the drug unless they first attested to their clinical abilities in a signed form kept on file by the manufacturer, and agreed to comply with reporting and other REMS requirements. FDA also imposed a Patient Form ETASU (later "ETASU D," pursuant to 21 U.S.C. § 355-1(f)(3)(D)), requiring the prescriber and patient to review and sign a special form with information about the mifepristone regimen and risks, and required the prescriber to provide the patient with a copy and place a copy in the patient's medical record. The same information contained in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling provided to patients with mifepristone.

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[15] Although the Subpart H regulations are sometimes referred to as FDA's "accelerated approval" regulations, FDA has explained elsewhere that its 2000 approval of Mifeprex, which occurred more than four years after the new drug application was submitted to FDA, did not involve an accelerated review.

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68. FDA's decision to subject Mifeprex to an ETASU under Subpart H was highly unusual. In the fifteen years from 1992 (the year the Subpart H regulations were promulgated) to February 2007 (just before the creation of the REMS statute), only seven NDAs, including Mifeprex, were approved subject to ETASU under Subpart H.[16] By comparison, FDA approved 961 NDAs with no additional restrictions in the roughly thirteen years from January 1993 to September 2005.[17]

69. The Food and Drug Administration Amendments Act of 2007 effectively replaced Subpart H of the FDCA regulations with the REMS statute. All drugs previously approved under Subpart H—including Mifeprex—were deemed by the Amendments Act to have a REMS in place. Following passage of the 2007 FDCA, Mifeprex continued to be subject to the same ETASU as before.

70. In 2011, FDA issued a new REMS for Mifeprex incorporating the same restrictions under which the drug was approved eleven years earlier.

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[16] *Id.* at 27.

[17] U.S. Gov't Accountability Off., *New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, GAO-07-49, 20 (Nov. 2006), http://www.gao.gov/assets/gao-07-49.pdf.

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71. In 2013, FDA reviewed the existing REMS and reaffirmed the restrictions already in place.[18]

72. In May 2015, Mifeprex's manufacturer (Danco) submitted a supplemental NDA proposing to update the label to reflect evidence-based practice across the country—mainly, the use of 200 mg of mifepristone instead of 600 mg. In July 2015, Danco also submitted its statutorily required REMS assessment, proposing minor modifications.

73. This submission prompted a review of the Mifeprex label and REMS by FDA in 2015-2016. As part of that review, FDA received letters from more than 40 medical experts, researchers, advocacy groups, and professional associations who asked, *inter alia*, that the REMS be eliminated in their entirety.

74. Signatories requesting that FDA eliminate the Mifeprex REMS included the American College of Obstetricians and Gynecologists (ACOG), the leading professional association of physicians specializing in the health care of women, which represents 58,000 physicians and partners in women's health; the American Public Health Association (APHA), the nation's leading public health organization; the Director of Stanford University School of Medicine's Division of Family Planning Services and Research; the Chair of the Department of Obstetrics and Gynecology at the University of New Mexico School of Medicine;

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[18]FDA Final Risk Evaluation and Mitigation Strategy (REMS) Review (Oct. 10, 2013), attached hereto as Ex. G.

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and the Senior Research Demographer in the Office of Population Research at Princeton University.

75. As one letter explained: "Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU)."[19] In asking FDA to "[e]liminate the REMS and ETASU for mifepristone," the letter specifically asked FDA to, among other things, (i) "[e]liminate the Prescriber Agreement certification requirement" and (ii) "remove the confusing and unnecessary Patient Agreement."[20]

76. The signatory organizations explained that the Prescriber Agreement certification requirement should be eliminated, because, among other things[21]:

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[19]Letter from SFP, *et al.*, to Stephen Ostroff, M.D., Robert M. Califf, M.D., & Janet Woodcock, M.D., 1 (Feb. 4, 2016) (SFP Letter to FDA), attached hereto as Ex. H.

[20]*Id.* at 2–4.

[21]*Id.* at 3.

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a. "*The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone*. . . . [H]ealth care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug, but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning and there is no medical reason for a Prescriber's Agreement to be required in addition."

b. "*The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats. Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence. Given such escalating harassment and violence against known abortion providers, clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers."

c. "*The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed . . . ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions."

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77. The organizations also argued that the Patient Agreement was unnecessary, explaining: "This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely."[22]

78. The letter also urged FDA to "[c]onsider the current legal and social climate," explaining that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[23] The letter concludes:

> Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that the drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS . . . .[24]

79. FDA summarized these "Advocacy Group Communications" as follows:

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[22] *Id.* at 4.

[23] *Id.* at 5.

[24] *Id.* at 6.

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> The Agency received three letters from representatives from academia and various professional organizations . . . . In general, these advocates requested FDA to revise labeling in a manner that would reflect current clinical practice, including the new dose regimen submitted by the Sponsor, and proposing to extend the gestational age through 70 days. Other requests were that the labeling not require that the drug-taking location for both Mifeprex and misoprostol be restricted to the clinic, and that labeling not specify that an in-person follow-up visit is required. The advocates also requested that any licensed healthcare provider should be able to prescribe Mifeprex and that the REMS be modified or eliminated, to remove the Patient Agreement and eliminate the prescriber certification, while allowing Mifeprex to be dispensed through retail pharmacies.[25]

80. A multidisciplinary FDA review team considered the requested changes. This review concluded that "no new safety concerns have arisen in recent years, and that the known serious risks occur rarely," and that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low."[26]

81. Following the multidisciplinary review team's analysis, FDA made several changes to Mifeprex's indication, labeling, and REMS. Relying on safety and efficacy data from multiple studies, FDA increased the gestational age limit from 49 to 70 days.[27] FDA also reduced the number of required in-person clinic

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[25]FDA, Ctr. for Drug Evaluation & Research, 020687Orig1s020, Cross Discipline Team Leader Review 25 (Mar. 29, 2016), attached as Ex. I.

[26]Ex. B (FDA 2016 Medical Review) at 9, 39, 47, 49.

[27]The overwhelming majority (80%) of abortions occur within the first 70 days (10 weeks) of pregnancy. Katherine Kortsmit, et al., *Abortion Surveillance*

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visits to one (whereas patients had previously been required to visit a clinic setting twice in order to receive the medication). FDA determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result in patients being in an "appropriate and safe location" when cramping and bleeding caused by the drug would begin.[28] FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments. Additionally, FDA allowed a broader set of healthcare providers, rather than only physicians, to prescribe mifepristone, finding no serious risk to patients from expanding the types of healthcare providers who could become

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– *United States, 2020*, 71 CDC Morbidity & Mortality Weekly Report 10 at 12 (Nov. 25, 2022), https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-H.pdf.

[28]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Summary Review at 15 (Mar. 29, 2016) (2016 Summary Review), attached hereto as Ex. J.

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certified under the 2016 REMS.[29] But FDA still required that mifepristone, the first drug in the regimen, be administered in a clinic setting.

82. In addition, FDA expert review team and the Director of FDA's Center for Drug Evaluation and Research recommended eliminating the Patient Agreement Form because it contains "duplicative information already provided by each healthcare provider or clinic," "does not add to safe use conditions," and "is a burden for patients."[30] But they were overruled by the FDA Commissioner, who directed the Form be retained.[31] FDA retained the in-person dispensing requirement and provider certification as well.

83. In 2019, FDA approved a different manufacturer's abbreviated new drug application for a generic version of mifepristone. When it approved the

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[29]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex REMS (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf (hereinafter 2016 REMS).

[30]Ex. J (2016 Summary Review) at 25.

[31]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, M.D., Ctr. for Drug Evaluation & Research, Regarding NDA 020687, Supp 20, 1 (Mar. 28, 2016) (hereinafter "Woodcock Patient Agreement Memo"), attached hereto as Ex. K.

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abbreviated NDA, FDA also established the Mifepristone REMS Program, which covers both Mifeprex and the generic.

84. In May 2020, the American College of Obstetricians and Gynecologists sued FDA, challenging the Mifepristone REMS Program's in-person dispensing requirement in light of the COVID-19 pandemic. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.). Over FDA's objection that "based on FDA's scientific judgment, the In-Person Requirements are necessary to assure safe use of mifepristone and thus to protect patients' safety," *id.* at 228, the U.S. District Court for the District of Maryland preliminarily enjoined the in-person dispensing requirements, allowing healthcare providers to forgo it based on their medical judgment for the duration of the declared COVID-19 public health emergency. *Id.* at 233.

85. In April 2021, FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of mifepristone by mail showed no increases in serious patient safety concerns. Thereafter, FDA commenced a formal REMS review.

86. Finally, on January 3, 2023, FDA modified the REMS by, *inter alia*, removing the in-person dispensing requirement entirely. However, as discussed

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further below, the Mifepristone REMS continue to impose both the Prescriber Agreement Form and the Patient Agreement Form. The 2023 REMS also added a new pharmacy-certification requirement.[32]

C. The Safety of Mifepristone

87. Mifepristone is extremely safe and effective for terminating early pregnancies.

88. As discussed above, FDA's approval of mifepristone in 2000 rested on a comprehensive evaluation of the scientific data, and FDA reasonably determined, in its expert judgment, that the evidence showed mifepristone is safe and effective for abortion of early pregnancy.

89. When FDA conducted another medical review of mifepristone in 2016 (based on the then 2.5 million uses of Mifeprex for medication abortion in the U.S. since the drug's 2000 approval) it found: "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely

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[32]FDA Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (2023 REMS), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf, attached hereto as Ex. L.

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rare."[33] FDA observed at that time that "[m]ajor adverse events . . . are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, *generally far below 0.1%* for any individual adverse event."[34] The Agency further stated that "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[35] Since that 2016 medical review, mifepristone has

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[33]Ex. B (FDA 2016 Medical Review) at 12; *see also* U.S. Food & Drug Admin., Full Prescribing Information for Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf ("Mifeprex Labeling"), attached hereto as Ex. M.

[34]Ex. B (FDA 2016 Medical Review) at 47 (emphasis added); *see also* Ex. M (Mifeprex Labeling) at 8, Table 2; *see also* Kelly Cleland et al., Significant Adverse Events and Outcomes After Medical Abortion, 121 OBSTETRICS & GYNECOLOGY 166, 166 (2013) ("Medical research has consistently demonstrated that mifepristone is safe and effective and that adverse events and outcomes are exceedingly rare, occurring in less than a fraction of 1% of cases.").

[35]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s):

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been used an additional 3 million times in the United States for medication abortion.

90. From the time mifepristone was approved in 2000, there have only been 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%.[36] Further, FDA acknowledges that *none* of these deaths can be causally attributed to mifepristone. The 28 reported deaths were included in the adverse events summary "regardless of causal attribution to mifepristone" and included cases of homicide, drug overdose, ruptured ectopic pregnancy, and sepsis (a life-threatening immune response to an infection).[37] And in its 2016 review, FDA noted that, while roughly half the deaths to that point were associated with Clostridial septic infections, "[t]here have been no Clostridial septic deaths reported in the US since 2009."[38]

91. In other cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but

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REMS Modification Memorandum at 3 (Mar. 29, 2016) (hereinafter 2016 REMS Modification Memorandum), attached hereto as Ex. N.

[36]Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[37]*Id.*

[38]*Id.*

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"pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[39]

92. The specific serious complications identified in the FDA-approved labeling for Mifeprex are "Serious and Sometimes Fatal Infections or Bleeding." But the labeling specifies that such "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion or childbirth"—in other words, any time after the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[40]

D. The January 2023 Mifepristone REMS

93. Despite this undisputed evidence of safety and effectiveness, FDA continues to impose a 2023 REMS with ETASU for mifepristone.

94. The current REMS was approved in January 2023 (the 2023 REMS).[41]

95. The 2023 REMS imposes three primary hurdles to accessing mifepristone. Two of these are continuing restrictions and the third is a new

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[39]Ex. F at 26 n.69.

[40]Ex. M (Mifeprex Labeling) at 2, 16.

[41]Ex. L (2023 REMS).

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restriction. Each hurdle unduly restricts mifepristone access without any corresponding medical benefit.

96. ***First***, the REMS continues to provide that mifepristone can only be prescribed by a health care provider who has undergone a "special[] certif[ication]" process in which they attest that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention or referral in the event of any complications.[42] This "special certification" must be submitted to each certified pharmacy to which a provider intends to submit Mifreprex prescriptions, and must also be submitted to the distributor if a prescriber intends to dispense in-office.

97. For many healthcare providers, becoming specially certified is unduly burdensome and raises safety concerns. Some providers are deterred by the unusual step of having to become certified to prescribe the medication; others, misled by mifepristone's REMS designation, misperceive it is a dangerous medication or out of the prescriber's scope of practice; and still others are not comfortable having their names compiled in a list of medication abortion prescribers for fear that they or their families may be targeted by anti-abortion activists. This fear is particularly acute for doctors who hold medical licenses in multiple states (with abortion laws different from the Plaintiff States'), and for medical residents in the Plaintiff States who intend to eventually practice in a

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[42]Mifepristone Prescriber Agreement Forms, attached as Ex. O.

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state that heavily restricts abortion. These concerns, which FDA was made aware of as far back as 2016, are heightened now due to the growing criminalization and penalization of abortion, including laws that subject health care providers to criminal penalties and significant monetary liability.

98. ***Second***, although the 2023 REMS allows mifepristone to be dispensed directly by pharmacies (as opposed to being dispensed by a provider in a healthcare clinic, as prior REMS required), the REMS unnecessarily requires dispensing pharmacies to be "specially certified" by the drug's sponsor.[43]

99. Special certification requires pharmacies to verify that mifepristone prescriptions are written only by "certified" providers and to adhere to additional burdensome communication, recordkeeping, and training requirements beyond what is required for the vast majority of prescription drugs. Under the REMS, a pharmacy cannot dispense mifepristone to a patient until it confirms that the provider who wrote the prescription is specially certified.[44] This hurdle creates new costs and administrative burdens for pharmacies—and worse, threatens unnecessary delay patients seeking time-sensitive medication.

100. Further, by limiting mifepristone dispensing to "certified" pharmacies, the REMS requires healthcare providers to track which pharmacies are certified to dispense mifepristone, rather than allowing patients to select their

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[43]Mifepristone Pharmacy Agreement Forms, attached as Ex. P.

[44]*Id.*

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pharmacy of choice. And the reverse is true as well—pharmacies that wish to dispense mifepristone must go through the added step of confirming that each mifepristone prescription comes from a "specially certified" provider.

101. ***Third***, the 2023 REMS retains the requirement that each patient sign a Patient Agreement Form in order to receive a mifepristone prescription.[45] This form, among other things, requires a patient to certify: "I have decided to take mifepristone and misoprostol to end my pregnancy."[46] This Patient Agreement Form must be signed by both the patient and provider, a copy must be placed into the patient's medical record, and a copy must be given to the patient along with the Medication Guide.

102. This Patient Agreement Form creates significant privacy and safety issues for both patients and providers. It specifically identifies the patient as taking the medication for the purpose of ending their pregnancy—as opposed to, for instance, miscarriage management, for which the medication is also frequently prescribed. Anyone who obtains access to the patient's medical record will thus have evidence that the patient received the medication for abortion, which is a particular concern for patients who receive care from a provider in a state where abortion is legal but reside in a state where abortion is illegal. Making matters worse, for patients who receive mifepristone for miscarriage

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[45]Mifepristone Patient Agreement Form, attached as Ex. Q.

[46]*Id.*

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management, the evidence will be false. The form also identifies the provider to anyone who obtains access to the patient's medical record or sees the copy of the form that must be provided to the patient—potentially including, for example, a patient's spouse, partner, or parent. This exposes providers and patients to threats of potential violence, threats of legal liability (even when the care provided is lawful in the relevant Plaintiff State), or other life-altering consequences. On top of that, because patients who take the medication for miscarriage management are also required to sign the Patient Agreement Form, it may be traumatizing for individuals experiencing a miscarriage to nonetheless have to attest that they are "decid[ing]" to "end [their] pregnancy."

103. None of the harms caused by the Patient Agreement Form is necessary, as the information contained on the form is duplicative of the information already provided to patients in the five-page Medication Guide that accompanies mifepristone. The comprehensive Medication Guide answers questions such as: "What symptoms should I be concerned with?"; "Who should not take Mifepristone tablets?"; "What should I tell my healthcare provider before taking Mifepristone tablets?"; "How should I take Mifepristone tablets?"; and "What are the possible side effects of Mifepristone tablets?"[47] The Patient Agreement Form is also duplicative of provider counseling, as medical

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[47]Mifepristone Medication Guide, attached as Ex. R.

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ethics require providers to counsel patients on the risks and benefits of all medications.

104. ***In sum***, although the 2023 REMS improved on the prior REMS by dropping the requirement to dispense mifepristone in person, the REMS nonetheless retains unduly burdensome, harmful, and unnecessary dispensing and prescribing requirements, continues to expose providers and patients to unnecessary privacy and safety risks, and creates new hurdles that further burden an already overstretched health care system.

E. The 2023 REMS Violate the FDCA

105. FDA's imposition of the burdensome 2023 REMS requirements is contrary to the FDCA.

106. As noted above, FDA may impose an ETASU on a medication only if the medication is "associated with a serious adverse drug experience," which the statute defines as one that "results in" death or "immediate risk of death," "inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or that "may jeopardize the patient and may require a medical or surgical intervention to prevent [such] an outcome . . . ." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4)(A)–(B). And an ETASU may be imposed only where "required . . . to mitigate a specific serious risk" of a serious adverse drug experience, and only where such risk is sufficiently severe

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that absent the ETASU, FDA would not approve or would withdraw approval of the medication. *Id.* §§ 355-1(b)(5), (f)(1)(A).

107. Mifepristone does not meet these stringent standards because it is not "associated with a serious adverse drug experience." To the contrary, FDA itself has concluded that serious adverse events following mifepristone use are "exceedingly rare."[48]

108. Since mifepristone was approved in 2000, there have been only 28 reported associated deaths out of 5.6 million uses—an associated fatality rate of .00005%. And not a single one of these deaths can be causally attributed to mifepristone.[49] By contrast, thousands of deaths have been associated with phosphodiesterase type-5 inhibitors for the treatment of erectile dysfunction (e.g., Viagra)—which are not subject to a REMS.[50] And "other drugs with higher

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[48]Ex. B (FDA 2016 Medical Review) at 47; *see also* Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[49]*Id.*

[50]Advancing New Standards in Reproductive Health , *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018"*, Mifepristone safety: Issue Brief (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

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complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[51]

109. Moreover, the ETASU violates the FDCA's requirement that such restrictions not be "*unduly burdensome* on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system[.]" 21 U.S.C. §§ 355-1(f)(2)(C)–(D) (emphasis added).[52]

110. As explained in more detail below, the 2023 REMS significantly burdens patient access to mifepristone without *any* appreciable safety benefits. These burdens fall particularly heavily on rural patients in the Plaintiff States because the vast majority of "specially certified" providers practice in cities. Plus, with a number of states imposing severe restrictions on access to abortion care that used to be constitutionally protected, many patients in these medically underserved areas of the country are turning to Plaintiff State providers for this care. This is particularly pronounced in Plaintiff States sharing borders with states

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[51]2018 Congress of Delegates, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone*, Am. Acad. Of Fam. Physicians (2019), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[52]*Supra* n.52.

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that allow little to no access—for example, in Washington, Oregon, and Nevada, which border Idaho, in Illinois, which borders Missouri and Indiana, and in New Mexico, which borders Texas. Against this backdrop, the 2023 REMS significantly and unduly burdens health care delivery in the Plaintiff States by imposing substantial, unjustified burdens on health care providers, clinics, pharmacies, and hospitals.

F. The 2023 REMS Are Unsupported by Science

111. The 2023 REMS requirements are not supported by scientific evidence.

112. First, the Patient Agreement Form remains in place even though the team of expert reviewers at FDA's Center for Drug Evaluation and Research (CDER) unanimously recommended eliminating it in 2016 because it is duplicative of informed consent laws and standards, "does not add to safe use conditions[,] . . . and is a burden for patients."[53] But this team of experts was overruled by the agency head.[54]

113. Similarly, the requirement that clinicians certify that they are competent to prescribe mifepristone provides no additional safety benefit beyond the numerous existing laws and safety standards already in place to ensure health care providers practice only within their competency. The certification

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[53]Ex. H (2016 Summary Review) at 25.

[54]Ex. I (Woodcock Patient Agreement Memo) at 1.

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requirement is also out of step with how FDA regulates other, less safe medications. Physicians are allowed to prescribe countless higher-risk drugs without first attesting to their competency to make an accurate diagnosis or provide follow-up care in the event of a complication.

114. The REMS requirement that pharmacies, too, must be "specially certified" in order to dispense mifepristone is similarly baseless. It requires pharmacies to confirm they have met the unnecessary provider-certification requirement before filling prescriptions, affords no patient safety benefits on top of the laws and standards governing the practice of pharmacy, and, instead, acts as a significant barrier to patient access to a time-sensitive medication.

115. Accordingly, the mifepristone REMS is opposed by leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA).

116. Since at least 2016, ACOG's position has been "that a Risk Evaluation and Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent

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with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients."[55]

117. And since at least 2018, AAFP's position has been that the REMS restrictions "are not based on scientific evidence"; are overly burdensome on practitioners and impede patient access to care, particularly "for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician"; cause "delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates"; and create "a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management[.]"[56]

118. In a June 21, 2022, letter to FDA Commissioner Califf, ACOG and AMA urged the Agency to "eliminate the requirement for patients to sign a form to get the drug" and "lift the requirement that prescribers acquire a certification from the manufacturer," noting that "[b]arriers to accessing mifepristone do not

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[55]Advocacy and Health Policy, *ACOG Statement on Medication Abortion*, ACOG (Mar. 30, 2016) https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion.

[56]*Supra* n.52.

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make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[57]

119. Further, in 2022, ACOG, along with 48 other organizations, submitted a citizen petition to FDA seeking to add miscarriage management as an indication to the drug's label, to eliminate or modify the REMS for that use, and more generally requesting the removal of the mifepristone REMS.[58]

120. The petition asked that "the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by [FDA Center for Drug Evaluation and Research] determined in 2016."[59]

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[57]Letter from Maureen G. Phipps, Am. Coll. of Obstetricians & Gynecologists, to Robert Califf, MD (Jun. 21, 2022), 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.

[58]Citizen Petition from Am. Coll. of Obstetricians & Gynecologists to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. FDA (Oct. 4, 2022), https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-website.pdf.

[59]*Id.* at 12.

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121. ACOG further explained that "the Certified Provider Requirement serves no benefit to patient safety," but is instead "redundant and unnecessary."[60] Moreover, ACOG noted that the provider-certification requirement has disproportionately affected rural patients because "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities."[61] Making matters worse, "rural residents are more likely to lack access to OBGYNs, meaning that surgical management is also less likely to be an option."[62] Moreover, "clinicians might have reasonable reservations about opting into a prescription system that could, if their certification were leaked, suggest they were an abortion provider and open them up to violence and harassment."[63]

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[60] *Id.* at 13.

[61] *Id.* at 14 (citing Bearak JM, Burke KL, Jones RK. *Disparities and change over time in distance women would need to travel to have an abortion in the USA: a spatial analysis*. Lancet Public Health. 2017; 2:e493–500 and Committee on Health Care for Underserved Women. *Health Disparities in Rural Women. American College of Obstetricians and Gynecologists.* Obstet Gynecol. 2014;123:384-388).

[62] *Id.* (citation omitted).

[63] *Id.*; *see also id.* ("Research has shown that without certification, more clinicians would prescribe mifepristone.") (citing Neill S, Goldberg AB, Janiak

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122. The ACOG's citizen petition also urged FDA not to include a pharmacy-certification requirement because "research . . . suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access."[64] The petition pointed specifically to a study "conducted . . . in California and Washington state suggest[ing] that pharmacies are already equipped to dispense the drug without

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E., *Medication management of early pregnancy loss: the impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy* [A289]. Obstet Gynecol. 2022 May;139: 83S; Calloway D, Stulberg DB, Janiak E. *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States.* Contraception. 2021 July; 104(1):24-28; *Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. "There's only one use for it": stigma as a barrier to mifepristone use for early pregnancy loss in Alabama*. [A31]. Obstet Gynecol. 2022 May:139:9S-10S; and Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics.* Contraception 2022;109(5):19-24).

[64] *Id.* at 15.

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special certification."[65] "As with the certified provider requirement," ACOG noted, "the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural [patients], contrary to the REMS statute."[66]

123. Finally, as ACOG pointed out, recent scholarship demonstrates that removing the REMS restrictions does not negatively affect patient safety:

> After Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ("normal prescribing"), there was no increase in complications from mifepristone use. [A] 2022 study . . . found no difference in the rate of any complication (0.67% vs. 0.69%) or in the rate of serious adverse events (0.03% vs. 0.04%) between the ten-month period when mifepristone was distributed with REMS-like restrictions and the twenty-eight-month period of normal prescribing after all such restrictions were lifted and mifepristone was prescribed with no special self-certification and dispensed routinely from pharmacies.[67]

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[65] *Id.* (citing Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. *Medication abortion with pharmacist dispensing of mifepristone.* Obstet Gynecol 2021;137(4):613-622).

[66] *Id.* at 16.

[67] *Id.* at 17 (citing Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*. N Engl J Med. 2022 Jan 6;386(1):57-67.)

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124. FDA rejected ACOG's citizen petition.[68]

125. In fact, FDA has repeatedly rejected the concerns raised by leading medical organizations and retained the medically unfounded REMS restrictions: renewing them in 2016,[69] 2019,[70] 2021,[71] and yet again in 2023.[72] FDA retained these restrictions notwithstanding its periodic reviews of the post-marketing data, which have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days' gestation (10 weeks).[73]

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[68]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Letter from Patrizia Cavazzoni, M.D., Regarding Docket No. FDA-2022-P-2425, (Jan. 3, 2023), https://www.regulations.gov/document/FDA-2022-P-2425-0003, attached hereto as Ex. S.

[69]Danco Labs., LLC, Mifeprex REMS (Mar. 2016), https://www.fda.gov/media/164649/download.

[70]Danco Labs., LLC, Mifepristone REMS (Apr. 2019), https://www.fda.gov/media/164650/download.

[71]Danco Labs., LLC, Mifepristone REMS (May 2021), https://www.fda.gov/media/164651/download.

[72]Ex. L (2023 REMS).

[73]U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-

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126. Even as mifepristone has remained subject to the unduly burdensome REMS restrictions, a less safe mifepristone product for the treatment of Cushing's syndrome has been available for over a decade with no similar restrictions. In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as treatment for Cushing's syndrome *without* a REMS.[74] This was done even though, as FDA noted in its 2016 Medical Review, Korlym "is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and] the rate of adverse events with Mifeprex is much lower."[75] Patients who are prescribed Korlym take one to four pills *daily*—which is 1.5 to 6 times the recommended dose for Mifeprex.[76]

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providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[74]HHS, Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number: 202107Orig1s000, Approval Letter* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Approv.pdf.

[75]Ex. B (2016 Medical Review) at 10.

[76]U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, *Application Number*: *202107Orig1s000, Labeling* (Feb. 17, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lbl.pdf.

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127. The risks associated with mifepristone are also lower than those of many other common medications, such as Viagra, Tylenol, anticoagulants (blood thinners), and penicillin. Again, since 2000, mifepristone has been used 5.6 million times with only 28 reported associated deaths, none of which can be causally attributed to mifepristone.[77] And in nearly all cases of fatal infections associated with mifepristone, FDA has acknowledged that "the critical risk factor" is not mifepristone but "pregnancy itself," as similar infections "have been identified both in pregnant women who have undergone medical abortion and those who have not[.]"[78]

128. By contrast, as the American Academy of Family Physicians has noted, "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]"[79]

129. Medications for erectile dysfunction have a mortality rate more than six times greater than mifepristone, and penicillin has a mortality rate three times greater than mifepristone.[80]

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[77]Ex. A (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[78]Ex. F at 26.

[79]*Supra* n.52.

[80]Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 651–52 (2022).

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130. Likewise, acetaminophen (Tylenol) toxicity is the most common cause of liver transplantation in the U.S. and is responsible for 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[81]

131. But none of these drugs is subject to a REMS.

132. And even though opioids are highly addictive and cause tens of thousands of fatalities per year from overdoses, the opioid REMS does not require providers to do anything; it only requires that opioid manufacturers *offer* optional training to healthcare providers who prescribe opioids, who may or may not choose to take it. FDA acknowledges that "[t]here is no mandatory federal requirement that prescribers or other [health care providers] take the training and no precondition to prescribing or dispensing opioid analgesics to patients."[82]

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[81]Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National Library of Medicine (Aug. 1, 2022), https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20responsible%20for%2056%2C000,is%20contained%20in%20combined%20products.

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

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133. Mifepristone use is also far safer than continuing a pregnancy. A person who carries a pregnancy to term is at least fourteen times more likely to die than a person who uses mifepristone to end a pregnancy.[83] Unequal access to adequate health care exacerbates the risk for those with less privilege. For example, Black women are three to four times more likely than white women to die a pregnancy-related death in the U.S.[84]

134. The two risks listed on the mifepristone label are also associated with many common obstetrical and gynecological procedures, such as vaginal delivery, surgical or medical miscarriage management, or insertion of an intrauterine long-acting reversible contraceptive (IUD). As the Mifeprisone Medication Guide acknowledges: "Although cramping and bleeding are an

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[83]Elizabeth G. Raymond & David E. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 215 (2012).

[84]Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe Maternal Morbidity and Mortality*, 61:2 Clinical Obstetrics & Gynecology 387, 387 (2018); *see also* Claire Cain Miller, Sarah Kliff, Larry Buchanan, *Childbirth is Deadlier for Black Families Even When They're Rich, Expansive Study Finds*, N.Y. Times (Feb. 12, 2023), https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share.

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expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a *miscarriage*, *surgical abortion*, medical abortion, or *childbirth*." (Emphasis added.)[85]

G. The 2023 REMS Unduly Burdens Access to Healthcare

135. The mifepristone REMS have significantly impeded access to abortion care. And the 2023 REMS is even more unduly burdensome than prior REMS in light of dramatically restricted access to care across the United States.

136. Even before *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), only a small fraction of counties in the United States had a clinician providing surgical abortions.[86] Mifepristone offers the possibility of vastly increased access to care by enabling primary care physicians to integrate abortion care into the services they provide. But the mifepristone REMS impedes the availability of medication abortion care, and so abortion care remains beyond

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[85]Ex. R (Mifepristone Medication Guide).

[86]Na'amah Razon, Sarah Wulf, et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, 109 Contraception 19 (May 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9018589/.

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the reach of many—even in states like the Plaintiff States in which abortion care is lawful and protected in various ways.[87]

137. According to one recent study, approximately 40 percent of "family physicians interviewed . . . either named or described the REMS criteria as a barrier to providing medication abortion."[88] These family physicians explained that "the REMS impede their ability to provide medication abortion within primary care" because they "require substantial involvement of clinic administration, who can be unsupportive," and because "[t]he complexity of navigating the REMS results in physicians and clinic administration . . . viewing medication abortion as not worth the effort, since it is only a small component of services offered in primary care."[89]

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[87] *Id.*

[88] *Id.*

[89] *Id.*; *see also* Sara Neill, MD, et al., *Medication Management of Early Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy* (describing a survey of obstetrician-gynecologists in which "[n]early all interviewees (17 of 19, 89%) listed the REMS as a barrier to mifepristone use. Barriers included [the] belief that the REMS indicated mifepristone was not available to general ob-gyns . . . and concerns about signing the required prescriber agreement").

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138. Another recent study of primary care physicians and administrators noted that "[a]bortion with mifepristone is safe and effective" and "falls well within the scope of primary care in the United States, as it involves patient assessment and health education for which primary care providers are extensively trained." But, the article concluded, the REMS are the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice."[90]

139. This, in turn, harms patients. Under the REMS, a person who turns to their trusted health care provider—often a family doctor or primary care physician—for a medication abortion cannot obtain that care unless the clinician is specially certified (or is willing to become specially certified), and either the clinician has arranged to stock the drug or a pharmacy serving the patient's area has also gone through the process to be specially certified. This is so even though that same provider can simply write the same patient a prescription for misoprostol, the second drug in FDA's approved regimen for medication abortion, or virtually any other prescription drug that the clinician deems medically appropriate—and a pharmacy can simply dispense it—without the need for any special certifications.

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[90]Danielle Calloway, Debra B Stulberg, & Elizabeth Janiak, *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, 104 Contraception 24 (July 2021).

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140. Forcing patients to go to "specifically certified" providers, as opposed to their primary care or family physicians, disrupts continuity of care, stigmatizes routine health care, and discourages patients from making the best healthcare choices for themselves and their families. This burden is especially harsh for patients whose access to healthcare is already diminished by poverty, language barriers, lack of transportation, racial discrimination, or other factors. And it is particularly burdensome given the limited time window in which medication abortion is available.

141. This results in worse health outcomes for patients who might otherwise rely on mifepristone to safely terminate their pregnancies, but are unable to obtain a medication abortion given the limited number of REMS-certified prescribers or pharmacies.

142. Some patients will effectively be unable to access abortion, and will carry an unwanted pregnancy to term, due to the limited number of providers who are able to prescribe mifepristone because of the REMS. A landmark study shows that patients denied abortion are more likely to: experience serious complications from the end of pregnancy, including eclampsia and death; stay tethered to abusive partners; suffer anxiety and loss of self-esteem in the short term after

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being denied abortion; and experience poor physical health for years after the pregnancy, including chronic pain and gestational hypertension.[91]

143. Still others will opt for surgical abortion, which FDA describes as a more "invasive medical procedure that increases health risks for some patients and that may be otherwise inaccessible to others."[92] As FDA acknowledges, access to mifepristone is particularly critical "[f]or patients for whom mifepristone is the medically indicated treatment because of the patient's pre-existing health condition."[93]

144. "For example," FDA has explained:

> surgical abortion involves anesthesia, but people who are allergic to anesthesia can experience a sudden drop in blood pressure with cardiorespiratory arrest, and death. And . . . patient populations for whom medication abortion is more appropriate than a surgical abortion include patients who are survivors of abuse, including rape and incest, for whom pelvic exams can recreate severe trauma, adolescent patients, who have not yet had a pelvic exam, and patients in the intensive care unit or trauma patients who have difficulty with the positioning required for suction D&C.

(Internal quotations and citations omitted.)[94]

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[91]Our Studies, *The Turnaway Study*, Advancing New Standards in Reproductive Health, https://www.ansirh.org/research/ongoing/turnaway-study.

[92]Defs.' [FDA] Opp'n to Pls.' Mot. for a Prelim. Inj., *All. for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023), ECF No. 28 at 38.

[93]*Id.* at 39.

[94]*Id.*

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145. Moreover, FDA itself has repeatedly confirmed and re-confirmed that mifepristone is safe and effective. According to FDA, mifepristone provides a "meaningful therapeutic benefit to patients" as compared to other treatments.

146. By unduly burdening patients' access to mifepristone through the 2023 REMS, FDA deprives patients of the therapeutic benefit of the drug without any scientific basis.

H. Injury to the Plaintiff States and Their Residents

Washington

147. The State of Washington's injuries exemplify those of other Plaintiff States caused by the mifepristone REMS.

148. In Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

149. In 2021 (the most recent year for which complete data is available), there were 15,358 abortions in Washington. Of those, 9,060—59%—were medication abortions using mifepristone. Fewer than 0.1% of mifepristone abortions in 2021 resulted in a complication that required hospitalization.

150. Washington providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. The 2023 REMS requirements pose substantial challenges to providers and patients, and have resulted in significant expenses for state institutions, including the University of Washington (UW).

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151. The State of Washington, through the UW, its largest institution of higher education, operates UW Medicine, a group of multiple public and private nonprofit entities sharing the mission to improve the health of the public. This includes the UW's two campuses of the University of Washington Medical Center, the UW Medicine Primary Care Clinics, the UW Medical School, and through a contract with King County, Harborview Medical Center. As an owner and operator of medical facilities that provide reproductive health care services and pharmacies that dispense mifepristone, Washington is subject to and harmed by the January 2023 REMS.

152. At the UW, for instance, implementation of the 2023 REMS requirements is currently being overseen by a subcommittee of more than 20 UW physicians, administrators, and staff. To date, the subcommittee members have expended hundreds of hours on REMS implementation work, with many outstanding tasks still to complete. This is valuable time that these UW employees could otherwise spend treating patients, conducting research, or attending to other critical job functions.

153. One area in which UW has dedicated substantial resources is in its work to make the REMS-required Patient Agreement Form available to its telemedicine patients. The 2023 REMS continues to require that the Patient Agreement Form be signed by both the patient and a certified provider before a prescription can be filled by a certified pharmacy. Completing the form

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is usually a simple task in person, but it poses significant challenges in the telehealth setting. UW staff have worked more than 100 hours on both operational and technical elements to implement this REMS component, including making the Patient Agreement Form accessible to telemedicine patients in a HIPAA-compliant form and designing a method to securely transmit the form to the patient for their signature and then securely re-route the form back to the provider.

154. This work has been further complicated by the fact that some patients may not have access to or comfort with certain technologies (such as smartphones with scanning apps), making it challenging for UW to create a technology process that does not exacerbate inequities in patient access to abortion care.

155. Another area of significant time and expense has been implementation of the provider-certification requirement for telehealth providers. UW has hundreds of providers who are eligible to provide telehealth services. To ensure UW providers who may want to prescribe mifepristone are in compliance with the 2023 REMS requirements, UW is currently conducting outreach to ensure all interested, qualified providers are aware of the 2023 REMS requirements. UW operational staff then has to work with each provider who expresses an interest in prescribing mifepristone to ensure that the physician completes the Prescriber Agreement Form and transmits it to the UW Pharmacy.

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Providers then have to be trained on the new technology interfaces required for the Patient Agreement Form as well as the additional steps required in order to submit a mifepristone prescription for a medication abortion to a UW pharmacy. This outreach will likewise need to be done for UW's medical residents. This will require ongoing work as new healthcare providers and residents join UW.

156. UW has also had to devote significant time to designing electronic safeguards to help protect the safety of its providers. Some UW physicians, for instance, have expressed concern that by completing the Prescriber Agreement Form and having their name on a list of certified medication abortion prescribers, they could become a target of anti-abortion violence or harassment in the event the list were leaked or compromised.[95] Given the growing criminalization and

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[95]Abortion providers have long faced stigma, harassment, and violence. In 2021, 182 death threats were made against abortion providers. *See* National Abortion Federation, *2021 Violence & Disruption Statistics*, https://prochoice.org/wp-content/uploads/2021_NAF_VD_Stats_Final.pdf; *see also, e.g.*, U.S. Dep't of Justice, *Recent Cases on Violence Against Reproductive Health Care Providers* (Oct. 18, 2022), https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers; Megan Burbank, *Planned Parenthood awarded $110K after Spokane clinic protests*, CROSSCUT (Dec. 20, 2022), https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-after-spokane-clinic-protests]; Ted McDermott, *Windows smashed at Planned*

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penalization of abortion following the *Dobbs* decision, these concerns are further heightened for doctors who hold medical licenses in multiple states (including states where abortion laws differ from Plaintiff States') and for medical residents who later intend to practice in states where abortion is illegal or heavily restricted.[96] While UW is working hard to protect its providers—by, for example, creating additional interfaces so that a telehealth appointment for a medication

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Parenthood in Spokane Valley; suspect arrested, THE SPOKESMAN-REVIEW (July 5, 2021), https://www.spokesman.com/stories/2021/jul/05/windows-smashed-at-planned-parenthood-in-spokane-v/.

[96]Recognizing the reality of potential prosecution of Washington abortion providers, the Washington's Office of the Insurance Commissioner (OIC) recently approved coverage to reimburse physician policyholders for legal fees and expenses incurred in defending against a criminal action that comes from providing direct patient care, including abortions. As Insurance Commissioner Mike Kreidler explained, "As states like Texas threaten legal and criminal action against physicians, the OIC is determined to counter this by assisting medical malpractice insurers wherever we can." Press Release, Office of the Insurance Commissioner, New insurance coverage approved to help doctors who face criminal charges for providing legal abortions (Sept. 27, 2022), https://www.insurance.wa.gov/news/new-insurance-coverage-approved-help-doctors-who-face-criminal-charges-providing-legal.

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abortion can only be booked with a telehealth clinic (not a specific provider), thereby ensuring that an individual provider's name is not made available before the appointment—many physicians remain concerned about having to become a "certified prescriber" of medication abortion. The provider-certification requirement thus creates additional, unnecessary risks for Washington employees, providers, and residents that would not exist without the REMS. These risks have become exponentially higher in the post-*Dobbs* era, even as Washington continues to protect the right to choose and provide abortion care.

157. FDA recognizes such concerns, but disregarded them in issuing the 2023 REMS. FDA shields the identities of its own employees whose work relates to mifepristone to protect their health and safety, in light of the violence and harassment surrounding the provision of abortion.

158. The January 2023 REMS also places a significant burden on UW's pharmacies. Prior to the January 2023 REMS, UW pharmacies did not distribute mifepristone for medication abortion, as those medications had to be provided directly to the patient by the provider at an in-patient visit in a UW clinic (or, during the COVID-19 pandemic, by the provider via mail). With the easing of the in-patient and provider-only distribution requirements, UW is now working to stock mifepristone at both its inpatient pharmacies and through its mail-order pharmacy for its telehealth patients. But the requirements

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associated with becoming a certified pharmacy have created a significant additional workload for UW pharmacy team members.

159. Most significant is the requirement that UW pharmacies verify that each prescriber of mifepristone has a signed Prescriber Agreement Form on file with the pharmacy before a prescription can be filled. This has required extensive work by both UW operations and IT staff to determine how to host a dynamic list of certified providers in a secure but easily verifiable manner for UW pharmacy personnel.

160. Under the 2023 REMS program requirements, UW's pharmacies are also required to ensure that the drug is dispensed within four calendar days after the pharmacy receives the prescription (or the pharmacy must engage in additional consultation with the prescribing physician), which has required an additional workflow to ensure compliance. The same is true for the REMS requirement that authorized pharmacies record the National Drug Code (a unique identifier for drug packages) and lot number from each package of mifepristone dispensed. To date, UW pharmacy staff has expended approximately 80–100 hours on implementation work to comply with the 2023 REMS, and this work is not yet complete. The pharmacy needs additional hours to finalize these workflows and to train staff on the mifepristone REMS program requirements.

161. As demonstrated by the hundreds of hours being spent by UW physicians and staff to implement the 2023 REMS program requirements,

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compliance with the REMS program creates an expensive and substantial burden for Washington's hospitals, clinics and pharmacies. This is a financial and administrative burden that many hospitals, clinics, and pharmacies in Washington—particularly small or family-operated ones—cannot shoulder.

162. As a result, the 2023 REMS requirements unnecessarily limit the number of providers in Washington who can prescribe mifepristone and the patients' options for filling a mifepristone prescription. These unnecessary limitations, in turn, unduly burden access to mifepristone for Washington patients.

163. In eastern Washington, the student medical center at Washington State University (WSU), Cougar Health Services, has no REMS-certified providers nor is its campus pharmacy REMS-certified. WSU students seeking medication abortion cannot obtain medication abortion services at the student medical center or have a mifepristone prescription filled at the campus pharmacy, but are instead referred off-campus. This referral process is time-sensitive, requires many students to establish care at a new facility, and often creates undue stress for the student attempting to access care.

164. As the WSU example highlights, the harms caused by the REMS are particularly pronounced in central and eastern Washington, where access to abortion is already limited by a smaller density of providers and more rural population. Of the 20 eastern Washington counties, only nine have abortion

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providers. By irrationally limiting who may prescribe and dispense mifepristone, the REMS ensure that abortion care remains unavailable to many rural Washingtonians.

165. The REMS certification requirements pose particular hardships in eastern Washington for providers and pharmacies who serve patients from other states—including Idaho—or who may live in Idaho themselves. For these providers and pharmacists, putting themselves on a list of abortion providers raises serious concerns about criminal or civil liability under Idaho's draconian anti-abortion laws.

166. Moreover, the REMS pharmacy requirements also limit the number of specially certified pharmacies in Washington, thereby limiting drug availability for patients, particularly in rural communities underserved by large pharmacy chains. While mail-order prescriptions may be desirable for some, they may be infeasible or impossible for others, including patients experiencing housing insecurity; traveling from other states; close to the gestational limit; living in rural areas dependent on P.O. boxes for mail delivery—which are ineligible for mail-order prescriptions; or for whom receipt of abortion medication at home may trigger domestic violence or housing loss. For these patients, local pharmacy pick-up may be necessary—but unavailable due to the 2023 REMS requirements.

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167. For patients receiving medical care in Washington, the Patient Agreement Form creates an additional, unnecessary risk. While medical institutions and providers have enacted safeguards to ensure the safety and privacy of all medical records, the simple fact that a patient has an additional document in their medical record attesting to their medication abortion creates an added risk for patients—particularly for those patients who travel to Washington for medical treatment from states where the abortion would be illegal. Abortion providers have been targets for hackers seeking to steal information about both patients and providers. In 2021, for example, hackers accessed data about roughly 400,000 patients from Planned Parenthood Los Angeles.[97] Here in Washington, providers report frequent phishing attacks aimed at illegally obtaining information about patients and providers.

168. This risk is compounded by the fact that providers are required to provide patients with a copy of the Patient Agreement Form, which could, in turn, be found by a patient's spouse, partner, or parent (who might otherwise be unaware of the patient's medication abortion), potentially putting the patient at risk of violence or abuse. And the Patient Agreement Form is uniquely

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[97]Gregory Yee and Christian Martinez, *Hack exposes personal information of 400,000 Planned Parenthood Los Angeles patients*, LOS ANGELES TIMES (Dec. 1, 2021), https://www.latimes.com/california/story/2021-12-01/data-breach-planned-parenthood-los-angeles-patients.

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problematic for patients who receive mifepristone for miscarriage management, as they must falsely attest that they are "decid[ing] . . . to end [their] pregnancy" and then have that document placed into their medical record. And again, all of these risks are compounded for individuals traveling to Washington to receive care they cannot access in their home state.

Oregon

169. As in Washington, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management in Oregon. The prescription and use of mifepristone with misoprostol is the standard of care for miscarriage management and medication abortion in Oregon.

170. According to state data for 2021, 4,246 medication abortions were administered by Oregon medical providers. Based on information available at the time of filing, it is likely that most of those medication abortions were effected with a mifepristone prescription.

171. Those 4,246 medication abortions constitute about 60 percent of abortions in Oregon in 2021. At the time of filing, the State of Oregon is not aware of any Oregon patient who has experienced serious adverse effects or death as the result of being prescribed and using mifepristone for miscarriage management or medication abortion.

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172. Oregon providers have been hindered in providing care, and patients have been hindered in receiving care, due to the mifepristone REMS. Medical providers, hospital administrators, and staff spend many hours implementing REMS requirements, including making Patient Agreement Forms available to patients and protecting the security of Provider Agreement Forms.

173. The REMS requirements also add to the amount of provider time required for each patient. Even at a conservative estimate of two to three minutes per patient, over a hundred—potentially hundreds—of provider hours are spent each year for the review, discussion, and signing of the Patient Agreement Forms. That is valuable time that those medical providers could otherwise spend treating patients or attending to other important work.

174. Those requirements are also duplicative of the counseling that Oregon providers already provide to their patients, namely in discussing risks and benefits, explaining the treatment and alternatives, and obtaining informed consent.

175. Oregon patients seeking care for miscarriage management have also experienced the same issues as similarly situated Washington patients. Namely, because the Patient Agreement Form is written specifically for the context of medication abortion, it requires them to inaccurately attest that they have decided to "end [their] pregnancy." That causes unnecessary confusion for those patients.

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176. In addition to the unnecessary (and sometimes frightening) confusion, the Patient Agreement Form has caused unwarranted additional anguish in some seeking care for miscarriage management. That is because the form does not distinguish between the use of mifepristone for miscarriage management and its use for the intentional termination of a pregnancy. Consequently, for those already dealing with the distress of losing a pregnancy, the medically unjustified REMS impose the additional emotional burden of requiring the patient to incorrectly attest that the pregnancy loss was intentional as a prerequisite for obtaining medically appropriate healthcare for their miscarriage.

177. The REMS requirements also reduce access to essential reproductive healthcare in Oregon. Namely, many rural providers in Oregon do not have the volume of patient care to justify the onerous steps required to comply with the REMS for mifepristone. As a result, rather than seek certification themselves, they often refer patients to other providers. That requires patients to see a second provider for something that their original provider otherwise could have handled quickly and safely, results in reduced patient choice, and also places the burden of additional patient loads on those certified providers that accept referrals.

178. And similar to Washington patients, the reduced access to essential reproductive health care results in additional delays to patients receiving

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healthcare. For example, it takes time for the patient to receive the referral from their primary provider. It takes time for the patient to establish care with the second provider. It can take additional time if the patient seeks in-person consultation and needs to travel for care. And it takes time for the patient to wait for any healthcare delays caused by the patient-load resulting from the number of referrals. Those are delays to healthcare for conditions for which time is of the essence. And those delays often contribute to patients having reduced availability of healthcare options and adverse effects to patient health.

Arizona

179. Access to safe and effective medication abortion is critically important for Arizonans. Arizonans experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Colorado

180. The State of Colorado, through the University of Colorado, its largest institution of higher education, operates a woman's health clinic. As an owner and operator of a medical clinic that provides reproductive health care services and dispenses mifepristone, Colorado is subject to and harmed by the January 2023 REMS.

181. Providers and staff at the University of Colorado have expended time and resources complying with the 2023 REMS requirement, including developing and processing the Prescriber Agreement Form and the

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Patient Agreement Form. Further, the 2023 REMS prevent non-certified providers from prescribing mifepristone to their patients. As a result, those patients often must make additional clinic visits—sometimes at different locations—to obtain mifepristone.

182. Further, patients in Colorado suffer the same harms experienced by patients in other states outlined above and below.

Connecticut

183. Access to safe and effective medication abortion is critically important for Connecticut residents. Connecticut residents experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Delaware

184. Like Washington, Delaware residents rely on mifepristone to access safe and effective abortion care and management of miscarriages. Analysis of data from 2014 to 2020 shows that Delawareans have increasingly relied on medication abortion for early pregnancy termination. In 2014, there were 2,937 abortions in Delaware. Of those, 1,292—44%—were medical abortions using mifepristone. In 2020 (the most recent year for which complete data is available), there were 2,281 abortions in Delaware. Of those, 1,492—65.4%—were medical abortions using mifepristone.

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185. Restricting access to mifepristone needlessly harms Delawareans who increasingly rely on it.

Illinois

186. In Illinois, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

187. In 2020 (the most recent year for with public data), there were 46,243 reported abortions in Illinois. Of those, 23,765—51%—were medication abortions using mifepristone.

188. The mifepristone REMS requirements impede drug availability for Illinois residents by limiting the providers that can prescribe and the pharmacies that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

189. Limited access to abortion and miscarriage management medication increases other health care costs, including more expensive procedural or later-stage abortion care, emergency care, and care related to complications due to unwanted pregnancies, childbirth, and miscarriage.

190. A significant proportion of this cost is borne by the State, which is one of only 16 states that goes beyond federal Medicaid limits and uses state funds to cover abortion care for people enrolled in Medicaid. From January 2019 to May 2022, the State covered approximately 29,000 mifepristone prescriptions.

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191. State Medicaid reimbursement rates are higher for procedural abortions and abortions taking place later in gestation. The bundled State Medicaid reimbursement rate for medication abortion is $558. In contrast, the lowest rate for a procedural abortion is $798. Because the 2023 REMS requirements artificially limit the number of providers who can prescribe mifepristone and the pharmacies that can fill prescriptions, fewer people have access to mifepristone abortions. This restriction results in more higher-cost procedural abortions. Broad mifepristone access is a critical tool for addressing the financial impact on the State.

192. As Illinois's neighboring states have curtailed abortion access, Illinois has seen a 28% increase in abortions from April 2022 to August 2022, creating additional strain on Illinois providers and healthcare systems. The REMS certification requirements pose particular hardships for Illinois providers and pharmacies because Illinois is an abortion oasis in the Midwest and a significant portion of patients seeking abortion care in Illinois are traveling from Indiana, Missouri, and other nearby states where abortion is restricted. For these providers and pharmacists, as well as patients traveling from out of state, the REMS certification requirements and Patient Agreement Form create additional risks of civil or criminal liability.

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Attorney General of Michigan

193. Access to safe and effective medication abortion is critically important for Michiganders. Michiganders experience harms as a result of the 2023 REMS that are similar to those experienced by residents of the Plaintiff States.

Nevada

194. In Nevada, mifepristone is widely used in combination with misoprostol as a safe, effective, FDA-approved regimen for medication abortions. It is also used in the medical management of early pregnancy loss.

195. Medication abortions represent the largest share of pregnancy termination procedures performed in Nevada. From December 2021 to November 2022, 49% of all abortions performed in Nevada were medication abortions.

196. The Nevada Department of Health and Human Services, Division of Health Care Financing and Policy (DHHS) administers the Medicaid program in Nevada. It is responsible for ensuring high quality, cost-effective care to Medicaid recipients while maintaining compliance with federal Medicaid requirements.

197. Nevada Medicaid fee-for-service covers mifepristone.

198. The reduced availability of mifepristone will financially impact DHHS. Providers and patients will be forced to adopt alternatives including

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surgical abortions which are more invasive, costly, and can expose patients to higher health risks, e.g., excessive bleeding.

199. Since the *Dobbs* decision, Nevada has experienced a marked increase in out-of-state patients seeking abortion care in state. In 2021, Nevada experienced an average of 47 out-of-state patients per month over a six-month period. In the first half of 2022, the average increased to 55 out-of-state patients. Post-*Dobbs*, there was an immediate spike of 113 in July 2022, after which the average leveled to 80 out-of-state patients per month.

200. The reduced availability of mifepristone will financially burden Nevada reproductive healthcare providers attempting to service this increased patient load.

201. The Mifepristone REMS program imposes medically unnecessary barriers to the prescription, distribution, and use of mifepristone by Nevada clinicians and patients. The REMS Patient Agreement Form must be signed by both a patient and a certified provider before a prescription can be filled by a qualified pharmacy. This imposes a significant burden for telehealth patients or patients without access to smartphones or scanning apps.

202. A pharmacy can only become qualified by undergoing the REMS certification process which further limits the availability of mifepristone in Nevada.

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203. The barriers created by the REMS program disproportionately burden people of color, low-income families, and communities within Nevada's large rural regions whose residents would have to travel long distances to seek alternative reproductive healthcare services.

204. These barriers interfere with Nevada's inherent authority to provide for the health and welfare of its residents.

New Mexico

205. New Mexico's injuries are exemplified in the sections discussing Washington's and the other Plaintiff States' injuries.

206. New Mexico repealed its antiquated prohibition of abortion in 2021.[98]

207. Nonetheless, many communities in New Mexico—particularly the rural communities—do not currently have adequate access to reproductive health care services.

208. New Mexico's injuries are exacerbated by various local cities and counties in the State of New Mexico enacting ordinances attempting to regulate abortion, declaring unlawful the delivery of abortion medications, and creating a private cause of action against abortion clinics. New Mexico residents in these cities and counties, as well as in other rural communities in the State, are particularly subject to the harms described in this Complaint.

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[98]NMSA 1978, §§ 30-5-1 to -3 (repealed 2021).

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Rhode Island

209. In Rhode Island, mifepristone is a critical medicine for providing safe and effective abortion care as well as for supporting miscarriage management.

210. The mifepristone REMS requirements impede drug availability for Rhode Islanders by limiting the providers that can prescribe and the pharmacies that can dispense the medication, while creating additional barriers to patient access through the Patient Agreement Form requirement.

211. Limited access to abortion and miscarriage management medication increases other health care utilization costs, including emergency care, resulting from complications due to unwanted pregnancies, childbirth, and miscarriage. A significant proportion of this cost is borne by the state, in which over 30% of Rhode Islanders are enrolled in Medicaid.

212. Rhode Islanders are harmed when access to mifepristone is limited, including the emotional, financial, and social harms that individuals experience by having to carry an unwanted pregnancy to term or not having access to the benefit of miscarriage management medication.

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Vermont

213. Medication abortion is critically important for Vermonters. In 2019, 59% of abortions in Vermont were medication abortions; in 2020, that number rose to 75%.[99]

214. The harms that the REMS cause are particularly acute in Vermont because the state's rurality makes it difficult for many Vermonters to access providers. Less than a third of Vermont counties have abortion providers—meaning that 43% of women of reproductive age live in a county without an abortion provider.[100]

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[99] Agency of Human Services, *Vermont 2019 Vital Statistics: 135th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 139, Vermont Department of Health (June 2021), https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-2019VSB_final.pdf; Agency of Human Services, *Vermont 2020 Vital Statistics: 136th Report Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and Dissolutions* at 142, Vermont Department of Health (July 2022) https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202020.pdf.

[100] Jesse Philbin, et al., *10 US States Would Be Hit Especially Hard by a Nationwide Ban on Medication Abortion Using Mifepristone*, GUTTMACHER

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V. FIRST CAUSE OF ACTION
(Administrative Procedure Act—Agency Action in Excess of Statutory Authority and Contrary to Law)

215. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

216. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

217. This Court must "hold unlawful and set aside agency action" that is, *inter alia*, "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law[.]" 5 U.S.C. § 706(2).

218. Through their actions described above, Defendants violated 5 U.S.C. § 706(2)(C) by acting in excess of statutory jurisdiction, authority, limitations, and short of statutory right in promulgating the mifepristone 2023 REMS.

INSTITUTE (Feb. 7, 2023), https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using.

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VI. SECOND CAUSE OF ACTION
(Administrative Procedure Act—Arbitrary and Capricious Agency Action)

219. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

220. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

221. FDA's promulgation of the mifepristone 2023 REMS was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

VII. THIRD CAUSE OF ACTION
(Administrative Procedure Act—Action Contrary to Constitutional Right)

222. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

223. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing the Plaintiff States irreparable harm for which the States have no other adequate remedy under 5 U.S.C. § 704.

224. FDA's promulgation of the mifepristone 2023 REMS treated similarly situated parties differently without adequate justification, and therefore violates the constitutional guarantee of equal protection in violation of 5 U.S.C. § 706(2)(B).

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VIII. FOURTH CAUSE OF ACTION
(Equal Protection)

225. The Plaintiff States reallege and incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

226. Through their actions described above, Defendants violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the United States Constitution.

227. Through the 2023 REMS, FDA reduces access to a critical and time-sensitive health care service needed by pregnant people. And FDA treats providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication. FDA's actions are irrational and violate the Fifth Amendment under any standard of review.

IX. PRAYER FOR RELIEF

WHEREFORE, Washington, Oregon, Arizona, Colorado, Connecticut, Delaware, Illinois, Attorney General of Michigan, Nevada, New Mexico, Rhode Island, and Vermont pray that the Court:

a. Declare, pursuant to 28 U.S.C. § 2201, that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;

b. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the Administrative Procedure Act;

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c. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the United States Constitution;

d. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from enforcing or applying the mifepristone REMS;

e. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from taking any action to remove mifepristone from the market or reduce its availability; and

f. Award such additional relief as the interests of justice may require.

DATED this 23rd day of February 2023.

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