

1 ROBERT W. FERGUSON
 Attorney General
 2 NOAH GUZZO PURCELL, WSBA #43492
 Solicitor General
 3 KRISTIN BENESKI, WSBA #45478
 First Assistant Attorney General
 4 COLLEEN M. MELODY, WSBA #42275
 Civil Rights Division Chief
 5 ANDREW R.W. HUGHES, WSBA #49515
 LAURYN K. FRAAS, WSBA #53238
 6 Assistant Attorneys General
 TERA M. HEINTZ, WSBA #54921
 7 Deputy Solicitor General
 800 Fifth Avenue, Suite 2000
 8 Seattle, WA 98104-3188
 (206) 464-7744
 9

10 **UNITED STATES DISTRICT COURT**
EASTERN DISTRICT OF WASHINGTON

11 STATE OF WASHINGTON;
 12 STATE OF OREGON; STATE OF
 ARIZONA; STATE OF
 13 COLORADO; STATE OF
 CONNECTICUT; STATE OF
 14 DELAWARE; STATE OF
 ILLINOIS; ATTORNEY GENERAL
 15 OF MICHIGAN; STATE OF
 NEVADA; STATE OF NEW
 16 MEXICO; STATE OF RHODE
 ISLAND; STATE OF VERMONT;
 17 DISTRICT OF COLUMBIA;
 STATE OF HAWAII; STATE OF
 18 MAINE; STATE OF MARYLAND;
 STATE OF MINNESOTA; and
 19 COMMONWEALTH OF
 PENNSYLVANIA,

20 **Plaintiffs,**

21 **v.**

NO. 1:23-cv-3026-TOR
 AMENDED COMPLAINT

1 UNITED STATES FOOD AND
2 DRUG ADMINISTRATION;
3 ROBERT M. CALIFF, in his official
4 capacity as Commissioner of Food
5 and Drugs; UNITED STATES
6 DEPARTMENT OF HEALTH AND
7 HUMAN SERVICES; and XAVIER
8 BECERRA, in his official capacity as
9 Secretary of the Department of
10 Health and Human Services,

Defendants.

11 I. INTRODUCTION

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

21 2. More than 22 years ago, the United States Food and Drug
22 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

1 review of the scientific evidence, which established that mifepristone is safe and
2 effective.

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

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

12 5. But FDA has continued to hamper access by singling out
13 mifepristone—and the people in the Plaintiff States who rely on it for their
14 reproductive health care—for a unique set of restrictions known as a
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16 ¹FDA, Mifepristone U.S. Post-Marketing Adverse Events Summary
17 through 06/30/2022, <https://www.fda.gov/media/164331/download>
18 (“Mifepristone U.S. Post-Marketing Adverse Events”), ECF No. 1-2.

19 ²FDA, Ctr. for Drug Evaluation & Research, No. 020687Orig1s020,
20 Mifeprex Medical Review(s) at 12 (Mar. 29, 2016),
21 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020M
22 [edR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf) (“FDA 2016 Medical Review”), ECF No. 1-3.

1 Risk Evaluation and Mitigation Strategy (REMS). The restrictions on
2 mifepristone are a particularly burdensome type of REMS known as Elements to
3 Assure Safe Use (ETASU), which strictly limit who can prescribe and dispense
4 the drug. FDA’s decision to continue these burdensome restrictions in
5 January 2023 on a drug that has been on the market for more than two decades
6 with only “exceedingly rare” adverse events has no basis in science. It only serves
7 to make mifepristone harder for doctors to prescribe, harder for pharmacies to
8 fill, harder for patients to access, and more burdensome for the Plaintiff States
9 and their health care providers to dispense.³ Not only that, but the REMS require
10 burdensome documentation of the patient’s use of mifepristone for the purpose
11 of abortion, making telehealth less accessible and creating a paper trail that puts
12 both patients and providers in danger of violence, harassment, and threats of
13 liability amid the growing criminalization and outlawing of abortion in other
14 states.

15 6. FDA has imposed REMS for only 60 of the more than 20,000⁴ FDA-
16 approved prescription drug products marketed in the U.S. These cover dangerous
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20 ³ECF No. 1-3 (FDA 2016 Medical Review) at 47.

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

1 | drugs such as fentanyl and other opioids, certain risky cancer drugs, and high-
2 | dose sedatives used for patients with psychosis.⁵

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

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

14 | **II. JURISDICTION AND VENUE**

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

18 | 10. This action for declaratory and injunctive relief is authorized by
19 | 28 U.S.C. §§ 2201 and 2202, by Federal Rules of Civil Procedure 57 and 65, and
20 | by the inherent equitable powers of this Court.

21 | _____
22 | ⁵*Id.*

1 11. The Court has personal jurisdiction over Defendants pursuant to
2 28 U.S.C. § 1391(e) because Defendants are agencies and officers of the
3 United States.

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

11 III. PARTIES

12 Washington

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

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

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

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

4 **Oregon**

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

10 **Arizona**

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

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

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

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

4 **Colorado**

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

10 **Connecticut**

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

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

18 25. Access to mifepristone for medicated abortions is increasingly
19 critical in Connecticut. An ongoing wave of hospital closures and consolidations
20 threaten to leave swaths of the state without access to on-site reproductive
21 healthcare, even as demand for abortion care has increased in the aftermath of
22 *Dobbs*.

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

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

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

14 **Delaware**

15 29. Plaintiff the State of Delaware is a sovereign state of the
16 United States of America. This action is brought on behalf of the State of
17 Delaware by Attorney General Kathleen Jennings, the “chief law officer of the
18 State.” *Darling Apartment Co. v. Springer*, 22 A.2d 397, 403 (Del. 1941).
19 Attorney General Jennings also brings this action on behalf of the State of
20 Delaware pursuant to her statutory authority. Del. Code Ann. tit. 29, § 2504.

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1 30. Delaware additionally brings this suit in its capacity as *parens*
2 *patriae* to protect its quasi-sovereign interest in the health and well-being of
3 Delaware residents.

4 **Illinois**

5 31. Plaintiff the State of Illinois is a sovereign state of the United States
6 of America. This action is brought on behalf of the State of Illinois by Attorney
7 General Kwame Raoul, the State’s chief legal officer. *See* Ill. Const. art. V, § 15;
8 15 ILCS 205/4.

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

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

16 **Attorney General of Michigan**

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

20 35. The Attorney General brings this suit in her capacity as
21 *parens patriae* to protect Michigan’s quasi-sovereign interest in the health and
22 well-being of Michigan residents.

1 **Nevada**

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

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

7 38. Nevada provides reproductive healthcare services including
8 medication abortions using mifepristone.

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

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

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

20 **New Mexico**

21 42. Plaintiff State of New Mexico, represented by and through its
22 Attorney General, is a sovereign state of the United States of America.

1 Attorney General Raúl Torrez is the chief legal officer of the State of
2 New Mexico. He is authorized to prosecute all actions and proceedings on behalf
3 of New Mexico when, in his judgment, the interest of the State requires such
4 action. N.M. Stat. Ann. § 8-5-2(B). Likewise, he shall appear before federal
5 courts to represent New Mexico when, in his judgment, the public interest of the
6 state requires such action. N.M. Stat. Ann. § 8-5-2(J). This challenge is brought
7 pursuant to Attorney General Torrez’s statutory authority.

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

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

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

18 **Rhode Island**

19 46. The Rhode Island Attorney General is the chief legal officer for the
20 State of Rhode Island. The Rhode Island Attorney General’s powers and duties
21 include acting in federal court on behalf of the State on matters of public concern.
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1 47. Rhode Island has standing because the 2023 REMS create barriers
2 to accessing medically necessary abortion and miscarriage care, leading to
3 subsequent health care utilization, including emergency care, some cost of which
4 is borne by the state through Medicaid expenditures.

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

8 **Vermont**

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

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

14 **District of Columbia**

15 51. Plaintiff the District of Columbia is a sovereign municipal
16 corporation organized under the Constitution of the United States. It is
17 empowered to sue and be sued, and it is the local government for the territory
18 constituting the permanent seat of the federal government. The District is
19 represented by and through its chief legal officer, the Attorney General for the
20 District of Columbia, Brian L. Schwalb. The Attorney General has general charge
21 and conduct of all legal business of the District and all suits initiated by and
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1 against the District and is responsible for upholding the public interest. D.C. Code
2 § 1-301.81 (2023).

3 **Hawaii**

4 52. The State of Hawaii, represented by and through its Attorney
5 General, is a sovereign state of the United States of America.

6 53. Attorney General Anne E. Lopez is the chief legal officer of the
7 State of Hawaii, and has the authority to appear, personally or by deputy, for the
8 State of Hawaii in all courts, criminal or civil, in which the State may be a party
9 or be interested. Haw. Rev. Stat. § 28-1 (2023). The Department of the Attorney
10 General has the authority to represent the State in all civil actions in which the
11 State is a party. Haw. Rev. Stat. § 26-7 (2023). This challenge is brought pursuant
12 to the Attorney General's constitutional, statutory, and common law authority.
13 *See* Haw. Const. art. V, § 6; Haw. Rev. Stat. § 26-7 (2023).

14 54. Hawaii has standing because the 2023 REMS creates barriers and
15 imposes substantial administrative burdens on Hawaii reproductive healthcare
16 providers, including pharmacies and State-operated healthcare facilities, seeking
17 to prescribe mifepristone for medication abortion within the timeframes of its
18 intended use.

19 55. Hawaii additionally brings this suit in its capacity as *parens patriae*
20 to protect its quasi-sovereign interest in the health and well-being of Hawaii
21 residents seeking timely access to medical care.

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Maine

56. Plaintiff the State of Maine is a sovereign state. This action is brought on behalf of the State of Maine by its Attorney General, who is a constitutional officer endowed with statutory and common law powers. As the chief legal officer for the State, the Attorney General may exercise all such power and authority as the public interest requires. The Attorney General has wide discretion in determining the public interest. The Attorney General’s powers and duties include appearing for the State in all civil actions and proceedings in which the State is a party or has an interest. Me .Rev. Stat. tit. 5, § 191 (2023); *Superintendent of Ins. v. Att’y Gen.*, 558 A.2d 1197 (Me. 1989)

57. Maine has a strong interest in the proper provision and broad access to health care services within the State.

58. Maine has standing because the 2023 REMS creates 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.

59. Maine further has standing because Maine provides state-funded abortion services to Medicaid-eligible pregnant people, per Me. Rev. Stat. tit. 22, § 3196 (2023) (Coverage for Non-Medicaid Services for MaineCare Members) and 10-144 Me. Code R. Ch. 104 (Maine State Services Manual), Section 7 (Abortion Services for MaineCare Members).

1 60. Because the 2023 REMS requirements improperly limit the number
2 of providers who can prescribe mifepristone and the pharmacies that can fill
3 prescriptions, fewer people have access to mifepristone abortions. This restriction
4 may result in more higher-cost surgical abortions, resulting in additional State
5 expenditures. Broad access to mifepristone is a critical tool for reducing the
6 financial impact to the State.

7 61. Maine additionally brings this suit in its capacity as *parens patriae*
8 to protect its quasi-sovereign interest in the health and well-being of Maine
9 residents.

10 **Maryland**

11 62. Plaintiff, the State of Maryland, by and through its Attorney General
12 Anthony G. Brown, brings this action. The Attorney General is Maryland's chief
13 legal officer with general charge, supervision, and direction of the State's legal
14 business. The Attorney General's powers and duties include acting on behalf of
15 the State and the people of Maryland in the federal courts on matters of public
16 concern. Under the Constitution of Maryland, and as directed by the Maryland
17 General Assembly, the Attorney General has the authority to file suit to challenge
18 action by the federal government that threatens the public interest and welfare of
19 Maryland residents. Md. Const. art. V, § 3(a)(2); 2017 Md. Laws, Joint
20 Resolution 1.

21 63. Maryland has standing because the 2023 REMS creates barriers to
22 accessing abortion care, leading to subsequent health care utilization, including

1 emergency and other hospital care, some cost of which is borne by the State
2 through Medicaid expenditures.

3 64. Maryland additionally brings this suit in its capacity as *parens*
4 *patriae* to protect its quasi-sovereign interest in the health and well-being of
5 Maryland residents.

6 **Minnesota**

7 65. Plaintiff State of Minnesota is represented by its Attorney General,
8 who is the chief legal officer for the State. The Attorney General’s
9 responsibilities include appearing in federal court on behalf of the State when the
10 interests of the State require it.

11 66. Minnesota has a strong interest in the proper provision of health care
12 within the State, particularly at public hospitals. Because hospitals and clinics
13 funded or operated by the State and its units of government provide reproductive
14 health care and pharmaceutical services, Minnesota is directly subject to the
15 January 2023 REMS and has standing to vindicate its proprietary interests in
16 delivering high-quality patient care.

17 67. Minnesota also has standing because the 2023 REMS creates and
18 maintains substantial and costly administrative burdens for health care and
19 pharmaceutical services provided in facilities owned or operated by the State and
20 its units of government. The 2023 REMS creates barriers to accessing medically
21 necessary abortion and miscarriage care, leading to subsequent increased health
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1 care costs, including emergency care. In many instances, this increased cost is
2 paid for by the State.

3 68. Additionally, Minnesota brings this suit in its capacity as *parens*
4 *patriae* to protect its quasi-sovereign interest in the health and well-being of
5 Minnesota residents.

6 **Pennsylvania**

7 69. Plaintiff the Commonwealth of Pennsylvania is a sovereign state of
8 the United States of America. This action is brought on behalf of the
9 Commonwealth of Pennsylvania by the Attorney General, who is the chief law
10 officer of the Commonwealth with statutory authority to bring actions on behalf
11 of the Commonwealth. Pa. Const. art. IV, § 4.1; 71 Pa. Stat. and Cons. Stat.
12 § 732-204 (West 2023).

13 **Plaintiff States**

14 70. The Plaintiff States collectively represent more than 87 million
15 Americans with protected rights to abortion care.

16 **Defendants**

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

21 72. Robert M. Califf is the Commissioner of the United States Food and
22 Drug Administration and is sued in his official capacity. He is responsible for

1 administering FDA and its duties under the federal Food, Drug, and
2 Cosmetic Act.

3 73. Defendant HHS is a federal agency within the executive branch of
4 the federal government.

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

8 IV. ALLEGATIONS

9 A. Statutory Background

10 75. Under the Food, Drug and Cosmetic Act (FDCA), a new drug
11 cannot be marketed and prescribed until it undergoes a rigorous approval process
12 to determine that it is safe and effective. *See generally* 21 U.S.C. § 355. An
13 approved prescription medication is subject to robust safeguards to ensure that it
14 is used safely and appropriately, including the requirement of a prescription by a
15 licensed medical provider, patient informed-consent laws, scope of practice laws,
16 professional and ethical guidelines, and state disciplinary laws regulating the
17 practice of medicine and pharmacy, as well as additional warnings, indications,
18 and instructions that FDA may impose specific to the medication.

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

21 77. A “Risk Evaluation and Mitigation Strategy” (REMS) is an
22 additional set of requirements, beyond the usual network of safeguards, that FDA

1 may impose in the rare case when—and only when—“necessary to ensure that
2 the benefits of the drug outweigh the risks of the drug[.]”
3 21 U.S.C. § 355-1(a)(1).

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

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

12 80. ETASU must not be “unduly burdensome on patient access to the
13 drug, considering in particular . . . patients in rural or medically underserved
14 areas,” and must “minimize the burden on the health care delivery system[.]”
15 *Id.* §§ 355-1(f)(2)(C)–(D).

16 81. In light of these stringent statutory limitations, REMS, and in
17 particular an ETASU, are exceptionally rare: of the more than 20,000 prescription
18 drug products approved by FDA and marketed in the U.S.,⁶ there are only
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22 ⁶*Supra* n.5.

1 60 REMS in place, 56 of which include an ETASU, covering dangerous drugs
2 like fentanyl and other opioids.⁷

3 **B. FDA’s Approval of Mifepristone and the History of the Mifepristone**
4 **REMS Program**

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

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

14 84. In 1996, the Population Council, a non-profit organization based in
15 the United States, sponsored a New Drug Application (NDA) for Mifeprex for
16 use in combination with misoprostol for the medical termination of early
17

18 ⁷ECF No. 1-4 (FDA Approved REMS).

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

1 pregnancy. In 1999, the Population Council contracted with Danco Laboratories,
2 L.L.C. (Danco) to manufacture and market the medication.

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

9 86. FDA's review included three clinical trials that together involved
10 4,000 women: two French trials that were complete at the time of the application,
11 and one then-ongoing trial in the United States for which summary data on
12 serious adverse events were available.¹¹ FDA has explained that "[t]he data from
13 these three clinical trials . . . constitute substantial evidence that Mifeprex is safe
14 and effective for its approved indication in accordance with the [FDCA]."¹² FDA
15

17 ⁹FDA NDA 20-687 Approval Memo, Sept. 28, 2000, ECF No. 1-5.

18 ¹⁰Food and Drug Administration Approval and Oversight of the Drug
19 Mifeprex, <https://www.gao.gov/assets/gao-08-751.pdf>, ECF No. 1-6.

20 ¹¹*Id.* at 5.

21 ¹²2016 FDA Letter to Am. Ass'n of Pro-Life Obstetricians &
22 Gynecologists, Christian Medical & Dental Ass'ns, and Concerned Women for

1 also considered: (1) results from other European trials from the 1980s and 1990s
2 in which mifepristone was studied alone or in combination with misoprostol or
3 similar drugs; (2) a European postmarket safety database of over 620,000 women
4 who used medication to terminate a pregnancy, approximately 415,000 of whom
5 had received a mifepristone/misoprostol regimen¹³; and (3) data on the drug’s
6 chemistry and manufacturing.¹⁴

7 87. Despite the strong findings on the safety and efficacy of Mifeprex
8 from clinical trials and European post-market experience, FDA originally
9 approved Mifeprex under Subpart H of the FDCA regulations (the predecessor
10 to the REMS statute) and imposed “restrictions to assure safe use”—a restricted
11 distribution system—as a condition of approval.¹⁵ For example, FDA imposed an
12 in-person dispensing requirement (later “ETASU C,” pursuant to
13 21 U.S.C. § 355-1(f)(3)(C)) and permitted the drug to be dispensed only in a
14

15 Am. denying 2002 Citizen Petition, Docket No. FDA-2002-P0364 (Mar. 29,
16 2016) (Citizen Petition Denial) at 8, Mar. 29, 2016, ECF No. 1-7.

17 ¹³*Id.* at 8.

18 ¹⁴ECF No. 1-6, *supra* n.10.

19 ¹⁵Although the Subpart H regulations are sometimes referred to as FDA’s
20 “accelerated approval” regulations, FDA has explained elsewhere that its 2000
21 approval of Mifeprex, which occurred more than four years after the new drug
22 application was submitted to FDA, did not involve an accelerated review.

1 hospital, clinic, or medical office, by or under the supervision of a “certified
2 provider” (discussed more below), who at that time could only be a physician.
3 FDA also imposed a prescriber-certification ETASU (later “ETASU A,”
4 pursuant to 21 U.S.C. § 355-1(f)(3)(A)), which prohibited health care providers
5 from prescribing the drug unless they first attested to their clinical abilities in a
6 signed form kept on file by the manufacturer, and agreed to comply with
7 reporting and other REMS requirements. FDA also imposed a Patient Form
8 ETASU (later “ETASU D,” pursuant to 21 U.S.C. § 355-1(f)(3)(D)), requiring
9 the prescriber and patient to review and sign a special form with information
10 about the mifepristone regimen and risks, and required the prescriber to provide
11 the patient with a copy and place a copy in the patient’s medical record. The same
12 information contained in the patient form is also included in the
13 “Medication Guide” that is part of the FDA-approved labeling provided to
14 patients with mifepristone.

15 88. FDA’s decision to subject Mifeprex to an ETASU under Subpart H
16 was highly unusual. In the fifteen years from 1992 (the year the Subpart H
17 regulations were promulgated) to February 2007 (just before the creation of the
18 REMS statute), only seven NDAs, including Mifeprex, were approved subject to
19 ETASU under Subpart H.¹⁶ By comparison, FDA approved 961 NDAs with no
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¹⁶*Id.* at 27.

1 additional restrictions in the roughly thirteen years from January 1993 to
2 September 2005.¹⁷

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

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

10 91. In 2013, FDA reviewed the existing REMS and reaffirmed the
11 restrictions already in place.¹⁸

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

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18 ¹⁷U.S. Gov’t Accountability Off., *New Drug Development: Science,*
19 *Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug*
20 *Development Efforts*, GAO-07-49, 20 (Nov. 2006).

21 ¹⁸FDA Final Risk Evaluation and Mitigation Strategy (REMS) Review
22 (Oct. 10, 2013), ECF No. 1-8.

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93. 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.

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

95. 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

1 Elements to Assure Safe Use (ETASU).”¹⁹ In asking FDA to “[e]liminate the
2 REMS and ETASU for mifepristone,” the letter specifically asked FDA to,
3 among other things, (i) “[e]liminate the Prescriber Agreement certification
4 requirement” and (ii) “remove the confusing and unnecessary
5 Patient Agreement.”²⁰

6 96. The signatory organizations explained that the
7 Prescriber Agreement certification requirement should be eliminated, because,
8 among other things²¹:

- 9 a. *“The Prescriber’s Agreement is unnecessary for the safe*
10 *dispensation of mifepristone. . . . [H]ealth care professionals are*
11 *already subject to many laws, policies, and ordinary standards of*
12 *practice that ensure they can accurately and safely understand and*
13 *prescribe medications. Provider certification is not required for*
14 *health care professionals to dispense other drugs, including drugs*
15 *that carry black box, or boxed, warnings about their medical risks.*
16 *Accutane, for example, has a boxed warning that describes the*
17 *potential risks of the drug, but Accutane prescribers are not required*
18 *to submit a certification form in order to prescribe it. Mifeprex also*
19 *has a boxed warning and there is no medical reason for a*
20 *Prescriber’s Agreement to be required in addition.”*
- 21 b. *“The Prescriber’s Agreement forces providers to identify themselves*
22 *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

19 ¹⁹Letter from SFP, *et al.*, to Stephen Ostroff, M.D., Robert M. Califf, M.D.,
20 & Janet Woodcock, M.D., 1 (Feb. 4, 2016) (SFP Letter to FDA), ECF No. 1-9.

21 ²⁰*Id.* at 2–4.

22 ²¹*Id.* at 3.

1 (52%) experienced threats and other types of targeted intimidation,
2 and one in five experienced severe violence, such as blockades,
3 invasions, bombings, arsons, chemical attacks, physical violence,
4 stalking, gunfire, bomb threats, arson threats, or death threats.
5 Robert Dear’s November 27, 2015, standoff at a
6 Planned Parenthood health center in Colorado, which resulted in
7 three deaths, provides one recent and chilling example of
8 anti-abortion violence. Given such escalating harassment and
9 violence against known abortion providers, clinicians may be
10 understandably reluctant to add their names to a centralized database
11 of mifepristone providers.”

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

13 97. The organizations also argued that the Patient Agreement was
14 unnecessary, explaining: “This requirement is medically unnecessary and
15 interferes with the clinician-patient relationship. It should be eliminated
16 entirely.”²²

17 98. The letter also urged FDA to “[c]onsider the current legal and social
18 climate,” explaining that “[t]he overall legal and social climate around abortion
19 care intensifies all of the burdens that the mifepristone REMS places on patients
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²²*Id.* at 4.

1 and makes it even more critical that the FDA lift medically unnecessary
2 restrictions on the drug.”²³ The letter concludes:

3 Mifepristone continues to hold immense promise for patient access
4 to a safe and effective early abortion option, but medically
5 unnecessary regulations are impeding its full potential. Extensive
6 scientific and clinical evidence of mifepristone’s safety and
7 efficacy, and the ever-increasing burden on patient access to
8 abortion care, clearly demonstrate that mifepristone’s REMS
9 program is not needed to protect patients. In light of the FDA’s
10 statutory mandate from Congress to consider the burden caused to
11 patients by REMS, and the agency’s own stated commitment to
12 ensuring that the drug restrictions do not unduly burden patient
13 access, we ask that the FDA lift mifepristone’s REMS²⁴

9 99. FDA summarized these “Advocacy Group Communications” as
10 follows:

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

19 ²³*Id.* at 5.

20 ²⁴*Id.* at 6.

21 ²⁵FDA, Ctr. for Drug Evaluation & Research, 020687Orig1s020,
22 Cross Discipline Team Leader Review 25 (Mar. 29, 2016), ECF No. 1-10.

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

6 101. Following the multidisciplinary review team’s analysis, FDA made
7 several changes to Mifeprex’s indication, labeling, and REMS. Relying on safety
8 and efficacy data from multiple studies, FDA increased the gestational age limit
9 from 49 to 70 days.²⁷ FDA also reduced the number of required in-person clinic
10 visits to one (whereas patients had previously been required to visit a clinic
11 setting twice in order to receive the medication). FDA determined that at-home
12 administration of misoprostol is safe because multiple studies showed that
13 administration of the drug was “associated with exceedingly low rates of serious
14 adverse events” and because administering misoprostol at home would more
15 likely result in patients being in an “appropriate and safe location” when

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17 ²⁶ECF No. 1-3 (FDA 2016 Medical Review) at 9, 39, 47, 49.

18 ²⁷The overwhelming majority (80%) of abortions occur within the first 70
19 days (10 weeks) of pregnancy. Katherine Kortsmitt, et al., *Abortion Surveillance*
20 – *United States, 2020*, 71 CDC Morbidity & Mortality Weekly Report 10 at 12
21 (Nov. 25, 2022), [https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-](https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-H.pdf)
22 [H.pdf](https://www.cdc.gov/mmwr/volumes/71/ss/pdfs/ss7110a1-H.pdf).

1 cramping and bleeding caused by the drug would begin.²⁸ FDA also found no
2 significant difference in outcomes based on whether patients had follow-up
3 appointments via phone call or in-person or based on the timing of those
4 appointments. Additionally, FDA allowed a broader set of healthcare providers,
5 rather than only physicians, to prescribe mifepristone, finding no serious risk to
6 patients from expanding the types of healthcare providers who could become
7 certified under the 2016 REMS.²⁹ But FDA still required that mifepristone, the
8 first drug in the regimen, be administered in a clinic setting.

9 102. In addition, FDA expert review team and the Director of FDA’s
10 Center for Drug Evaluation and Research recommended eliminating the
11 Patient Agreement Form because it contains “duplicative information already
12 provided by each healthcare provider or clinic,” “does not add to safe use
13 conditions,” and “is a burden for patients.”³⁰ But they were overruled by the FDA
14

15 ²⁸U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research,
16 020687Orig1s020, Mifeprex Summary Review at 15 (Mar. 29, 2016)
17 (2016 Summary Review), ECF No. 1-11.

18 ²⁹U.S. Food & Drug Admin., Ctr. for Drug Evaluation &
19 Research, 020687Orig1s020, Mifeprex REMS (Mar. 2016),
20 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Re
21 [msR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Re) (hereinafter 2016 REMS).

22 ³⁰ECF No. 1-11 (2016 Summary Review) at 25.

1 Commissioner, who directed the Form be retained.³¹ FDA retained the in-person
2 dispensing requirement and provider certification as well.

3 103. In 2019, FDA approved a different manufacturer’s abbreviated new
4 drug application for a generic version of mifepristone. When it approved the
5 abbreviated NDA, FDA also established the Mifepristone REMS Program, which
6 covers both Mifeprex and the generic.

7 104. In May 2020, the American College of Obstetricians and
8 Gynecologists sued FDA, challenging the Mifepristone REMS Program’s in-
9 person dispensing requirement in light of the COVID-19 pandemic. *See Am. Coll.*
10 *of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020),
11 *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578,
12 578 (2021) (mem.). Over FDA’s objection that “based on FDA’s scientific
13 judgment, the In-Person Requirements are necessary to assure safe use of
14 mifepristone and thus to protect patients’ safety,” *id.* at 228, the U.S. District
15 Court for the District of Maryland preliminarily enjoined the in-person
16 dispensing requirements, allowing healthcare providers to forgo it based on their
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18 ³¹U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research,
19 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s):
20 Letter from Janet Woodcock, M.D., Ctr. for Drug Evaluation & Research,
21 Regarding NDA 020687, Supp 20, 1 (Mar. 28, 2016) (hereinafter “Woodcock
22 Patient Agreement Memo”), ECF No. 1-12.

1 | medical judgment for the duration of the declared COVID-19 public health
2 | emergency. *Id.* at 233.

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

8 | 106. Finally, on January 3, 2023, FDA modified the REMS by, *inter alia*,
9 | removing the in-person dispensing requirement entirely. However, as discussed
10 | further below, the Mifepristone REMS continue to impose both the
11 | Prescriber Agreement Form and the Patient Agreement Form. The 2023 REMS
12 | also added a new pharmacy-certification requirement.³²

13 | **C. The Safety of Mifepristone**

14 | 107. Mifepristone is extremely safe and effective for terminating early
15 | pregnancies.

16 | 108. As discussed above, FDA's approval of mifepristone in 2000 rested
17 | on a comprehensive evaluation of the scientific data, and FDA reasonably
18 |

19 | ³²FDA Risk Evaluation and Mitigation Strategy (REMS) Single Shared
20 | System for Mifepristone 200 MG (2023 REMS),
21 | https://www.accessdata.fda.gov/drugsatfda_docs/remss/Mifepristone_2023_01_
22 | [03_REMS_Full.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/remss/Mifepristone_2023_01_03_REMS_Full.pdf), ECF No. 1-13.

1 determined, in its expert judgment, that the evidence showed mifepristone is safe
2 and effective for abortion of early pregnancy.

3 109. When FDA conducted another medical review of mifepristone in
4 2016 (based on the then 2.5 million uses of Mifeprex for medication abortion in
5 the U.S. since the drug's 2000 approval) it found: "[Mifeprex] has been
6 increasingly used as its efficacy and safety have become well established by both
7 research and experience, and serious complications have proven to be extremely
8 rare."³³ FDA observed at that time that "[m]ajor adverse events . . . are reported
9 rarely in the literature on over 30,000 patients. The rates, when noted, are
10 exceedingly rare, *generally far below 0.1%* for any individual adverse event."³⁴
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13 ³³ECF No. 1-3 (FDA 2016 Medical Review) at 12; *see also* U.S. Food
14 & Drug Admin., Full Prescribing Information for
15 Mifeprex 7–8, Tables 1 & 2 (approved Mar. 2016),
16 https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf
17 (“Mifeprex Labeling”), ECF No. 1-14.

18 ³⁴ECF No. 1-3 (FDA 2016 Medical Review) at 47 (emphasis added); *see*
19 *also* ECF No. 1-14 (Mifeprex Labeling) at 8, Table 2; *see also* Kelly Cleland et
20 al., Significant Adverse Events and Outcomes After Medical Abortion, 121
21 OBSTETRICS & GYNECOLOGY 166, 166 (2013) (“Medical research has
22 consistently demonstrated that mifepristone is safe and effective and that adverse

1 The Agency further stated that “[t]he safety profile of Mifeprex is
2 well-characterized and its risks well-understood after more than 15 years of
3 marketing. Serious adverse events are rare and the safety profile of Mifeprex has
4 not substantially changed.”³⁵ Since that 2016 medical review, mifepristone has
5 been used an additional 3 million times in the United States for medication
6 abortion.

7 110. From the time mifepristone was approved in 2000, there have only
8 been 28 reported associated deaths out of 5.6 million uses—an associated fatality
9 rate of .00005%.³⁶ Further, FDA acknowledges that *none* of these deaths can be
10 causally attributed to mifepristone. The 28 reported deaths were included in the
11 adverse events summary “regardless of causal attribution to mifepristone” and
12 included cases of homicide, drug overdose, ruptured ectopic pregnancy, and

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16 events and outcomes are exceedingly rare, occurring in less than a fraction of 1%
17 of cases.”).

18 ³⁵U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research,
19 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s):
20 REMS Modification Memorandum at 3 (Mar. 29, 2016) (hereinafter 2016 REMS
21 Modification Memorandum), ECF No. 1-15.

22 ³⁶ECF No. 1-2 (Mifepristone U.S. Post-Marketing Adverse Events
Summary).

1 sepsis (a life-threatening immune response to an infection).³⁷ And in its 2016
2 review, FDA noted that, while roughly half the deaths to that point were
3 associated with Clostridial septic infections, “[t]here have been no Clostridial
4 septic deaths reported in the US since 2009.”³⁸

5 111. In other cases of fatal infections associated with mifepristone, FDA
6 has acknowledged that “the critical risk factor” is not mifepristone but
7 “pregnancy itself,” as similar infections “have been identified both in pregnant
8 women who have undergone medical abortion and those who have not[.]”³⁹

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

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19 ³⁷*Id.*

20 ³⁸*Id.*

21 ³⁹ECF No. 1-7 at 26 n.69.

22 ⁴⁰ECF No. 1-14 (Mifeprex Labeling) at 2, 16.

1 **D. The January 2023 Mifepristone REMS**

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

4 114. The current REMS was approved in January 2023 (the
5 2023 REMS).⁴¹

6 115. The 2023 REMS imposes three primary hurdles to accessing
7 mifepristone. Two of these are continuing restrictions and the third is a new
8 restriction. Each hurdle unduly restricts mifepristone access without any
9 corresponding medical benefit.

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

18 117. For many healthcare providers, becoming specially certified is
19 unduly burdensome and raises safety concerns. Some providers are deterred by

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21 ⁴¹ECF No. 1-13 (2023 REMS).

22 ⁴²Mifepristone Prescriber Agreement Forms, ECF No. 1-16.

1 the unusual step of having to become certified to prescribe the medication; others,
2 misled by mifepristone’s REMS designation, misperceive it is a dangerous
3 medication or out of the prescriber’s scope of practice; and still others are not
4 comfortable having their names compiled in a list of medication abortion
5 prescribers for fear that they or their families may be targeted by anti-abortion
6 activists. This fear is particularly acute for doctors who hold medical licenses in
7 multiple states (with abortion laws different from the Plaintiff States’), and for
8 medical residents in the Plaintiff States who intend to eventually practice in a
9 state that heavily restricts abortion. These concerns, which FDA was made aware
10 of as far back as 2016, are heightened now due to the growing criminalization
11 and penalization of abortion, including laws that subject health care providers to
12 criminal penalties and significant monetary liability.

13 118. **Second**, although the 2023 REMS allows mifepristone to be
14 dispensed directly by pharmacies (as opposed to being dispensed by a provider
15 in a healthcare clinic, as prior REMS required), the REMS unnecessarily requires
16 dispensing pharmacies to be “specially certified” by the drug’s sponsor.⁴³

17 119. Special certification requires pharmacies to verify that mifepristone
18 prescriptions are written only by “certified” providers and to adhere to additional
19 burdensome communication, recordkeeping, and training requirements beyond
20 what is required for the vast majority of prescription drugs. Under the REMS, a
21

22 ⁴³Mifepristone Pharmacy Agreement Forms, ECF No. 1-17.

1 pharmacy cannot dispense mifepristone to a patient until it confirms that the
2 provider who wrote the prescription is specially certified.⁴⁴ This hurdle creates
3 new costs and administrative burdens for pharmacies—and worse, threatens
4 unnecessary delay patients seeking time-sensitive medication.

5 120. Further, by limiting mifepristone dispensing to “certified”
6 pharmacies, the REMS requires healthcare providers to track which pharmacies
7 are certified to dispense mifepristone, rather than allowing patients to select their
8 pharmacy of choice. And the reverse is true as well—pharmacies that wish to
9 dispense mifepristone must go through the added step of confirming that each
10 mifepristone prescription comes from a “specially certified” provider.

11 121. *Third*, the 2023 REMS retains the requirement that each patient sign
12 a Patient Agreement Form in order to receive a mifepristone prescription.⁴⁵ This
13 form, among other things, requires a patient to certify: “I have decided to take
14 mifepristone and misoprostol to end my pregnancy.”⁴⁶ This Patient Agreement
15 Form must be signed by both the patient and provider, a copy must be placed into
16 the patient’s medical record, and a copy must be given to the patient along with
17 the Medication Guide.

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⁴⁴*Id.*

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⁴⁵Mifepristone Patient Agreement Form, ECF No. 1-18.

22

⁴⁶*Id.*

1 122. This Patient Agreement Form creates significant privacy and safety
2 issues for both patients and providers. It specifically identifies the patient as
3 taking the medication for the purpose of ending their pregnancy—as opposed to,
4 for instance, miscarriage management, for which the medication is also
5 frequently prescribed. Anyone who obtains access to the patient’s medical record
6 will thus have evidence that the patient received the medication for abortion,
7 which is a particular concern for patients who receive care from a provider in a
8 state where abortion is legal but reside in a state where abortion is illegal. Making
9 matters worse, for patients who receive mifepristone for miscarriage
10 management, the evidence will be false. The form also identifies the provider to
11 anyone who obtains access to the patient’s medical record or sees the copy of the
12 form that must be provided to the patient—potentially including, for example, a
13 patient’s spouse, partner, or parent. This exposes providers and patients to threats
14 of potential violence, threats of legal liability (even when the care provided is
15 lawful in the relevant Plaintiff State), or other life-altering consequences. On top
16 of that, because patients who take the medication for miscarriage management
17 are also required to sign the Patient Agreement Form, it may be traumatizing for
18 individuals experiencing a miscarriage to nonetheless have to attest that they are
19 “decid[ing]” to “end [their] pregnancy.”

20 123. None of the harms caused by the Patient Agreement Form is
21 necessary, as the information contained on the form is duplicative of the
22 information already provided to patients in the five-page Medication Guide that

1 accompanies mifepristone. The comprehensive Medication Guide answers
2 questions such as: “What symptoms should I be concerned with?”; “Who should
3 not take Mifepristone tablets?”; “What should I tell my healthcare provider
4 before taking Mifepristone tablets?”; “How should I take Mifepristone tablets?”;
5 and “What are the possible side effects of Mifepristone tablets?”⁴⁷ The
6 Patient Agreement Form is also duplicative of provider counseling, as medical
7 ethics require providers to counsel patients on the risks and benefits of all
8 medications.

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

15 **E. The 2023 REMS Violate the FDCA**

16 125. FDA’s imposition of the burdensome 2023 REMS requirements is
17 contrary to the FDCA.

18 126. As noted above, FDA may impose an ETASU on a medication only
19 if the medication is “associated with a serious adverse drug experience,” which
20 the statute defines as one that “results in” death or “immediate risk of death,”
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22 ⁴⁷Mifepristone Medication Guide, ECF No. 1-19.

1 “inpatient hospitalization or prolongation of existing hospitalization,” “persistent
 2 or significant incapacity or substantial disruption of the ability to conduct normal
 3 life functions,” or “a congenital anomaly or birth defect,” or that “may jeopardize
 4 the patient and may require a medical or surgical intervention to prevent [such]
 5 an outcome” 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4)(A)–(B). And an ETASU
 6 may be imposed only where “required . . . to mitigate a specific serious risk” of
 7 a serious adverse drug experience, and only where such risk is sufficiently severe
 8 that absent the ETASU, FDA would not approve or would withdraw approval of
 9 the medication. *Id.* §§ 355-1(b)(5), (f)(1)(A).

10 127. Mifepristone does not meet these stringent standards because it is
 11 not “associated with a serious adverse drug experience.” To the contrary, FDA
 12 itself has concluded that serious adverse events following mifepristone use are
 13 “exceedingly rare.”⁴⁸

14 128. Since mifepristone was approved in 2000, there have been only
 15 28 reported associated deaths out of 5.6 million uses—an associated fatality rate
 16 of .00005%. And not a single one of these deaths can be causally attributed to
 17 mifepristone.⁴⁹ By contrast, thousands of deaths have been associated with
 18 phosphodiesterase type-5 inhibitors for the treatment of erectile dysfunction
 19

20 ⁴⁸ECF No. 1-3 (FDA 2016 Medical Review) at 47; *see also* ECF No. 1-2
 21 (Mifepristone U.S. Post-Marketing Adverse Events Summary).

22 ⁴⁹*Id.*

1 (e.g., Viagra)—which are not subject to a REMS.⁵⁰ And “other drugs with higher
2 complication rates, such as acetaminophen, aspirin, loratadine, and sildenafil, do
3 not have REMS restrictions[.]”⁵¹

4 129. Moreover, the ETASU violates the FDCA’s requirement that such
5 restrictions not be “*unduly burdensome* on patient access to the drug, considering
6 in particular . . . patients in rural or medically underserved areas,” and must
7 “minimize the burden on the health care delivery system[.]”
8 21 U.S.C. §§ 355-1(f)(2)(C)–(D) (emphasis added).

9 130. As explained in more detail below, the 2023 REMS significantly
10 burdens patient access to mifepristone without *any* appreciable safety benefits.

11
12 ⁵⁰Advancing New Standards in Reproductive Health , *Analysis of*
13 *Medication Abortion Risk and the FDA report “Mifepristone U.S. Post-*
14 *Marketing Adverse Events Summary through 12/31/2018”*, Mifepristone safety:
15 Issue Brief (Apr. 2019),
16 [https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety](https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf)
17 [_4-23-2019.pdf](https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf).

18 ⁵¹2018 Congress of Delegates, *Resolution No. 506 (Co-Sponsored C) –*
19 *Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on*
20 *Mifepristone*, Am. Acad. Of Fam. Physicians (2019),
21 [https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-](https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf)
22 [No.-506-REMS.pdf](https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf).

1 These burdens fall particularly heavily on rural patients in the Plaintiff States
2 because the vast majority of “specially certified” providers practice in cities. Plus,
3 with a number of states imposing severe restrictions on access to abortion care
4 that used to be constitutionally protected, many patients in these medically
5 underserved areas of the country are turning to Plaintiff State providers for this
6 care. This is particularly pronounced in Plaintiff States sharing borders with states
7 that allow little to no access—for example, in Washington, Oregon, and Nevada,
8 which border Idaho, in Illinois, which borders Missouri and Indiana, and in New
9 Mexico, which borders Texas. Against this backdrop, the 2023 REMS
10 significantly and unduly burdens health care delivery in the Plaintiff States by
11 imposing substantial, unjustified burdens on health care providers, clinics,
12 pharmacies, and hospitals.

13 **F. The 2023 REMS Are Unsupported by Science**

14 131. The 2023 REMS requirements are not supported by scientific
15 evidence.

16 132. First, the Patient Agreement Form remains in place even though the
17 team of expert reviewers at FDA’s Center for Drug Evaluation and Research
18 (CDER) unanimously recommended eliminating it in 2016 because it is
19 duplicative of informed consent laws and standards, “does not add to safe use
20
21
22

1 conditions[,] . . . and is a burden for patients.”⁵² But this team of experts was
2 overruled by the agency head.⁵³

3 133. Similarly, the requirement that clinicians certify that they are
4 competent to prescribe mifepristone provides no additional safety benefit beyond
5 the numerous existing laws and safety standards already in place to ensure health
6 care providers practice only within their competency. The certification
7 requirement is also out of step with how FDA regulates other, less safe
8 medications. Physicians are allowed to prescribe countless higher-risk drugs
9 without first attesting to their competency to make an accurate diagnosis or
10 provide follow-up care in the event of a complication.

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

17 135. Accordingly, the mifepristone REMS is opposed by leading medical
18 organizations, including the American College of Obstetricians and
19

20
21 _____
⁵²ECF No. 1-9 (2016 Summary Review) at 25.

22 ⁵³ECF No. 1-10 (Woodcock Patient Agreement Memo) at 1.

1 Gynecologists (ACOG), the American Academy of Family Physicians (AAFP),
2 and the American Medical Association (AMA).

3 136. Since at least 2016, ACOG’s position has been “that a Risk
4 Evaluation and Mitigation Strategy (REMS) is no longer necessary for
5 mifepristone, given its history of safe use. The REMS requirement is inconsistent
6 with requirements for other drugs with similar or greater risks, especially in light
7 of the significant benefit that mifepristone provides to patients.”⁵⁴

8 137. And since at least 2018, AAFP’s position has been that the REMS
9 restrictions “are not based on scientific evidence”; are overly burdensome on
10 practitioners and impede patient access to care, particularly “for patients who
11 might prefer to go to their own physician and for rural patients who have no other
12 access points beyond their local physician”; cause “delays in care, thereby
13 increasing second-trimester and surgical abortions, both of which have increased
14 complication rates”; and create “a barrier to safe and effective off-label uses of
15 mifepristone, such as for anti-corticoid treatment of Cushing’s disease, term labor
16 induction, and miscarriage management[.]”⁵⁵

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19 ⁵⁴Advocacy and Health Policy, *ACOG Statement on Medication*
20 *Abortion*, ACOG (Mar. 30, 2016) [https://www.acog.org/news/news-](https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion)
21 [releases/2016/03/acog-statement-on-medication-abortion](https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion).

22 ⁵⁵*Supra* n.51.

1 138. In a June 21, 2022, letter to FDA Commissioner Califf, ACOG and
2 AMA urged the Agency to “eliminate the requirement for patients to sign a form
3 to get the drug” and “lift the requirement that prescribers acquire a certification
4 from the manufacturer,” noting that “[b]arriers to accessing mifepristone do not
5 make care safer, are not based on medical evidence, and create barriers to patient
6 access to essential reproductive health care.”⁵⁶

7 139. Further, in 2022, ACOG, along with 48 other organizations,
8 submitted a citizen petition to FDA seeking to add miscarriage management as
9 an indication to the drug’s label, to eliminate or modify the REMS for that use,
10 and more generally requesting the removal of the mifepristone REMS.⁵⁷

11 140. The petition asked that “the Patient Agreement Form be removed
12 entirely because it is medically unnecessary and repetitive of informed consent,
13

14 ⁵⁶Letter from Maureen G. Phipps, Am. Coll. of Obstetricians &
15 Gynecologists, to Robert Califf, MD (Jun. 21, 2022), [https://searchlf.ama-
16 assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lf-
17 dr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf](https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lf-dr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf).

18 ⁵⁷Citizen Petition from Am. Coll. of Obstetricians & Gynecologists to
19 Lauren Roth, Assoc. Comm’r for Pol’y, U.S. FDA (Oct. 4, 2022),
20 [https://emaaproject.org/wp-content/uploads/2022/10/Citizen-Petition-from-the-
21 American-College-of-Obstetrician-and-Gynecologists-et-al-10.3.22-EMAA-
22 website.pdf](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).

1 as a previous review conducted by [FDA Center for Drug Evaluation and
2 Research] determined in 2016.”⁵⁸

3 141. ACOG further explained that “the Certified Provider Requirement
4 serves no benefit to patient safety,” but is instead “redundant and unnecessary.”⁵⁹
5 Moreover, ACOG noted that the provider-certification requirement has
6 disproportionately affected rural patients because “clinicians who have already
7 navigated mifepristone REMS compliance to provide abortion care . . . are
8 almost always located in cities.”⁶⁰ Making matters worse, “rural residents are
9 more likely to lack access to OBGYNs, meaning that surgical management is also
10 less likely to be an option.”⁶¹ Moreover, “clinicians might have reasonable
11 reservations about opting into a prescription system that could, if their
12

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14 ⁵⁸*Id.* at 12.

15 ⁵⁹*Id.* at 13.

16 ⁶⁰*Id.* at 14 (citing Bearak JM, Burke KL, Jones RK. *Disparities and change*
17 *over time in distance women would need to travel to have an abortion in the USA:*
18 *a spatial analysis.* *Lancet Public Health.* 2017; 2:e493–500 and Committee on
19 Health Care for Underserved Women. *Health Disparities in Rural Women.*
20 *American College of Obstetricians and Gynecologists.* *Obstet Gynecol.*
21 2014;123:384-388).

22 ⁶¹*Id.* (citation omitted).

1 certification were leaked, suggest they were an abortion provider and open them
2 up to violence and harassment.”⁶²

3 142. The ACOG’s citizen petition also urged FDA not to include a
4 pharmacy-certification requirement because “research . . . suggests that the
5 pharmacy requirement is unnecessary to ensure that mifepristone’s benefits
6 outweigh its risks and unduly burden[s] access.”⁶³ The petition pointed
7

8 ⁶²*Id.*; see also *id.* (“Research has shown that without certification, more
9 clinicians would prescribe mifepristone.”) (citing Neill S, Goldberg AB, Janiak
10 E., *Medication management of early pregnancy loss: the impact of the US Food
11 and Drug Administration Risk Evaluation and Mitigation Strategy* [A289].
12 *Obstet Gynecol.* 2022 May;139: 83S; Calloway D, Stulberg DB, Janiak E.
13 *Mifepristone restrictions and primary care: Breaking the cycle of stigma through
14 a learning collaborative model in the United States.* *Contraception.* 2021 July;
15 104(1):24-28; Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. “There’s
16 only one use for it”: stigma as a barrier to mifepristone use for early pregnancy
17 loss in Alabama. [A31]. *Obstet Gynecol.* 2022 May;139:9S-10S; and Razon N,
18 Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the impact of
19 mifepristone’s risk evaluation and mitigation strategy (REMS) on the integration
20 of medication abortion into US family medicine primary care clinics.*
21 *Contraception* 2022;109(5):19-24).

22 ⁶³*Id.* at 15.

1 specifically to a study “conducted . . . in California and Washington state
2 suggest[ing] that pharmacies are already equipped to dispense the drug without
3 special certification.”⁶⁴ “As with the certified provider requirement,” ACOG
4 noted, “the burdens associated with the certified pharmacy requirement will also
5 fall disproportionately on poor and rural [patients], contrary to the REMS
6 statute.”⁶⁵

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

9 After Canada removed all restrictions on prescribing mifepristone
10 for abortion, thereby allowing it to be prescribed and dispensed like
11 any other drug (“normal prescribing”), there was no increase in
12 complications from mifepristone use. [A] 2022 study . . . found no
13 difference in the rate of any complication (0.67% vs. 0.69%) or in
14 the rate of serious adverse events (0.03% vs. 0.04%) between the
15 ten-month period when mifepristone was distributed with
16 REMS-like restrictions and the twenty-eight-month period of
17 normal prescribing after all such restrictions were lifted and
18 mifepristone was prescribed with no special self-certification and
19 dispensed routinely from pharmacies.⁶⁶

16 ⁶⁴*Id.* (citing Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al.
17 *Medication abortion with pharmacist dispensing of mifepristone*. *Obstet Gynecol*
18 2021;137(4):613-622).

19 ⁶⁵*Id.* at 16.

20 ⁶⁶*Id.* at 17 (citing Schummers L, Darling EK, Dunn S, McGrail K,
21 Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed*
22 *Mifepristone in Canada*. *N Engl J Med*. 2022 Jan 6;386(1):57-67.)

1 144. FDA rejected ACOG’s citizen petition.⁶⁷

2 145. In fact, FDA has repeatedly rejected the concerns raised by leading
3 medical organizations and retained the medically unfounded REMS restrictions:
4 renewing them in 2016,⁶⁸ 2019,⁶⁹ 2021,⁷⁰ and yet again in 2023.⁷¹ FDA retained
5 these restrictions notwithstanding its periodic reviews of the post-marketing data,
6 which have not identified any new safety concerns with the use of mifepristone
7 for medical termination of pregnancy through 70 days’ gestation (10 weeks).⁷²

8
9 _____
10 ⁶⁷U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research, Letter
11 from Patrizia Cavazzoni, M.D., Regarding Docket No. FDA-2022-P-2425,
12 (Jan. 3, 2023), <https://www.regulations.gov/document/FDA-2022-P-2425-0003>,
13 ECF No. 1-20.

14 ⁶⁸Danco Labs., LLC, Mifeprex REMS (Mar. 2016),
15 <https://www.fda.gov/media/164649/download>.

16 ⁶⁹Danco Labs., LLC, Mifepristone REMS (Apr. 2019),
17 <https://www.fda.gov/media/164650/download>.

18 ⁷⁰Danco Labs., LLC, Mifepristone REMS (May 2021),
19 <https://www.fda.gov/media/164651/download>.

20 ⁷¹ECF No. 1-13 (2023 REMS).

21 ⁷²U.S. Food & Drug Admin., *Questions and Answers on Mifepristone for*
22 *Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 4, 2023),
<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and->

1 146. Even as mifepristone has remained subject to the unduly
2 burdensome REMS restrictions, a less safe mifepristone product for the treatment
3 of Cushing’s syndrome has been available for over a decade with no similar
4 restrictions. In 2012, FDA approved Korlym (mifepristone) tablets, 300 mg, as
5 treatment for Cushing’s syndrome *without* a REMS.⁷³ This was done even
6 though, as FDA noted in its 2016 Medical Review, Korlym “is taken in higher
7 doses, in a chronic, daily fashion unlike the single 200 mg dose of
8 Mifeprex . . . [and] the rate of adverse events with Mifeprex is much lower.”⁷⁴
9 Patients who are prescribed Korlym take one to four pills *daily*—which is 1.5 to
10 6 times the recommended dose for Mifeprex.⁷⁵

11
12 [providers/questions-and-answers-mifepristone-medical-termination-pregnancy-](#)
13 [through-ten-weeks-gestation.](#)

14 ⁷³HHS, Food & Drug Admin., Ctr. for Drug Evaluation & Research,
15 *Application Number: 202107Orig1s000, Approval Letter* (Feb. 17, 2012),
16 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000A
17 [pprov.pdf](#).

18 ⁷⁴ECF No. 1-3 (2016 Medical Review) at 10.

19 ⁷⁵U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Research,
20 *Application Number: 202107Orig1s000, Labeling* (Feb. 17, 2012),
21 https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lb
22 [l.pdf](#).

1 147. The risks associated with mifepristone are also lower than those of
2 many other common medications, such as Viagra, Tylenol, anticoagulants (blood
3 thinners), and penicillin. Again, since 2000, mifepristone has been used 5.6
4 million times with only 28 reported associated deaths, none of which can be
5 causally attributed to mifepristone.⁷⁶ And in nearly all cases of fatal infections
6 associated with mifepristone, FDA has acknowledged that “the critical risk
7 factor” is not mifepristone but “pregnancy itself,” as similar infections “have
8 been identified both in pregnant women who have undergone medical abortion
9 and those who have not[.]”⁷⁷

10 148. By contrast, as the American Academy of Family Physicians has
11 noted, “other drugs with higher complication rates, such as acetaminophen,
12 aspirin, loratadine, and sildenafil, do not have REMS restrictions[.]”⁷⁸

13 149. Medications for erectile dysfunction have a mortality rate more than
14 six times greater than mifepristone, and penicillin has a mortality rate three times
15 greater than mifepristone.⁷⁹

17 ⁷⁶ECF No. 1-2 (Mifepristone U.S. Post-Marketing Adverse Events
18 Summary).

19 ⁷⁷ECF No. 1-7 at 26.

20 ⁷⁸*Supra* n.51.

21 ⁷⁹Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L.
22 REV. 627, 651–52 (2022).

1 150. Likewise, acetaminophen (Tylenol) toxicity is the most common
2 cause of liver transplantation in the U.S. and is responsible for 56,000 emergency
3 department visits, 2,600 hospitalizations, and 500 deaths per year in the
4 United States.⁸⁰

5 151. But none of these drugs is subject to a REMS.

6 152. And even though opioids are highly addictive and cause tens of
7 thousands of fatalities per year from overdoses, the opioid REMS does not
8 require providers to do anything; it only requires that opioid manufacturers *offer*
9 optional training to healthcare providers who prescribe opioids, who may or may
10 not choose to take it. FDA acknowledges that “[t]here is no mandatory federal
11 requirement that prescribers or other [health care providers] take the training and
12 no precondition to prescribing or dispensing opioid analgesics to patients.”⁸¹

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14

15 ⁸⁰Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National
16 Library of Medicine (Aug. 1, 2022),
17 [https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20respons
18 ible%20for%2056%2C000,is%20contained%20in%20combined%20products.](https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20respons,ible%20for%2056%2C000,is%20contained%20in%20combined%20products.)

19 ⁸¹Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS),
20 U.S. FOOD & DRUG ADMIN. (Sept. 2018),
21 [https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-
22 evaluation-and-mitigation-strategy-rem.s.](https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-22 evaluation-and-mitigation-strategy-rem.s)

1 153. Mifepristone use is also far safer than continuing a pregnancy. A
2 person who carries a pregnancy to term is at least fourteen times more likely to
3 die than a person who uses mifepristone to end a pregnancy.⁸² Unequal access to
4 adequate health care exacerbates the risk for those with less privilege. For
5 example, Black women are three to four times more likely than white women to
6 die a pregnancy-related death in the U.S.⁸³

7 154. The two risks listed on the mifepristone label are also associated
8 with many common obstetrical and gynecological procedures, such as vaginal
9 delivery, surgical or medical miscarriage management, or insertion of an
10 intrauterine long-acting reversible contraceptive (IUD). As the Mifepristone
11 Medication Guide acknowledges: “Although cramping and bleeding are an
12

13 ⁸²Elizabeth G. Raymond & David E. Grimes, *The Comparative Safety of*
14 *Legal Induced Abortion and Childbirth in the United States*, 119 *Obstetrics &*
15 *Gynecology* 215, 215 (2012).

16 ⁸³Elizabeth A. Howell, MD, MPP, *Reducing Disparities in Severe*
17 *Maternal Morbidity and Mortality*, 61:2 *Clinical Obstetrics & Gynecology* 387,
18 387 (2018); *see also* Claire Cain Miller, Sarah Kliff, Larry Buchanan, *Childbirth*
19 *is Deadlier for Black Families Even When They’re Rich, Expansive Study Finds*,
20 N.Y. Times (Feb. 12, 2023),
21 [https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-](https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share)
22 [mortality-rich-poor.html?smid=url-share](https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share).

1 expected part of ending a pregnancy, rarely, serious and potentially
 2 life-threatening bleeding, infections, or other problems can occur following a
 3 *miscarriage, surgical abortion, medical abortion, or childbirth.*” (Emphasis
 4 added.)⁸⁴

5 **G. The 2023 REMS Unduly Burdens Access to Healthcare**

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

9 156. Even before *Dobbs v. Jackson Women’s Health Organization*,
 10 142 S. Ct. 2228 (2022), only a small fraction of counties in the United States had
 11 a clinician providing surgical abortions.⁸⁵ Mifepristone offers the possibility of
 12 vastly increased access to care by enabling primary care physicians to integrate
 13 abortion care into the services they provide. But the mifepristone REMS impedes
 14 the availability of medication abortion care, and so abortion care remains beyond
 15

16
 17 ⁸⁴ECF No. 1-19 (Mifepristone Medication Guide).

18 ⁸⁵Na’amah Razon, Sarah Wulf, et al., *Exploring the impact of*
 19 *mifepristone’s risk evaluation and mitigation strategy (REMS) on the integration*
 20 *of medication abortion into US family medicine primary care clinics*,
 21 109 Contraception 19 (May 2022),
 22 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9018589/>.

1 the reach of many—even in states like the Plaintiff States in which abortion care
2 is lawful and protected in various ways.⁸⁶

3 157. According to one recent study, approximately 40 percent of “family
4 physicians interviewed . . . either named or described the REMS criteria as a
5 barrier to providing medication abortion.”⁸⁷ These family physicians explained
6 that “the REMS impede their ability to provide medication abortion within
7 primary care” because they “require substantial involvement of clinic
8 administration, who can be unsupportive,” and because “[t]he complexity of
9 navigating the REMS results in physicians and clinic administration . . . viewing
10 medication abortion as not worth the effort, since it is only a small component of
11 services offered in primary care.”⁸⁸

12
13
14 ⁸⁶*Id.*

15 ⁸⁷*Id.*

16 ⁸⁸*Id.*; see also Sara Neill, MD, et al., *Medication Management of Early*
17 *Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk*
18 *Evaluation and Mitigation Strategy* (describing a survey of
19 obstetrician-gynecologists in which “[n]early all interviewees (17 of 19, 89%)
20 listed the REMS as a barrier to mifepristone use. Barriers included [the] belief
21 that the REMS indicated mifepristone was not available to general
22 ob-gyns . . . and concerns about signing the required prescriber agreement”).

1 158. Another recent study of primary care physicians and administrators
2 noted that “[a]bortion with mifepristone is safe and effective” and “falls well
3 within the scope of primary care in the United States, as it involves patient
4 assessment and health education for which primary care providers are extensively
5 trained.” But, the article concluded, the REMS are the “linchpin of a cycle of
6 stigmatization that continues to keep mifepristone out of primary care practice.”⁸⁹

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

18
19
20 ⁸⁹Danielle Calloway, Debra B Stulberg, & Elizabeth Janiak, *Mifepristone*
21 *restrictions and primary care: Breaking the cycle of stigma through a learning*
22 *collaborative model in the United States*, 104 *Contraception* 24 (July 2021).

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

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

13 162. Some patients will effectively be unable to access abortion, and will
14 carry an unwanted pregnancy to term, due to the limited number of providers who
15 are able to prescribe mifepristone because of the REMS. A landmark study shows
16 that patients denied abortion are more likely to: experience serious complications
17 from the end of pregnancy, including eclampsia and death; stay tethered to
18 abusive partners; suffer anxiety and loss of self-esteem in the short term after
19 being denied abortion; and experience poor physical health for years after the
20
21
22

1 pregnancy, including chronic pain and gestational hypertension.⁹⁰

2 163. Still others will opt for surgical abortion, which FDA describes as a
3 more “invasive medical procedure that increases health risks for some patients
4 and that may be otherwise inaccessible to others.”⁹¹ As FDA acknowledges,
5 access to mifepristone is particularly critical “[f]or patients for whom
6 mifepristone is the medically indicated treatment because of the patient’s
7 pre-existing health condition.”⁹²

8 164. “For example,” FDA has explained:

9 surgical abortion involves anesthesia, but people who are allergic to
10 anesthesia can experience a sudden drop in blood pressure with
11 cardiorespiratory arrest, and death. And . . . patient populations for
12 whom medication abortion is more appropriate than a surgical
13 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.

14 (Internal quotations and citations omitted.)⁹³

17 ⁹⁰Our Studies, *The Turnaway Study*, Advancing New Standards in
18 Reproductive Health, <https://www.ansirh.org/research/ongoing/turnaway-study>.

19 ⁹¹Defs.’ [FDA] Opp’n to Pls.’ Mot. for a Prelim. Inj., *All. for Hippocratic*
20 *Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex. Jan. 13, 2023), ECF No. 28 at 38.

21 ⁹²*Id.* at 39.

22 ⁹³*Id.*

1 165. Moreover, FDA itself has repeatedly confirmed and re-confirmed
2 that mifepristone is safe and effective. According to FDA, mifepristone provides
3 a “meaningful therapeutic benefit to patients” as compared to other treatments.

4 166. By unduly burdening patients’ access to mifepristone through the
5 2023 REMS, FDA deprives patients of the therapeutic benefit of the drug without
6 any scientific basis.

7 **H. Injury to the Plaintiff States and Their Residents**

8 **Washington**

9 167. The State of Washington’s injuries exemplify those of other
10 Plaintiff States caused by the mifepristone REMS.

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

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

17 170. Washington providers have been hindered in providing care, and
18 patients have been hindered in receiving care, due to the mifepristone REMS.
19 The 2023 REMS requirements pose substantial challenges to providers and
20 patients, and have resulted in significant expenses for state institutions, including
21 the University of Washington (UW).
22

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

10 172. At the UW, for instance, implementation of the 2023 REMS
11 requirements is currently being overseen by a subcommittee of more than
12 20 UW physicians, administrators, and staff. To date, the subcommittee members
13 have expended hundreds of hours on REMS implementation work, with many
14 outstanding tasks still to complete. This is valuable time that these
15 UW employees could otherwise spend treating patients, conducting research, or
16 attending to other critical job functions.

17 173. One area in which UW has dedicated substantial resources is in its
18 work to make the REMS-required Patient Agreement Form available to its
19 telemedicine patients. The 2023 REMS continues to require that the
20 Patient Agreement Form be signed by both the patient and a certified provider
21 before a prescription can be filled by a certified pharmacy. Completing the form
22 is usually a simple task in person, but it poses significant challenges in the

1 | telehealth setting. UW staff have worked more than 100 hours on both
2 | operational and technical elements to implement this REMS component,
3 | including making the Patient Agreement Form accessible to telemedicine patients
4 | in a HIPAA-compliant form and designing a method to securely transmit the form
5 | to the patient for their signature and then securely re-route the form back to the
6 | provider.

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

12 | 175. Another area of significant time and expense has been
13 | implementation of the provider-certification requirement for telehealth providers.
14 | UW has hundreds of providers who are eligible to provide telehealth services. To
15 | ensure UW providers who may want to prescribe mifepristone are in compliance
16 | with the 2023 REMS requirements, UW is currently conducting outreach to
17 | ensure all interested, qualified providers are aware of the 2023 REMS
18 | requirements. UW operational staff then has to work with each provider who
19 | expresses an interest in prescribing mifepristone to ensure that the physician
20 | completes the Prescriber Agreement Form and transmits it to the UW Pharmacy.
21 | Providers then have to be trained on the new technology interfaces required for
22 | the Patient Agreement Form as well as the additional steps required in order to

1 submit a mifepristone prescription for a medication abortion to a UW pharmacy.
 2 This outreach will likewise need to be done for UW's medical residents. This will
 3 require ongoing work as new healthcare providers and residents join UW.

4 176. UW has also had to devote significant time to designing electronic
 5 safeguards to help protect the safety of its providers. Some UW physicians, for
 6 instance, have expressed concern that by completing the Prescriber Agreement
 7 Form and having their name on a list of certified medication abortion prescribers,
 8 they could become a target of anti-abortion violence or harassment in the event
 9 the list were leaked or compromised.⁹⁴ Given the growing criminalization and
 10

11 _____
 12 ⁹⁴Abortion providers have long faced stigma, harassment, and violence. In
 13 2021, 182 death threats were made against abortion providers. *See* National
 14 Abortion Federation, *2021 Violence & Disruption Statistics*,
 15 https://prochoice.org/wp-content/uploads/2021_NAF_VD_Stats_Final.pdf; *see*
 16 *also, e.g.*, U.S. Dep't of Justice, *Recent Cases on Violence Against Reproductive*
 17 *Health Care Providers* (Oct. 18, 2022), [https://www.justice.gov/crt/recent-cases-](https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers)
 18 [violence-against-reproductive-health-care-providers](https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers); Megan Burbank, *Planned*
 19 *Parenthood awarded \$110K after Spokane clinic protests*, CROSSCUT (Dec. 20,
 20 2022), [https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-](https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-after-spokane-clinic-protests)
 21 [after-spokane-clinic-protests](https://crosscut.com/news/2022/12/planned-parenthood-awarded-110k-after-spokane-clinic-protests)]; Ted McDermott, *Windows smashed at Planned*
 22 *Parenthood in Spokane Valley; suspect arrested*, THE SPOKESMAN-REVIEW (July

1 penalization of abortion following the *Dobbs* decision, these concerns are further
2 heightened for doctors who hold medical licenses in multiple states (including
3 states where abortion laws differ from Plaintiff States’) and for medical residents
4 who later intend to practice in states where abortion is illegal or heavily
5 restricted.⁹⁵ While UW is working hard to protect its providers—by, for example,
6 creating additional interfaces so that a telehealth appointment for a medication
7 abortion can only be booked with a telehealth clinic (not a specific provider),

8
9 5, 2021), [https://www.spokesman.com/stories/2021/jul/05/windows-smashed-
10 at-planned-parenthood-in-spokane-v/](https://www.spokesman.com/stories/2021/jul/05/windows-smashed-at-planned-parenthood-in-spokane-v/).

11 ⁹⁵Recognizing the reality of potential prosecution of Washington abortion
12 providers, the Washington’s Office of the Insurance Commissioner (OIC)
13 recently approved coverage to reimburse physician policyholders for legal fees
14 and expenses incurred in defending against a criminal action that comes from
15 providing direct patient care, including abortions. As Insurance Commissioner
16 Mike Kreidler explained, “As states like Texas threaten legal and criminal action
17 against physicians, the OIC is determined to counter this by assisting medical
18 malpractice insurers wherever we can.” Press Release, Office of the Insurance
19 Commissioner, New insurance coverage approved to help doctors who face
20 criminal charges for providing legal abortions (Sept. 27, 2022),
21 [https://www.insurance.wa.gov/news/new-insurance-coverage-approved-help-
22 doctors-who-face-criminal-charges-providing-legal](https://www.insurance.wa.gov/news/new-insurance-coverage-approved-help-doctors-who-face-criminal-charges-providing-legal).

1 thereby ensuring that an individual provider’s name is not made available before
2 the appointment—many physicians remain concerned about having to become a
3 “certified prescriber” of medication abortion. The provider-certification
4 requirement thus creates additional, unnecessary risks for Washington
5 employees, providers, and residents that would not exist without the REMS.
6 These risks have become exponentially higher in the post-*Dobbs* era, even as
7 Washington continues to protect the right to choose and provide abortion care.

8 177. FDA recognizes such concerns, but disregarded them in issuing the
9 2023 REMS. FDA shields the identities of its own employees whose work relates
10 to mifepristone to protect their health and safety, in light of the violence and
11 harassment surrounding the provision of abortion.

12 178. The January 2023 REMS also places a significant burden on
13 UW’s pharmacies. Prior to the January 2023 REMS, UW pharmacies did not
14 distribute mifepristone for medication abortion, as those medications had to be
15 provided directly to the patient by the provider at an in-patient visit in a
16 UW clinic (or, during the COVID-19 pandemic, by the provider via mail). With
17 the easing of the in-patient and provider-only distribution requirements, UW is
18 now working to stock mifepristone at both its inpatient pharmacies and through
19 its mail-order pharmacy for its telehealth patients. But the requirements
20 associated with becoming a certified pharmacy have created a significant
21 additional workload for UW pharmacy team members.

22

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

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

18 181. As demonstrated by the hundreds of hours being spent by
19 UW physicians and staff to implement the 2023 REMS program requirements,
20 compliance with the REMS program creates an expensive and substantial burden
21 for Washington’s hospitals, clinics and pharmacies. This is a financial and
22

1 administrative burden that many hospitals, clinics, and pharmacies in
2 Washington—particularly small or family-operated ones—cannot shoulder.

3 182. As a result, the 2023 REMS requirements unnecessarily limit the
4 number of providers in Washington who can prescribe mifepristone and the
5 patients’ options for filling a mifepristone prescription. These unnecessary
6 limitations, in turn, unduly burden access to mifepristone for
7 Washington patients.

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

16 184. As the WSU example highlights, the harms caused by the REMS are
17 particularly pronounced in central and eastern Washington, where access to
18 abortion is already limited by a smaller density of providers and more rural
19 population. Of the 20 eastern Washington counties, only nine have abortion
20 providers. By irrationally limiting who may prescribe and dispense mifepristone,
21 the REMS ensure that abortion care remains unavailable to many rural
22 Washingtonians.

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

7 186. Moreover, the REMS pharmacy requirements also limit the number
8 of specially certified pharmacies in Washington, thereby limiting drug
9 availability for patients, particularly in rural communities underserved by large
10 pharmacy chains. While mail-order prescriptions may be desirable for some, they
11 may be infeasible or impossible for others, including patients experiencing
12 housing insecurity; traveling from other states; close to the gestational limit;
13 living in rural areas dependent on P.O. boxes for mail delivery—which are
14 ineligible for mail-order prescriptions; or for whom receipt of abortion
15 medication at home may trigger domestic violence or housing loss. For these
16 patients, local pharmacy pick-up may be necessary—but unavailable due to the
17 2023 REMS requirements.

18 187. For patients receiving medical care in Washington, the Patient
19 Agreement Form creates an additional, unnecessary risk. While medical
20 institutions and providers have enacted safeguards to ensure the safety and
21 privacy of all medical records, the simple fact that a patient has an additional
22 document in their medical record attesting to their medication abortion creates an

1 added risk for patients—particularly for those patients who travel to Washington
2 for medical treatment from states where the abortion would be illegal.
3 Abortion providers have been targets for hackers seeking to steal information
4 about both patients and providers. In 2021, for example, hackers accessed data
5 about roughly 400,000 patients from Planned Parenthood Los Angeles.⁹⁶ Here in
6 Washington, providers report frequent phishing attacks aimed at illegally
7 obtaining information about patients and providers.

8 188. This risk is compounded by the fact that providers are required to
9 provide patients with a copy of the Patient Agreement Form, which could, in turn,
10 be found by a patient’s spouse, partner, or parent (who might otherwise be
11 unaware of the patient’s medication abortion), potentially putting the patient at
12 risk of violence or abuse. And the Patient Agreement Form is uniquely
13 problematic for patients who receive mifepristone for miscarriage management,
14 as they must falsely attest that they are “decid[ing] . . . to end [their] pregnancy”
15 and then have that document placed into their medical record. And again, all of
16 these risks are compounded for individuals traveling to Washington to receive
17 care they cannot access in their home state.

18
19 ⁹⁶Gregory Yee and Christian Martinez, *Hack exposes personal information*
20 *of 400,000 Planned Parenthood Los Angeles patients*, LOS ANGELES TIMES
21 (Dec. 1, 2021), [https://www.latimes.com/california/story/2021-12-01/data-](https://www.latimes.com/california/story/2021-12-01/data-breach-planned-parenthood-los-angeles-patients)
22 [breach-planned-parenthood-los-angeles-patients](https://www.latimes.com/california/story/2021-12-01/data-breach-planned-parenthood-los-angeles-patients).

1 **Oregon**

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

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

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

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

21 193. The REMS requirements also add to the amount of provider time
22 required for each patient. Even at a conservative estimate of two to three minutes

1 per patient, over a hundred—potentially hundreds—of provider hours are spent
2 each year for the review, discussion, and signing of the Patient Agreement Forms.
3 That is valuable time that those medical providers could otherwise spend treating
4 patients or attending to other important work.

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

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

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

197. 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.

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

1 **Arizona**

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

5 **Colorado**

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

11 201. Providers and staff at the University of Colorado have expended
12 time and resources complying with the 2023 REMS requirement, including
13 developing and processing the Prescriber Agreement Form and the
14 Patient Agreement Form. Further, the 2023 REMS prevent non-certified
15 providers from prescribing mifepristone to their patients. As a result, those
16 patients often must make additional clinic visits—sometimes at different
17 locations—to obtain mifepristone.

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

20 **Connecticut**

21 203. Access to safe and effective medication abortion is critically
22 important for Connecticut residents. Connecticut residents experience harms as a

1 result of the 2023 REMS that are similar to those experienced by residents of the
2 Plaintiff States.

3 **Delaware**

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

12 205. Restricting access to mifepristone needlessly harms Delawareans
13 who increasingly rely on it.

14 **Illinois**

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

17 207. In 2020 (the most recent year for with public data), there were
18 46,243 reported abortions in Illinois. Of those, 23,765—51%—were medication
19 abortions using mifepristone.

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

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

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

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

20 212. As Illinois's neighboring states have curtailed abortion access,
21 Illinois has seen a 28% increase in abortions from April 2022 to August 2022,
22 creating additional strain on Illinois providers and healthcare systems. The

1 REMS certification requirements pose particular hardships for Illinois providers
2 and pharmacies because Illinois is an abortion oasis in the Midwest and a
3 significant portion of patients seeking abortion care in Illinois are traveling from
4 Indiana, Missouri, and other nearby states where abortion is restricted. For these
5 providers and pharmacists, as well as patients traveling from out of state, the
6 REMS certification requirements and Patient Agreement Form create additional
7 risks of civil or criminal liability.

8 **Attorney General of Michigan**

9 213. Access to safe and effective medication abortion is critically
10 important for Michiganders. Michiganders experience harms as a result of the
11 2023 REMS that are similar to those experienced by residents of the Plaintiff
12 States.

13 **Nevada**

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

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

21 216. The Nevada Department of Health and Human Services, Division of
22 Health Care Financing and Policy (DHHS) administers the Medicaid program in

1 Nevada. It is responsible for ensuring high quality, cost-effective care to
2 Medicaid recipients while maintaining compliance with federal Medicaid
3 requirements.

4 217. Nevada Medicaid fee-for-service covers mifepristone.

5 218. The reduced availability of mifepristone will financially impact
6 DHHS. Providers and patients will be forced to adopt alternatives including
7 surgical abortions which are more invasive, costly, and can expose patients to
8 higher health risks, e.g., excessive bleeding.

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

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

18 221. The Mifepristone REMS program imposes medically unnecessary
19 barriers to the prescription, distribution, and use of mifepristone by Nevada
20 clinicians and patients. The REMS Patient Agreement Form must be signed by
21 both a patient and a certified provider before a prescription can be filled by a
22

1 qualified pharmacy. This imposes a significant burden for telehealth patients or
2 patients without access to smartphones or scanning apps.

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

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

10 224. These barriers interfere with Nevada’s inherent authority to provide
11 for the health and welfare of its residents.

12 **New Mexico**

13 225. New Mexico's injuries are exemplified in the sections discussing
14 Washington’s and the other Plaintiff States’ injuries.

15 226. New Mexico repealed its antiquated prohibition of abortion in
16 2021.⁹⁷

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

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⁹⁷NMSA 1978, §§ 30-5-1 to -3 (repealed 2021).

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

7 **Rhode Island**

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

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

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

20 232. Rhode Islanders are harmed when access to mifepristone is limited,
21 including the emotional, financial, and social harms that individuals experience
22

1 by having to carry an unwanted pregnancy to term or not having access to the
2 benefit of miscarriage management medication.

3 **Vermont**

4 233. Medication abortion is critically important for Vermonters. In 2019,
5 59% of abortions in Vermont were medication abortions; in 2020, that number
6 rose to 75%.⁹⁸

7 234. The harms that the REMS cause are particularly acute in Vermont
8 because the state’s rurality makes it difficult for many Vermonters to access
9 providers. Less than a third of Vermont counties have abortion providers—
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14 ⁹⁸Agency of Human Services, *Vermont 2019 Vital Statistics: 135th Report*
15 *Relating to the Registry and Return of Births, Deaths, Marriages, Divorces, and*
16 *Dissolutions* at 139, Vermont Department of Health (June 2021),
17 [https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-](https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-2019VSB_final.pdf)
18 [2019VSB_final.pdf](https://www.healthvermont.gov/sites/default/files/documents/pdf/HS-VR-2019VSB_final.pdf); Agency of Human Services, *Vermont 2020 Vital Statistics:*
19 *136th Report Relating to the Registry and Return of Births, Deaths, Marriages,*
20 *Divorces, and Dissolutions* at 142, Vermont Department of Health (July 2022)
21 [https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Stati](https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202020.pdf)
22 [stics%20Bulletin%202020.pdf](https://www.healthvermont.gov/sites/default/files/documents/pdf/Vital%20Statistics%20Bulletin%202020.pdf).

1 meaning that 43% of women of reproductive age live in a county without an
2 abortion provider.⁹⁹

3 **District of Columbia**

4 235. In the District of Columbia, mifepristone is a critical medicine for
5 providing safe and effective abortion care. The prescription and use of
6 mifepristone with misoprostol is the standard of care for medication abortion in
7 the District.

8 236. Medication abortion is critically important for District residents. In
9 2020, 2,358 medication abortions were administered by District medical
10 providers, accounting for roughly 53% of all abortions in the District.¹⁰⁰

11 237. The mifepristone REMS requirements impede drug availability for
12 District residents by limiting the providers that can prescribe and the pharmacies
13 that can dispense the medication. The certification process is onerous and can
14 deter providers from undergoing the process, which in turn limits patients’ access
15 to medication abortion services. The REMS also create additional barriers to
16 patient access through the Patient Agreement Form requirement.

17 _____
18 ⁹⁹Jesse Philbin, et al., *10 US States Would Be Hit Especially Hard by a*
19 *Nationwide Ban on Medication Abortion Using Mifepristone*, GUTTMACHER
20 INSTITUTE (Feb. 7, 2023), [https://www.guttmacher.org/2023/02/10-us-states-](https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using)
21 [would-be-hit-especially-hard-nationwide-ban-medication-abortion-using](https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using).

22 ¹⁰⁰ https://www.cdc.gov/mmwr/volumes/71/ss/ss7110a1.htm#T12_down

1 **Hawaii**

2 238. Patients in the State of Hawaii suffer the same harms experienced
3 by patients in other Plaintiff States.

4 239. Access to safe and effective medication abortion is critically
5 important for the State of Hawaii.

6 240. Limitation on access to safe and effective medication abortion
7 increases other health care costs, including the more expensive procedural or
8 later-stage abortion care, emergency care, and care related to complications due
9 to unwanted pregnancies, childbirth, and miscarriage.

10 241. As Hawaii is a state of several islands, the aforementioned health
11 care costs are further increased if a patient must travel to another island in order
12 to seek the appropriate care.

13 **Maine**

14 242. Medication abortion is essential to reproductive health care in
15 Maine. According to the Maine Centers for Disease Control, in 2021, a total of
16 1,915 abortions were performed in Maine. Of that total, 1,159 (more than 60%)
17 were medication abortions using mifepristone.

18 243. According to the Maine Department of Health and Human Services,
19 in 2021, the State paid for 770 abortions under the state-funded abortion services
20 program. Of that total, 463 (about 60%) were medication abortions using
21 mifepristone.

22

1 244. Access to medication abortion – including provision of mifepristone
2 via mail, is particularly important in Maine, which is a large rural state. Many
3 Maine residents live far away from health care providers offering abortion
4 services, and access to mifepristone via mail is critical to their healthcare.

5 245. The 2023 REMS makes it more difficult for pregnant people to
6 access the abortion services to which they are entitled. This leads to delay in
7 abortion services, which could require a person to obtain a surgical abortion, as
8 well as increased health care costs, including emergency care, care related to
9 complications due to unwanted pregnancies, childbirth, and miscarriage. Some
10 of these costs are borne by the state through its Medicaid program, in which
11 approximately 30% of Maine residents are enrolled as of October 2022.

12 246. Access to safe and effective medication abortion is critically
13 important for Maine residents. Maine residents experience harms as a result of
14 the 2023 REMS that are similar to those experienced by residents of the other
15 Plaintiff States.

16 247. Maine provides state-funded abortion services to Medicaid-eligible
17 pregnant people. The burdens and obstacles created by the 2023 REMS may
18 result in increased state expenditures. For example, the delays imposed by the
19 REMS could require a more complicated and expensive surgical abortion
20 procedure.

21
22

1 248. The 2023 REMS creates and maintains substantial and costly
2 administrative burdens for health care and pharmaceutical services provided in
3 the State of Maine.

4 **Maryland**

5 249. Access to safe and effective medication abortion is critically
6 important for Maryland residents. Maryland residents experience harms as a
7 result of the 2023 REMS that are similar to those experienced by residents of the
8 Plaintiff States.

9 **Minnesota**

10 250. Mifepristone is critical to reproductive healthcare providers and
11 patients in Minnesota. Minnesota residents rely on mifepristone to access safe
12 and effective abortion care and miscarriage management. Medication abortions
13 using mifepristone represent the majority of pregnancy termination procedures
14 performed in Minnesota. Data from 2008 to 2021 shows that Minnesotan patients
15 and providers have increasingly relied on medication for early pregnancy
16 termination. In 2008, there were 12,948 abortions in Minnesota. Of those,
17 2,226—17%—were non-surgical medical abortions. In 2017, there were 10,177
18 abortions in Minnesota. Of those, 3,997—39%—were medication abortions
19 using mifepristone. In 2021, there were 10,136 abortions in Minnesota. Of those,
20 5,894—58%—were medication abortions using mifepristone.

21 251. The 2023 REMS limits Minnesotans' access to reproductive
22 healthcare by limiting the providers that can prescribe mifepristone and the

1 pharmacies that can dispense it. It also creates additional barriers to patient access
2 by requiring the Patient Agreement Form. As a result of this limited access,
3 Minnesotan providers are sometimes forced to provide, and patients are
4 sometimes forced to seek, alternative care. This alternative care includes surgical
5 abortions and miscarriage management procedures which are more invasive,
6 costly, and expose patients to additional medical risks.

7 252. The burden of this reduced availability disproportionately impacts
8 people of color, low-income families, and rural Minnesota communities whose
9 residents must travel long distances to seek alternative reproductive healthcare
10 services.

11 253. Minnesotans are harmed because access to mifepristone is limited.
12 These harms include the emotional, financial, and social harms that individuals
13 may experience when they have to carry an unwanted pregnancy to term or when
14 they do not have access to medication to manage a miscarriage.

15 254. Additionally, this limited access to medication abortion and
16 medication miscarriage management increases other health care costs, including
17 more expensive procedural or later-stage abortion care, emergency care, and care
18 related to complications due to unwanted pregnancies, childbirth, and
19 miscarriage. Some of this increased cost is paid by the State, which is one of 16
20 states that uses state funds to cover abortion care for people enrolled in Medicaid.
21 Ensuring Minnesotans have access to mifepristone is critical to managing health
22 care costs borne by the State.

1 255. The 2023 REMS also puts additional demand pressure on the
2 providers who are able to prescribe mifepristone and the pharmacies that are able
3 to dispense it. Since the *Dobbs* decision, Minnesota has experienced a significant
4 increase in out-of-state-patients seeking abortion care in the state. In the months
5 after *Dobbs*, Minnesota’s Planned Parenthood clinics reported a 150% surge in
6 call center traffic, and a 13% increase in patients. Whole Woman’s Health in
7 Minnesota reported a 50% increase in patients. The reduced availability of
8 mifepristone financially burdens Minnesotan reproductive healthcare providers
9 working to meet this increased patient demand.

10 **Pennsylvania**

11 256. Medication abortion is vital to the reproductive health care of
12 Pennsylvanians. According to the Centers for Disease Control and Prevention,
13 approximately 51% of abortions in Pennsylvania in 2020 (the most recent year
14 for which complete data is available) were medication abortions. Of the 18
15 existing abortion-service providers in Pennsylvania, 8 of them exclusively
16 provide medication abortions, and most providers are located near larger cities in
17 the eastern and western portions of the Commonwealth, limiting access to these
18 services for residents in much of the Commonwealth. Restrictions on the use of
19 mifepristone only serve to further limit access to safe and effective reproductive
20 health to Pennsylvanians.

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

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

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

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

13 260. Through their actions described above, Defendants violated
14 5 U.S.C. § 706(2)(C) by acting in excess of statutory jurisdiction, authority,
15 limitations, and short of statutory right in promulgating the mifepristone
16 2023 REMS.

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

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

21 262. FDA’s promulgation of the mifepristone 2023 REMS was a final
22 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.

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

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

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

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

11 266. FDA’s promulgation of the mifepristone 2023 REMS treated
12 similarly situated parties differently without adequate justification, and therefore
13 violates the constitutional guarantee of equal protection in violation of
14 5 U.S.C. § 706(2)(B).

15 **VIII. FOURTH CAUSE OF ACTION**
16 **(Equal Protection)**

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

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

22

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

7 **IX. PRAYER FOR RELIEF**

8 WHEREFORE, Washington, Oregon, Arizona, Colorado, Connecticut,
9 Delaware, Illinois, Attorney General of Michigan, Nevada, New Mexico,
10 Rhode Island, Vermont, District of Columbia, Hawaii, Maine, Maryland,
11 Minnesota, and Pennsylvania pray that the Court:

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

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

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

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

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

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

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DATED this 9th day of March, 2023.

ROBERT W. FERGUSON
Attorney General of Washington

/s/ Kristin Beneski
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744
Attorneys for Plaintiff State of Washington

ELLEN F. ROSENBLUM
Attorney General of Oregon

/s/ Marc Hull
SANDER MARCUS HULL WSBA #35986
Senior Assistant Attorney General
YOUNGWOON JOH OSB #164105
Assistant Attorney General
Trial Attorneys
Tel (971) 673-1880
Fax (971) 673-5000
marcus.hull@doj.state.or.us
youngwoon.joh@doj.state.or.us
Attorneys for State of Oregon

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KRIS MAYES
Attorney General of Arizona

/s/ Daniel C. Barr

Daniel C. Barr (Arizona No. 010149)
Chief Deputy Attorney General
Luci D. Davis (Arizona No. 35347)
Assistant Attorney General
Office of the Attorney General of Arizona
2005 N. Central Ave.
Phoenix, AZ 85004-1592
Phone: (602) 542-8080
Email: Daniel.Barr@azag.gov
Luci.Davis@azag.gov
Attorneys for Plaintiff State of Arizona

PHILIP J. WEISER
Attorney General of Colorado

/s/ Eric Olson

ERIC OLSON, CO #36414
Solicitor General
MICHAEL MCMASTER, CO #42368
Assistant Solicitor General
Office of the Attorney General
Colorado Department of Law
1300 Broadway, 10th Floor
Denver, CO 80203
Phone: (720) 508-6000
Attorneys for Plaintiff State of Colorado

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WILLIAM TONG
Attorney General of Connecticut

/s/ Joshua Perry
Joshua Perry*
Solicitor General
Office of the Connecticut Attorney General
165 Capitol Ave, Hartford, CT 06106
Joshua.perry@ct.gov
(860) 808-5372
Fax: (860) 808-5387
Attorney for Plaintiff State of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

/s/ Vanessa L. Kassab
VANESSA L. KASSAB*
Deputy Attorney General
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801
302-683-8899
vanessa.kassab@delaware.gov
Attorney for Plaintiff State of Delaware

KWAME RAOUL
Attorney General of Illinois

/s/ Liza Roberson-Young
Liza Roberson-Young*
Public Interest Counsel
Office of the Illinois Attorney General
100 West Randolph Street
Chicago, IL 60601
Phone: (872) 272-0788
E.RobersonYoung@ilag.gov
Attorney for Plaintiff State of Illinois

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DANA NESSEL
Attorney General of Michigan

/s/ Stephanie M. Service
Stephanie M. Service (P73305)
Assistant Attorney General
Michigan Department of Attorney General
Health, Education & Family
Services Division
P.O. Box 30758
Lansing, MI 48909
(517) 335-7603
ServiceS3@michigan.gov
*Attorney for Plaintiff Attorney General of
Michigan*

AARON D. FORD
Attorney General of Nevada

/s/ Heidi Parry Stern
Heidi Parry Stern (Bar. No. 8873)*
Solicitor General
Office of the Nevada Attorney General
555 E. Washington Ave., Ste. 3900
Las Vegas, NV 89101
HStern@ag.nv.gov
Attorney for Plaintiff State of Nevada

RAÚL TORREZ
Attorney General of New Mexico

/s/ Aletheia Allen
Aletheia Allen
Solicitor General
New Mexico Office of the Attorney General
201 Third St. NW, Suite 300
Albuquerque, NM 87102
AAllen@nmag.gov
Attorney for Plaintiff State of New Mexico

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PETER F. NERONHA
Attorney General of Rhode Island

/s/ Julia C. Harvey
JULIA C. HARVEY #10529
Special Assistant Attorney General
150 S. Main Street
Providence, RI 02903
(401) 274-4400 x2103
Attorney for Plaintiff State of Rhode Island

CHARITY R. CLARK
Attorney General of Vermont

/s/ Eleanor L.P. Spottswood
ELEANOR L.P. SPOTTSWOOD*
Solicitor General
109 State Street
Montpelier, VT 05609-1001
(802)793-1646
eleanor.spottswood@vermont.gov
Attorney for Plaintiff State of Vermont

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BRIAN L. SCHWALB
Attorney General for the District of
Columbia
JENNIFER C. JONES
Deputy Attorney General
Public Advocacy Division
WILLIAM STEPHENS
Counsel to the Deputy

/s/ Nicole S. Hill
NICOLE S. HILL*
Assistant Attorney General
Office of the Attorney General for the
District of Columbia
400 Sixth Street, N.W.
Washington, D.C. 20001
(202) 727-4171
nicole.hill@dc.gov
Attorneys for Plaintiff District of Columbia

ANNE E. LOPEZ
Attorney General
/s/ Erin N. Lau
Erin N. Lau 009887*
465 South King St., Room 200
Honolulu, Hawaii 96813
Erin.N.Lau@hawaii.gov
Counsel for the State of Hawaii

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AARON M. FREY
Attorney General

/s/ Halliday Moncure
Halliday Moncure, Bar No. 4559*
Assistant Attorney General
Office of the Maine Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8800
halliday.moncure@maine.gov

ANTHONY G. BROWN
Attorney General of Maryland

/s/Steven M. Sullivan
STEVEN M. SULLIVAN*
Solicitor General
Office of the Attorney General of Maryland
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
(410) 576-6427
ssullivan@oag.state.md.us
Attorney for Plaintiff State of Maryland

KEITH ELLISON
Attorney General
State of Minnesota

/s/Liz Kramer
LIZ KRAMER (#0325089)*
Solicitor General
JENNIFER OLSON (#0391356)*
Assistant Attorney General
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 757-1010 (Voice)
(651) 282-5832 (Fax)
liz.kramer@ag.state.mn.us
jennifer.olson@ag.state.mn.us
Attorneys for Plaintiff State of Minnesota

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MICHELLE A. HENRY
Attorney General of Pennsylvania

/s/ Jill M. Graziano
JILL M. GRAZIANO (Pa Bar No. 82725)*
Chief Counsel to the Attorney General
1000 Madison Ave., Ste. 310
Norristown, PA 19403
jgraziano@attorneygeneral.gov
(484) 460-1330
*Attorney for the Commonwealth of
Pennsylvania*

**Applications for pro hac vice admission
forthcoming*

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CERTIFICATE OF SERVICE

I hereby certify that on March 9, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 9th day of March, 2023, at Seattle, Washington.

/s/Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General