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CITIZEN PETITION

Pursuant to 21 C.F.R. § 10.30, the Commonwealth of Massachusetts, along with the states of California, New Jersey, and New York (together, the Petitioner States) submit this petition to request that the Food and Drug Administration (FDA) remove the current shared system risk evaluation and mitigation strategy program, known as the Mifepristone REMS Program, for Mifeprex and its generic, Mifepristone Tablets, 200 mg (referred to collectively as "mifepristone"). Alternatively, Petitioner States ask FDA to exercise its discretion not to enforce certain aspects of the Elements to Assure Safe Use—specifically, the Prescriber Certification, Patient Certification, and Pharmacy Certification elements—in Petitioner States given the rigorous regulations already in place around the practice of medicine.

On May 14, 2025, Robert F. Kennedy, Jr., Secretary of Health and Human Services (HHS), testified before the Senate Health, Education, Labor and Pensions Committee that he had ordered FDA administrator Martin A. Makary to conduct a "complete review" of mifepristone and its labeling requirements.[1] In response to Secretary Kennedy's statements, and in light of the complete review being conducted by FDA, the Petitioner States respectfully submit this petition.

Since FDA approved mifepristone for early-stage abortion care in 2000, approximately 7.5 million Americans have safely used the medication as part of a two-drug regimen.[2] It is the

[1] *Hearing on Fiscal Year 2026 Department of Health and Human Services Budget: Hearing Before the S. Comm. On Health, Educ., Labor & Pensions*, 119th Cong. (2025) (statement of Robert F. Kennedy, Jr., Secretary, Health and Human Services), https://www.help.senate.gov/hearings/hearing-on-fiscal-year-2026-department-of-health-and-human-services-budget.

[2] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024* 1, https://www.fda.gov/media/185245/download) [hereinafter FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024].

primary form of abortion care in most Petitioner States and has proven to be incredibly safe and effective. Given mifepristone's well-established, 25-year safety record, FDA's current restrictions on mifepristone are no longer justified by science or law, particularly in the Petitioner States where the right to abortion is legal, protected, and comprehensively regulated by state law. The Petitioner States therefore respectfully request that FDA fully lift the Mifepristone REMS Program, or, alternatively, exercise enforcement discretion and not enforce the Mifepristone REMS Program (or elements thereof) for prescribers practicing within the Petitioner States.[3]

ACTION REQUESTED

The Petitioner States request that the FDA remove the Mifepristone REMS Program, including but not limited to the Prescriber Certification, Pharmacy Certification, and Patient Agreement form. Alternatively, the Petitioner States request that the FDA exercise its discretion to not enforce the requirements of Prescriber Certification, Pharmacy Certification, and Patient Agreement form (or elements thereof) within Petitioner States, which already impose ample protections to ensure patient safety, to minimize these unnecessary, duplicative, and burdensome requirements and maximize access to this critical medication.[4]

STATEMENT OF GROUNDS

Mifepristone, in a regimen with misoprostol, has for 25 years been the only FDA-approved method to end an intrauterine pregnancy through 10 weeks' gestation, and is currently the most common method of ending early pregnancy in the United States.[5] Since its approval in 2000, mifepristone has proven extraordinarily safe. As FDA's 2016 medical review (based on 2.5 million U.S. uses at that time) explained: "[Medication abortion] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare."[6] Today, the evidence of mifepristone's

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[3] By submitting this Citizen Petition, the Petitioner States seek to ensure that FDA appropriately considers numerous studies that post-date FDA's July 26, 2021 literature review and FDA's January 2023 REMS decision. The Petitioner States also advocate for FDA's consideration of many earlier studies and other materials that FDA erroneously excluded from consideration in its 2023 REMS decision, which bear on issues of patient access and burdens on the healthcare system. *See* Ctr. for Drug Evaluation and Rsch., FDA, Application No. 20687 and 91178 (Review Completion Date Dec. 16, 2021), Appendix A at 45-59 (listing references excluded from FDA's 2021 mifepristone REMS review as though incorporated herein). Finally, the Petitioner States also request FDA consider the declarations filed by abortion providers, pharmacists, and healthcare administrators in the *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.) case as though incorporated herein—which provide additional evidence of how the Mifepristone REMS Program impedes patient access and unduly burdens the healthcare system—and to consider those declarations as stakeholder feedback, which FDA previously requested from the mifepristone sponsors.

[4] For the reasons stated herein expressing why the current Mifepristone REMS Program is unnecessary and burdensome, FDA should not revert to prior versions of the REMS Program that required additional actions on the part of prescribers, patients, or pharmacies, nor include any additional elements to the current Mifepristone REMS Program.

[5] *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last visited May 30, 2025).

[6] Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Orig1s020 Mifeprex Medical Review(s)* 12 (Mar. 29, 2016) [hereinafter FDA Mifeprex Medical Review(s) March 29, 2016]; *see also* Mifeprex REMS Study

safety is clearer than ever: Mifepristone's "associated" fatality rate is a miniscule **0.00048%** for the 25 years it has been on the U.S. market, and not one of these exceedingly rare deaths from among the now 7.5 million uses can "with certainty be causally attributed to mifepristone."[7] As the former President of the American Medical Association (AMA) recently explained, "[i]t is rare for a patient to experience even a minor complication from a medication abortion, and the risk of death is so small . . . as to be nearly nonexistent."[8]

The current Mifepristone REMS is medically unnecessary and unduly burdensome on patient access to mifepristone, particularly in rural and medically underserved areas, and imposes an unnecessary burden on the health delivery system. Based on mifepristone's extensive safety record established over the last 25 years and the important and often critical benefits that the medication provides patients, FDA should remove the restrictive Mifepristone REMS Program in its entirety. At minimum, FDA should exercise its discretion and ensure that these requirements are not enforced in Petitioner States, all of which have robust legal and regulatory protections in place to rigorously oversee the medical professions, maximize patient safety, and ensure informed consent.

I. Statutory Framework Relevant to the Mifepristone REMS Program

The risk evaluation and mitigation strategy (REMS) program was established in 2007 as a drug safety program with the goal of ensuring that the benefits of a drug with certain serious safety concerns outweigh the risks of the drug.[9] 21 U.S.C. § 355-1(a). FDA has the authority to impose a REMS when it determines that restrictions are necessary based on the consideration of six interrelated statutory factors:

(1) "[t]he estimated size of the population likely to use the drug involved;"

Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex,* 376 NEJM 790, 791 (Feb. 23, 2017); Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 NEJM 597, 597-98 (Aug. 15, 2019); WHO Expert Comm. on Selection and Use of Essential Medicines, World Health Org., *The Selection and Use of Essential Medicines* 422, 426 (2019) (recommending the addition of mifepristone to its Essential Medicines List based on the accumulated evidence "that close medical supervision is not required for its safe and effective use.").

[7] FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024, *supra* note 2, at 1 (36 deaths from approximately 7.5 million uses; included among the deaths possibly associated with mifepristone use were cases of homicide and suspected homicide, suicide, substance abuse/drug overdose, and methadone overdose); FDA, *Mifepristone 2023 Labeling and Medication Guide* 16 (2023) ("Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifeprex and misoprostol caused these deaths.") [hereinafter Mifepristone 2023 Labeling and Medication Guide]; *see also* Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone US Post-Marketing Adverse Events Summary through 6/30/2021"* 1-2 (Nov. 2022), https://www.ansirh.org/sites/default/files/2022-11/mifepristone_safety_11-15-22_Updated_0.pdf.

[8] Dr. Jack Resneck Jr., Former AMA President, *Reducing access to mifepristone would harm patients*, AMA (Mar. 25, 2024), https://www.ama-assn.org/about/leadership/reducing-access-mifepristone-would-harm-patients (citing Advancing New Standards in Reprod. Health, *supra* note 7, at 3); *see also* Citizen Petition from Sandra E. Brooks, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, et al. to FDA (Jan. 31, 2025) [hereinafter Citizen Petition from ACOG (Jan. 2025)] (describing the risk of death as "almost non-existent").

[9] *See* FDA, *Risk Evaluation and Mitigation Strategies (REMS)*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last visited May 30, 2025).

(2) "[t]he seriousness of the disease or condition that is to be treated with the drug;"
(3) "[t]he expected benefit of the drug with respect to such disease or condition;"
(4) "[t]he expected or actual duration of treatment with the drug;"
(5) "[t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug;" and,
(6) "[w]hether the drug is a new molecular entity."

21 U.S.C. § 355-1(a)(1). FDA itself has published guidance on the application of these factors.[10] These factors are also relevant when FDA considers modifications to a REMS program. *See Washington v. United States Food & Drug Admin.*, 668 F. Supp. 3d 1125, 1140–41 (E.D. Wash.) (explaining that "it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and [Elements to Assure Safe Use] should be removed in whole or part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1)").[11]

A REMS can include one or more elements, such as a Medication Guide, a patient package insert, and/or a communication plan.[12] In cases where a drug is shown to be effective but "because of its inherent toxicity or potential harmfulness" is associated with a "specific serious risk" and cannot be approved without extra safety controls, FDA is authorized to impose additional elements called Elements to Assure Safe Use (ETASU). *Id.* § 355-1(f)(1)(A). Any ETASU must be "commensurate with the specific serious risk listed in the labeling of the drug" and "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)." *Id.* § 355-1(f)(2)(C)(ii). Further, any ETASU must, to the extent practicable, "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(D).

Importantly, REMS requirements are not permanent but can change as data from clinical research and postmarketing surveillance emerges. Congress has expressly authorized FDA to require a REMS modification or removal when FDA determines that it is necessary to "ensure the benefits of the drug outweigh the risks of the drug" or to "minimize the burden on the health care delivery system of complying with the strategy." *Id.* § 355-1(g)(4)(B).

II. Based on 25 Years of Evidence and Safe Use, Mifepristone Does Not Need a REMS Program

Based on mifepristone's extensive safety record established over the last 25 years and the important and often critical benefits that the medication provides patients, the restrictive Mifepristone REMS Program should be eliminated because: (A) the current Mifepristone REMS is medically unjustified under the REMS statutory factors; (B) mifepristone's safety has remained stable even as its restrictions have been lessened; (C) the Mifepristone REMS Program

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[10] FDA, Health & Hum. Servs., *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary – Guidance for Industry* 5 - 9 (Apr. 2019), https://www.fda.gov/media/100307/download.

[11] FDA has also acknowledged that it "generally considers these factors in determining whether (based on new safety information) a REMS is necessary for a drug that is the subject of an approved application." *Id.* at 5 n.24.

[12] *Id.* at 2.

is unduly burdensome on patients, providers, pharmacies, and states' healthcare delivery system; and (D) its continuation cannot be squared with the FDA's lack of REMS programs on drugs that have significantly more risks than mifepristone. Thus, FDA should eliminate the Mifepristone REMS Program and treat mifepristone consistent with other safe, effective medications used by millions of people.

A. The Mifepristone REMS Program Is Unnecessary Under the REMS Statutory Factors

Consideration of the REMS statutory factors set forth below compels the conclusion that the Mifepristone REMS Program is no longer warranted as the medication has been safely used by more than 7.5 million women and serious adverse events have been, in the FDA's own words, "extremely rare."[13]

1. The estimated size of the population likely to use the drug involved

The population of patients likely to use mifepristone is significant. Indeed, since mifepristone was first approved in September 2000 through the end of December 2024 (09/28-00-12/31/24), more than 7.5 million women in the United States have taken mifepristone for medical termination of early pregnancy.[14] That number is continuing to increase in the Petitioner States, where abortion remains legal and protected.

It is estimated that by age 45, one in four women in the United States will have had an abortion, and at least as many will have had a miscarriage.[15] Abortions are most commonly performed in the first trimester, with the majority of abortions occurring before 10 weeks gestation.[16] Mifepristone, in a regimen with misoprostol, is the standard and only FDA-approved method to end an intrauterine pregnancy through 10 weeks' gestation.[17] Given that the majority of abortions occur in the first trimester, the majority of US women seeking abortion care do so within the gestational age for which they are eligible to obtain a medication abortion.

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[13] FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 12; FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024, *supra* note 2, at 1.

[14] FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024, *supra* note 2, at 1.

[15] Jessica Beaman et al., *Medication to Manage Abortion and Miscarriage*, 35 J. Gen. Internal Med. 2398, 2398 (2020) (citing Rachel K. Jones, & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008-2014*, 107 Am. J. Public Health, 1904, 1904–09 (2017); *Early Pregnancy Loss – Frequently Asked Questions*, Am. Coll. of Obstetricians & Gynecologists, https://www.acog.org/womens-health/faqs/early-pregnancy-loss?utm_source=redirect&utm_medium=web&utm_campaign=otn (last updated Sept. 2024).

[16] *See* Stephanie Ramer et al., *Abortion Surveillance — United States, 2022,* 73 Morbidity & Mortality Weekly Rep. Surveillance Summaries 1, 6 (Nov. 28, 2024) ("For 2022, among the 41 areas that reported gestational age at the time of abortion, 78.6% of abortions were performed at ≤9 weeks' gestation, and 92.8% were performed at ≤13 weeks' gestation."); Katherine Kortsmit et al., *Abortion Surveillance — United States, 2021*, 72 Morbidity & Mortality Weekly Rep. Surveillance Summaries 1, 6 (Nov. 24, 2023) ("For 2021, among the 41 areas that reported gestational age at the time of abortion, 80.8% of abortions were performed at ≤9 weeks' gestation, and 93.5% were performed at ≤13 weeks' gestation.").

[17] *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 5.

In 2022, a total of 613,383 abortions were reported to Centers for Disease Control and Prevention (CDC) from 48 areas in the United States.[18] Among the 47 continuously reporting areas, the abortion rate was 11.2 abortions per 1,000 women aged 15–44 years, and the abortion ratio was 199 abortions per 1,000 live births.[19] During 2022, approximately four of five abortions occurred early in gestation (≤9 weeks).[20] Among abortions occurring at ≤9 weeks' gestation in 2022, approximately two thirds (70.2%) were reported as medication abortions.[21] In 2022, the most common method among abortions reported overall was medication abortion at ≤9 weeks' gestation (53.3%).[22] Among continuously reporting areas that reported by method type and included medication abortion on their reporting form, the percentage of all abortions performed by medication abortion increased 129% from 2013 to 2022 and increased 4% from 2021 to 2022.[23]

Medication abortion is the primary means by which patients access abortion in the Petitioner States. For instance, in Massachusetts, approximately 65% of abortions in the state were medication abortions in 2023.[24] In California, in 2023, 71% of abortions in the state were medication abortions.[25] In New York, in 2023, 58% of abortions in the state were medication abortions.[26] In New Jersey, in 2023, 57% of abortions in the state were medication abortions.[27]

Further, the Mifepristone REMS Program applies to the use of the mifepristone-misoprostol regimen for early miscarriage management, which is recommended by the American College of Obstetricians and Gynecologists (ACOG)[28] and commonly used by physicians to facilitate (complete) the termination of a pregnancy once a miscarriage has begun.[29] Because most miscarriages occur in the first trimester[30], and mifepristone is indicated

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[18] Stephanie Ramer et al., *Abortion Surveillance — United States, 2022*, *supra* note 16, at 13, 17.

[19] *Id.* at 4.

[20] *Id.* at 7.

[21] *Id.* at 8. Within this data, "early medication abortion is defined as the administration of medications (typically mifepristone followed by misoprostol) to induce an abortion at ≤9 completed weeks' gestation, consistent with U.S. Food and Drug Administration (FDA) labeling for mifepristone that was implemented in 2016." *Id.* at 3.

[22] *Id.* at 8.

[23] *Id.*

[24] *See* Mass. Dep't Public Health, *Massachusetts Induced Termination of Pregnancy 2023* 5 (Nov. 2024), https://www.mass.gov/doc/massachusetts-induced-termination-of-pregnancy-2023-pdf/download.

[25] *California Abortion Data*, KFF, https://www.kff.org/interactive/womens-health-profiles/california/abortion-statistics/ (last visited May 15, 2025).

[26] *New York Abortion Data*, KFF, https://www.kff.org/interactive/womens-health-profiles/new-york/abortion-statistics/ (last visited May 31, 2025).

[27] *New Jersey Abortion Data*, KFF, https://www.kff.org/interactive/womens-health-profiles/new-jersey/abortion-statistics/ (last visited May 31, 2025).

[28] *See* Elise W. Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, 330 JAMA 766 (2023) (noting that a regimen of mifepristone with misoprostol is now recommended by the American College of Gynecologists for medical management of miscarriage).

[29] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 NEJM 2161, 2162 (June 7, 2018); Justin J. Chu, et al., *Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): a randomised, double-blind, placebo-controlled trial*, 396 Lancet 770, 771 (2020).

[30] *Early Pregnancy Loss, Practice Bulletin No. 200*, Am. College Obstetricians & Gynecologists (Nov. 2018), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss (noting 80% of pregnancy loss occur in the first trimester).

for incomplete miscarriage, it is currently the standard of care for a majority of women experiencing early miscarriage.[31]

2. The seriousness of the disease or condition that is to be treated with the drug

Mifepristone safely and effectively treats unintended or compromised pregnancy. For over 25 years, mifepristone has been effective at terminating pregnancy for pregnant patients who need an abortion, regardless of the reason. Pregnancy is a condition that involves changes to many bodily systems and itself carries significant medical risks for many patients. Common complications of pregnancy include, but are not limited to, high blood pressure, gestational diabetes, infections, preeclampsia, preterm labor, depression and anxiety, pregnancy loss/miscarriage, stillbirth, among other complications.[32] Many, if not all, of these conditions are resolved upon termination or resolution of pregnancy.[33] For patients whose health is already compromised, pregnancy can be a serious medical condition.

Research indicates that "the health of pregnant women in the US has worsened over the past three decades and that it continues to do so at alarming rates."[34] According to the CDC, studies show that an increasing number of pregnant women in the United States have chronic health conditions such as hypertension, diabetes, and chronic heart disease, and that these conditions may put a woman at higher risk of complications during or within one year of the end of pregnancy.[35] Research shows that as many as 13% of U.S. women reported frequent symptoms of depression after childbirth, and that anxiety co-occurs in up to 43% of depressed pregnant and postpartum women, making pregnancy-related depression and anxiety among the more common pregnancy complications.[36] In addition, as noted above, use of mifepristone is part of the "gold standard" treatment for miscarriage management, and, if not properly managed,

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[31] Elise W. Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, *supra* note 28.

[32] *What are some common complications of pregnancy?*, Eunice Kennedy Shriver Nat'l Inst. of Child Health & Hum. Dev. (May 29, 2024), https://www.nichd.nih.gov/health/topics/pregnancy/conditioninfo/complications.

[33] *See, e.g.,* Christopher Ives et al., *Preeclampsia—Pathophysiology and Clinical Presentations,* Journal of the American College of Cardiology 1690-702, 1691 (2020) (delivery is the "only definitive treatment" for preeclampsia); Cleveland Clinic, *High Blood Pressure (Hypertension) During Pregnancy*, https://my.clevelandclinic.org/health/diseases/4497-gestational-hypertension (noting high blood pressure typically resolves after delivery).

[34] Eran Bornstein et al., *Concerning Trends in Maternal Risk Factors in the United States: 1989—2018*, 29-30 eClinical Med. at 1, 8 (Nov. 2020).

[35] CDC, Pregnancy Mortality Surveillance System 4 (Nov. 14, 2024) (citing Nicole N. Ford et al., *Hypertensive Disorders in Pregnancy and Mortality at Delivery Hospitalization – United States, 2017-2019*, 71 Morbidity & Mortality Weekly Rep. 585, 585–591 (Apr. 29, 2022); Lindsay L. Admon et al., *Disparities in Chronic Conditions Among Women Hospitalized for Delivery in the United States, 2005–2014*, 130 Obstetrics & Gynecology 1319, 1319–1326 (2017); Lindsey P. Gorsch et al., *Trends in delivery hospitalizations with pregestational and gestational diabetes and associated outcomes: 2000-2019* 229 Am. J. Obstetrics & Gynecology 63.e1, 63.e1-63.e4 (2023); Monil Majmundar et al., *Prevalence, trends, and outcomes of cardiovascular diseases in pregnant patients in the USA: 2010-2019*, 44 Eur. Heart J. 726, 726-737 (2023)).

[36] *What are some common complications of pregnancy?*, *supra* note 32 (citing Yann Le Strat et al., *Prevalence and correlates of major depressive episode in pregnant and postpartum women in the United States,* 135 J. Affective Disorders 128-138 (2011)).

miscarriages can lead to severe complications including excessive bleeding, sepsis, and endometritis.[37]

Not only can pregnancy be risky, but it can also be deadly. In 2023, 669 women died of maternal causes in the United States.[38] Maternal mortality rates in the United States have more than doubled during the past three decades, increasing from 7.9 per 100,000 live births in 1989 to 17.4 per 100,000 live births in 2018.[39] And this number has continued upward with a maternal mortality rate of 18.3 deaths per 100,000 live births in 2023.[40] Abortion, by comparison is very safe. According to the CDC, during 2013-2021, the national case-fatality rate for legal induced abortion was 0.46 deaths per 100,000 reported legal abortions.[41] Thus, according to these federal statistics, the risk of death in childbirth is more than ***39 times greater*** than the risk of death with abortion by any method.[42]

Causes of pregnancy-related deaths in the United States include cardiovascular conditions, infection or sepsis, hemorrhage, cardiomyopathy, thrombotic pulmonary or other embolisms, hypertensive disorders of pregnancy, amniotic fluid embolism, cerebrovascular accidents, and anesthesia complications.[43] Further, the risks associated with childbirth are particularly pronounced for Black women, who are approximately 3.5 times more likely than white women to die around the time of childbirth (50.3 deaths per 100,000 live births for black women compared to 14.5 deaths per 100,000 live births for white women).[44] And women age 40 and older also have much greater risk of maternal mortality, with a death rate nearly five times higher than the rate for women younger than age 25.[45]

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37 *See* Ashley Redinger & Hao Nguyen, *Incomplete Miscarriage* 8 (updated Feb. 12, 2024), https://www.ncbi.nlm.nih.gov/books/NBK559071/ (describing complications associated with incomplete miscarriage).

38 Nat'l Ctr. for Health Stat., CDC, *Health E-Stats: Maternal Mortality Rates in the United States*, *2023* 6 (Feb. 2025).

39 Eran Bornstein et al., *Concerning trends in maternal risk factors in the United States: 1998—2018*, *supra* note 34, at 1.

40 Nat'l Ctr. for Health Stat., *supra* note 38, at 1.

41 Stephanie Ramer et al., *Abortion Surveillance — United States, 2022*, *supra* note 16, at 8, 28.

42 *Id*. Earlier studies put the risk of death associated with childbirth at approximately 14 times higher than that with abortion. *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216 (2021). But that determination was based on a pregnancy-associated mortality rate of 8.8 deaths per 100,000 live births and a mortality rate of legal induced abortion of 0.6 deaths per 100,000 abortions. *See id.* (evaluating data from 1998-2005). Since that time, however, the risk of death during childbirth has more than doubled and the risk of death during a legal abortion has further decreased. *See* Nat'l Ctr. for Health Stat., *supra* note 38, at 1; Stephanie Ramer et al., *Abortion Surveillance — United States, 2022*, *supra* note 16, at 8, 28.

43 CDC, *supra* note 35, at 4.

44 *Id.*; *see also* Claire Cain Miller et al., *Childbirth is Deadlier for Black Families Even When They're Rich, Expansive Study Finds*, N.Y. Times (Feb. 12, 2023), https://www.nytimes.com/interactive/2023/02/12/upshot/child-maternal-mortality-rich-poor.html?smid=url-share.

45 CDC, supra note 35, at 5.

The higher rates of significant and mounting risks associated with pregnancy and childbirth, when compared to the low risk of serious complications from mifepristone, further highlight mifepristone's safety and demonstrate that the mifepristone REMS are unnecessary.[46]

3. The expected benefit of the drug with respect to such disease or condition

The mifepristone-misoprostol regimen is highly effective at ending early pregnancy. This regimen successfully terminates pregnancy in approximately 97% of patients with a gestational age of 10 weeks or less.[47] For these reasons, the World Health Organization (WHO) includes the mifepristone-misoprostol regimen on its core list of essential and life-saving medications (EML), reflecting the medication's critical role to women's health.[48]

As FDA has acknowledged, mifepristone may be "preferable and safer in [a patient's] particular situation," compared to procedural abortion.[49] This is true for several reasons. From a medical standpoint, as the American College of Obstetricians and Gynecologists (ACOG) explains, there are various medical conditions for which a medication abortion may be safer for a patient than a procedural abortion.[50] Some examples include uterine fibroids that significantly distort the cervical canal or uterine cavity, congenital uterine anomalies, or introital scarring related to infibulation.[51] Some patients may wish to avoid the invasive nature of a procedural abortion, or may prefer the relative flexibility and privacy that medication abortion offers.

Physicians also use mifepristone in combination with misoprostol to complete the termination of a pregnancy once a miscarriage has begun.[52] Using mifepristone in combination with misoprostol for treatment of early pregnancy loss results in "a significantly higher rate of complete gestational sac expulsion by approximately 2 days after treatment than misoprostol use

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46 *See, e.g.,* Committee on Practice Bulletins—Gynecology and the Society of Family Planning, Practice Bulletin, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e38 (Oct. 2020); Nathalie Kapp & Patricia A. Lohr, *Modern methods to induce abortion: Safety, efficacy and choice*, 63 Best Prac. & Rsch. Clinical Obstetrics & Gynecology 37, 41 & 42 (2020).

47 *See, e.g.*, FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 29; *see also* Nat'l Acad. of Sci., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* 100 (2018); Lauren Porsch et al., *Advanced Practice Clinicians and Medication Abortion Safety: A 10-Year Retrospective Review (Abstract)*, 101 Contraception 357, 357 (Mar. 15, 2020).

48 WHO Expert Comm. on Selection and Use of Essential Medicines, World Health Org., *The Selection and Use of Essential Medicines* 17, 635 (2019).

49 Letter from Dr. Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., FDA, to Donna Harrison, Exec. Dir., Am. Assoc. Pro Life Obstetricians & Gynecologists, et al. 5 (Mar. 29, 2016) (denying the AAPLOG citizen petition) [hereinafter Denial of AAPLOG Citizen Petition (Mar. 2016)]; FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 9.

50 Committee on Practice Bulletins, *Medication Abortion Up to 70 Days of Gestation*, *supra* note 46, at e32.

51 *Id*.

52 Courtney A. Schreiber, *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, *supra* note 29, at 2161; Justin J. Chu, *Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): a randomised, double-blind, placebo-controlled trial*, *supra* note 29, at 770; Courtney C. Baker et al., *Early pregnancy loss medical management in clinical practice,* 126 Contraception 110134 at 1, 4 (2023) (finding that "[o]utside of a clinical trial setting, medical management of EPL with mifepristone and misoprostol remains effective and safe.").

alone."[53] Using a combination of mifepristone and misoprostol is also associated with decreased needs for emergency care or procedural intervention than misoprostol alone.[54]

4. The expected or actual duration of treatment with the drug

When used for medication abortion, patients take one 200 mg mifepristone tablet prescribed for a single use, followed by 800 mcg of misoprostol taken buccally 24 to 48 hours later at a place of their choosing, usually at home.[55] Most patients expel the pregnancy tissue within 2 to 24 hours after taking the misoprostol tablets.[56] Patients are directed to follow up with their health care provider 7 to 14 days after taking the mifepristone.[57] In the infrequent cases where there is incomplete expulsion of pregnancy tissue, this is managed via an additional dose of misoprostol or uterine aspiration; no additional dose of mifepristone is required.[58] There is no evidence that mifepristone requires long-term therapy or threatens serious adverse events immediately after administration. Accordingly, mifepristone does not implicate concerns regarding duration of treatment or the impact of treatment length on likelihood and severity of adverse events.

5. The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug

As with all prescription drugs, the FDA-approved labeling for mifepristone provides important information about potential serious risks, but makes clear that these risks are both rare and not inherent to mifepristone itself. Specifically, mifepristone's labeling states: "Serious and sometimes fatal infections and bleeding occur very rarely *following spontaneous, surgical, and medical abortions*, including following [mifepristone] use. No causal relationship between the use of [mifepristone] and misoprostol and these events has been established."[59] Furthermore, the labeling highlights that the risk of severe adverse reactions is very low, occurring in less than 0.5% of patients.[60] More importantly, the labeling specifies that these risks are inherent whenever the pregnant uterus is evacuated, whether by "miscarriage, surgical abortion, medical

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[53] Courtney A. Schreiber, *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, *supra* note 29, at 2167.

[54] Lyndsey S. Benson et al., *Outcomes After Early Pregnancy Loss Management with Mifepristone Plus Misoprostol vs Misoprostol Alone,* 7 JAMA Network Open 1, 1 (Oct. 8, 2024).

[55] Mifepristone 2023 Labeling and Medication Guide*, supra* note 7, at 1, 3, 5.

[56] *Id.* at 3, 18.

[57] *Id.* at 4, 18.

[58] Committee on Practice Bulletins, *Medication Abortion Up to 70 Days of Gestation*, *supra* note 46, at e38 (2020).

[59] Mifepristone 2023 Labeling and Medication Guide*, supra* note 7, at 2 (emphasis added).

[60] *Id.* at 7; *see also* FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 56; Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion,* 125 Obstetrics & Gynecology 175, 181 (2015) (study of over 55,000 abortions found a major complications rate of 0.23% – 0.31% for medication abortion; 0.16% for procedural abortion (i.e., abortion by aspiration)); Advancing New Standards In Reprod. Health, *U.S. Studies on Medication Abortion without In-Person Clinician Dispensing of Mifepristone* 1 – 3 (May 2024).

abortion, or childbirth."[61] And as the FDA has previously acknowledged, "the critical risk factor" for certain rare infections following mifepristone use was "pregnancy itself"—not mifepristone.[62] These risks are accurately reiterated in the Medication Guide that accompanies the medication.

6. Whether the drug is a new molecular entity

Far from being a new molecular entity, mifepristone has been marketed in the U.S. for decades and has been safely used by more than 7.5 million women in the United States. Moreover, no new evidence raising safety concerns has emerged in the last two decades.[63] The extensive post-marketing data and real-world use overwhelmingly and repeatedly demonstrate mifepristone's safety.

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Taking these statutory factors into consideration, it is evident that the Mifepristone REMS restrictions are unjustified both on patients and the healthcare system. As former FDA Commissioner Dr. Jane Henney wrote in 2019: "The accumulated knowledge about mifepristone strongly suggests that the current restricted distribution system is not aligned with the limited risks that are now known to be posed by the drug."[64] Leading medical organizations have long opposed the unduly burdensome restrictions of the Mifepristone REMS Program.[65] Last year ACOG, joined by the American Academy of Pediatrics, the American College of Preventive Medicine, the AMA, the American Society for Reproductive Medicine, the American Urogynecologic Society, the National Association of Nurse Practitioners in Women's Health, the Society for Academic Specialists in General Obstetrics and Gynecology, the Society of Family Planning (SFP), the Society for Maternal-Fetal Medicine (SMFM), and the Society of General Internal Medicine collectively asked FDA to remove the Mifepristone REMS Program, explaining that "[r]obust clinical evidence backed by decades of use by millions of patients has

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61 Mifepristone 2023 Labeling and Medication Guide*, supra* note 7, at 16; *see also* Mifeprex REMS Study Group, *Sixteen Years of Overregulation, supra* note 6, at 792 ("One or both of the two serious risks described on the Mifeprex label—atypical infection and prolonged heavy vaginal bleeding—also may occur after many other common obstetrical and gynecological procedures, including vaginal delivery, medical and surgical management of miscarriage, and insertion of intrauterine devices.").

62 Denial of AAPLOG Citizen Petition (Mar. 2016), *supra* note 49, at 25-26 n.69.

63 As discussed in depth below at pp. 16-20, a 2025 purported "study" related to mifepristone safety is biased and scientifically flawed; it does not change the overwhelming weight of scientific evidence supporting mifepristone's safety.

64 Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 NEJM 597, 597 (Aug. 15, 2019).

65 *Improving Access to Mifepristone for Reproductive Health Indications – Position Statement*, Am. Coll. Obstetricians & Gynecologists (June 2018, reaff'd March 2021), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications#:~:text=In%20line%20with%20its%20safety,certification%20or%20patient%20consent%20requirements; Congress of Delegates, Am. Acad. Of Fam. Physicians, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* (May 24, 2018); *see also* Letter from Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Obstetricians & Gynecologists, & James L. Madara, Chief Exec. Officer, Am. Med. Ass'n, to Dr. Robert Califf, Comm'r, FDA (June 21, 2022); *see also* Letter from Dr. Graham Chelius, Soc'y Family Planning, to Dr. Janet Woodcock, Acting Comm'r, FDA (Sept. 29, 2021), https://societyfp.org/wp-content/uploads/2022/08/Letter-to-FDA_Mifepristone-REMS.pdf.

proven incontrovertibly that mifepristone is safe and effective for use in medication abortion and miscarriage management" and "[c]omplications associated with mifepristone are exceedingly rare, minor, and easily treatable."[66] And earlier this year, ACOG, SFP, and SMFM filed a citizen petition once again asking FDA to remove the mifepristone REMS including all of its ETASU.[67]

Petitioner States respectfully ask FDA to afford due weight to the expert opinions of the country's leading medical organizations and experts on this issue and conclude that the Mifepristone REMS Program is no longer needed to ensure that the benefits of this important and well-established medication outweigh the drug's minimal risks under the statute authorizing its use.

B. Mifepristone's Safety Record Has Remained Stable Over Time

1. Mifepristone's safety record has not changed even as regulatory restrictions have eased

Mifepristone's well-established safety record has remained stable over time, even as some of the REMS restrictions have been lifted. As FDA observed in 2016, mifepristone's safety record is "well-characterized" and "has not changed over the period of surveillance."[68] There has likewise been no change in mifepristone's safety profile following changes to mifepristone's labeling, prescribing, and dispensing requirements, including following elimination of the in-person dispensing requirement. To the contrary, research and clinical experience continue to show that mifepristone is—in the words of former Secretary of Health and Human Services Xavier Becerra—"one of the safest and most effective medicines that we have seen over the last 20 years to help women with their health care[.]"[69] This was echoed by 13 leading medical organizations with reproductive care expertise in a May 22, 2025 statement urging that "FDA approval of mifepristone must reflect the rigorous clinical evidence that has proven unequivocally that it is safe and effective," such that mifepristone is "accessible to those whose health and lives will benefit from it."[70]

FDA's decision to remove the in-person dispensing requirement was based in large part on FDA's extensive literature review,[71] as well as mifepristone's stable safety record during the

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66 Press Release, Am. Coll. Obstetricians & Gynecologists et al., Leading Medical Organizations Call for the FDA to Permanently Remove Restrictions on Mifepristone (June 18, 2024), https://www.acog.org/news/news-releases/2024/06/leading-medical-organizations-call-for-fda-to-permanently-remove-restrictions-on-mifepristone.

67 Citizen Petition from ACOG (Jan. 2025), *supra* note 8.

68 Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687, 91178 REMS Modification Rationale Review* 15 (Dec. 16, 2021) [hereinafter FDA Mifepristone REMS Modification Rationale Review (Dec. 2021)]; *see also* Letter from Dr. Patrizia A. Cavazzoni, Dir. Ctr. for Drug Evaluation & Rsch., FDA, to Dr. Donna J. Harrison, Exec. Dir, Am. Ass'n Pro-Life Obstetricians & Gynecologists, & Dr. Quentin L. Van Meter, President, Am. Coll. Pediatricians (Dec. 16, 2021) (responding to AAPLOG citizen petition).

69 Associated Press, *Health secretary slams abortion pill ruling as `not America'*, NBC News (Apr. 9, 2023), https://www.nbcnews.com/news/health-secretary-slams-abortion-pill-ruling-not-america-rcna78861.

70 Press Release, Am. Coll. Obstetricians & Gynecologists et al., Leading Medical Organizations Reaffirm the Safety of Mifepristone (May 22, 2025), https://www.acog.org/news/news-releases/2025/05/leading-medical-organizations-reaffirm-the-safety-of-mifepristone.

71 Ctr. for Drug Evaluation & Rsch., *supra* note 68, at 24 – 36 (Dec. 16, 2021) (citing Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100

COVID-19 pandemic when in-person dispensing was temporarily unenforced.[72] Since then, additional peer-reviewed literature post-dating the FDA's July 2021 literature review continues to support the FDA's decision to remove the in-person dispensing requirement. Indeed, recent research demonstrates that medication abortion care provided by telehealth is highly safe and effective,[73] and that patients are highly satisfied with telehealth medication abortion care.[74]

One recent large multi-center study, for instance, which included 3,779 U.S. patients who received medication abortion either in-person or through telehealth, "found high effectiveness and safety rates" overall, with "similarly high effectiveness and safety rates comparing patients who received medications in-person vs by mail."[75] This 2022 peer-reviewed study published in JAMA Internal Medicine further found that "[t]he effectiveness rate of 95% is comparable to studies of medication abortion models with screening ultrasonography that found effectiveness rates of 93% to 98%."[76]

Contraception 173, 173 – 177 (2019); Erica Chong et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 Contraception 43, 43 – 48 (2021); Holly A. Anger et al., *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the U.S.*, 104 Contraception 659, 659 – 665 (2021); Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49, 49 – 53 (2021); Ara Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, 128 BJOG: Int'l J. Obstetrics & Gynaecology 1464, 1464–1474 (2021); Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36, 36 – 41 (2021); Paul Hyland, Elizabeth G. Raymond, & Erica Chong, *A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months*, 58 Australian & New Zealand J. Obstetrics & Gynaecology 335, 335 – 340 (2018)).

[72] *Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin*., 472 F. Supp. 3d 183 (D. Md. 2020).

[73] *See, e.g.*, Jane W. Seymour et al., *Potential Impact of Telemedicine for Medication Abortion Policy and Programming Changes on Abortion Accessibility in the United States*, 112 Am. J. Public Health. 1202, 1202 – 1211 (2022); Samantha Ruggiero et al., *Patient and provider experiences using a site-to-site telehealth model for medication abortion*, 8 mHealth 1, 1 – 9 (2002); Abigail R.A. Aiken et al., *Safety and effectiveness of self-managed medication abortion provided using online telemedicine in the United States: A population based study*, 10 Lancet Regional Health – Americas 1, 1 – 7 (2022); Ushma Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA Internal Med. 482, 482 – 491 (2022); Ushma Upadhyay et al., *Safety and effectiveness of synchronous and asynchronous telehealth medication abortion provided by us virtual clinics (Abstract)*, 116 Contraception. 69-70 (2022); Ushma D. Upadhyay, Leah R. Koenig, & Karen R. Meckstroth, *Safety and Efficacy of Telehealth Medication Abortions in the US During the COVID-19 Pandemic*, 4 JAMA Network Open 1, 1 – 2 (2021).

[74] *See, e.g.*, Courtney Kerestes et al., *Person-centered, high-quality care from a distance: A qualitative study of patient experiences of TelAbortion, a model for direct-to-patient medication abortion by mail in the United States,* 54 Perspectives Sexual & Reprod. Health 177, 177 – 187 (2022); Ushma Upadhyay et al., *Safety and effectiveness of synchronous and asynchronous telehealth medication abortion provided by us virtual clinics (Abstract)*, *supra* note 73; Leah R. Koenig et al., *Mailing abortion pills does not delay care: A cohort study comparing mailed to in-person dispensing of abortion medications in the United States*, 121 Contraception 1, 1 – 7 (May 2023).

[75] Ushma Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, *supra* note 73, at 487 – 89 ("The adjusted rate of major abortion-related adverse events was 0.54% (95% CI, 0.18%-0.90%) and was not statistically significantly different for patients who received medications in-person (0.46%; 95% CI, 0.09%-0.83%) and by mail (0.76%; 95% CI, 0.00%-1.57%).").

[76] *Id.* at 488 (citing Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 Contraception 173-177 (2019); Mary Gatter, Kelly Cleland, & Deborah Nucatola, *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91

Another peer-reviewed published study, which included 6,034 U.S. patients who obtained medication abortion via telehealth in 20 states from April 2021 to January 2022, found an overall effectiveness rate of 97.7% and an overall safety rate of 99.7%.[77] The study further found that "[t]he serious adverse event rate of 0.25% and ectopic pregnancy rate of 0.14% were also similar to previous studies of in-person medication abortion care, which found adverse event rates of 0.2–0.5%, and ectopic pregnancy rates of 0.2%," and that "[b]oth effectiveness and safety rates were similar to the rates for medication abortions with in-person screening tests as published on the FDA label."[78]

A 2024 prospective, observational study designed with a noninferiority analysis examined 585 U.S. patients who obtained medication abortion from May 2021 to March 2023. This peer-reviewed study published in JAMA found that "medication abortion following no-test telehealth screening and mail-order pharmacy dispensing of medications was associated with similar rates of complete abortion as in-person care with ultrasonography, met the prespecified threshold for noninferiority, and had a low rate of AEs [adverse events] overall."[79] Moreover, "[l]evels of effectiveness with models of care incorporating telehealth and eligibility assessment in this study were comparable to large 2022 and 2024 studies of no-test telehealth patients."[80]

Another 2024 peer-reviewed study, published in the Journal of the American Board of Family Medicine, involved a pre-specified statistical plan to conduct a retrospective electronic medical record review of 267 U.S. medication abortions and concluded that telehealth medication abortion is "as effective, timelier, and potentially more accessible than in-clinic care."[81] In accordance with this recent, and mounting, safety data on telehealth abortion care, medical specialty and professional organizations including the National Abortion Federation, ACOG, and the Society of Family Planning, have issued clinical practice guidelines supporting

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Contraception 269-273 (2015); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion, supra* note 60, at 181 (2015).

[77] Ushma Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, 30 Nature Med. 1191, 1192, 1196 (2024).

[78] *Id.* at 1194 (citing Mifepristone 2023 Labeling and Medication Guide*, supra* note 7; Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 Contraception 26, 26 – 37 (2013); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion, supra* note 60, at 181; Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics & Gynecology 166, 166–171 (2013)).

[79] Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024).

[80] *Id.* (citing Ushma Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, *supra* note 73; Ushma Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the United States*, *supra* note 77.

[81] Silpa Srinivasulu et al., *Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care*, 37 J. of the Am. Board of Fam. Med. 295, 299 (2024).

the provision of telehealth medication abortion care,[82] and the same organizations support lifting the mifepristone REMS.[83]

This extensive safety data is bolstered by data from Canada, including a 2022 study from the New England Journal of Medicine that demonstrates that mifepristone remains safe following deregulation.[84] That study examined data before and after Canada deregulated mifepristone in November 2017 and concluded that "[w]hen mifepristone became available as a normally prescribed medication in Canada"—which allowed "any physician or nurse practitioner to prescribe, any pharmacist to dispense, and patients to independently administer mifepristone when, where, and if they chose"—there was no increase in complications from mifepristone use."[85]

Importantly, evidence shows that easing regulatory restrictions to-date enabling prescribing medication for abortion via telehealth care has significantly reduced burdens on patient access to medication abortion, *see* 21 U.S.C. 355-1(f)(2),(f)(5), including by minimizing the need for abortion-related travel, expanding geographic access to abortion, reducing cost barriers, and lessening stigma.[86] One recently published peer-reviewed study of 6,027 U.S. patients who received medication abortion by telehealth, for instance, found that "survey participants averted 41,746 miles and 1096 hours of driving, and 3070 hours of public transit time."[87] This study explains that the continued availability of telehealth medication abortion care is particularly important to patient access given that "abortion care is largely siloed to abortion facilities, which are few and far between and are now closing in record numbers," making "the impact of telehealth on improving equitable abortion access [] even greater than for other health

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[82] Nat'l Abortion Fed., *Clinical Policy Guidelines for Abortion Care* 1 (2024) (explaining that "[t]elemedicine can be safely used to provide abortion care, including medication abortion provision, informed consent, and follow-up"); Committee on Practice Bulletins, *Medication Abortion Up to 70 Days of Gestation*, *supra* note 46, at e35 ("Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction, and telemedicine improves access to early abortion care, particularly in areas that lack a health care practitioner.").

[83] *Understanding the Practical Implications of the FDA's December 2021 and January 2023 Mifepristone REMS Decisions*, Am. Coll. Of Obstetricians & Gynecologists (Mar. 28, 2022, republished Dec. 4, 2023), https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision; Press Release, Nat'l Abortion Fed., FDA Approves Modifications to Mifepristone REMS Program (Jan. 2, 2023), https://prochoice.org/fda-approves-modifications-to-mifepristone-rems-program/#:~:text=January%202%2C%202023,abortion%20care%20for%20more%20people.

[84] Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57, 66 (Jan. 6, 2022).

[85] *Id.* at 58, 66.

[86] Leah R. Koenig et al., *The role of telehealth in promoting equitable abortion access in the United States: spatial analysis,* 9 JMIR Public Health Surveillance e45671, e45679 (2023); Kathleen Marie Beardsworth et al., *Miles and days until medical abortion via TelAbortion versus clinic in Oregon and Washington, USA*, 48 BMJ Sex Reprod Health, 38-e43 (2021); Ushma Upadhyay et al., *Pricing of medication abortion in the United States, 2021–2023*, 56 Persp. on Sexual & Reprod. Health 282, 292 (2024); Andréa Becker et al., *"It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion*, 0 J. of Health & Soc. Behav. 1, 10 (2025); Anna Fiastro et al., *Telehealth vs In-Clinic Medication Abortion Services,* 6 JAMA Network Open 1-5, 4 (Sept. 1, 2023); Emily M. Godfrey et al., *Patient Perspectives Regarding Clinician Communication During Telemedicine Compared With In-Clinic Abortion*, 141 Obstetrics & Gynecology 1139, 1143 (June 1, 2023).

[87] Leah R. Koenig et al., *The role of telehealth in promoting equitable abortion access in the United States: spatial analysis*, *supra* note 86, at e45674.

care services."[88] Telehealth is also generally less expensive than in-person care. As one study found, "[t]he median cost of a medication abortion offered in-person increased from $580 in 2021 to $600 by 2023," while "[t]he median cost of a medication abortion offered by virtual clinics decreased from $239 in 2021 to $150 in 2023."[89] "Thus, expansion of telehealth and no-test or history-based models offers a safe and effective, as well as urgently needed, way to overcome at least some of the logistical, cost, and geographic barriers to accessing abortion."[90]

In sum, removing restrictions on mifepristone has not increased risks whatsoever. On the contrary, an extensive and ever-growing scientific, peer-reviewed evidence-based record proves the continued safety of mifepristone through patient telehealth following FDA's removal of the in-person dispensing requirement more than two years ago.

2. No scientific data has emerged that alters the conclusion that mifepristone is safe and effective.

Moreover, no new scientific data has emerged since the FDA's last regulatory actions that would alter the conclusion that mifepristone remains exceptionally safe and effective. Those studies that have frequently been cited to undermine mifepristone's extensive safety record have been widely criticized, retracted, or both. For example, three studies purporting to show adverse events or increased morbidity from medication abortions were retracted by the medical journals in which they had been published for failure to disclose serious conflicts of interest on the part of their authors, who were affiliated with the Charlotte Lozier Institute—the research of arm of Susan B. Anthony Pro-Life America, an anti-abortion think tank—and for containing serious methodological flaws. The flaws referenced included "fundamental problems with the study design and methodology, unjustified or incorrect factual assumptions, material errors in the authors' analysis of the data, and misleading presentations of the data that … demonstrate a lack of scientific rigor and invalidate the authors' conclusions in whole or in part."[91]

Similarly, on April 28, 2025, the Ethics and Public Policy Center (EPPC) produced what it has touted as the "largest-known study of the abortion pill."[92] This paper has not been published in any medical journal or otherwise peer-reviewed. The paper reportedly retrospectively analyzed an "all-payer insurance claims" database for prescriptions of mifepristone from 2017 to 2023, concluding that, under its reading, 10.93% of women

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88 *Id.* at e45679 (citing Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Institute (2022)).

89 Ushma Upadhyay et al., *Pricing of medication abortion in the United States, 2021–2023*, 56 Persp. on Sexual & Reprod. Health 282, 288 (2024).

90 Lauren J. Ralph et al., *Comparison of No-Test Telehealth and In-Person Medication Abortion*, 332 JAMA 898, 903 (2024).

91 Sage Journals, Retraction Notice: https://journals.sagepub.com/doi/10.1177/23333928231216699; RETRACTED: *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, https://journals.sagepub.com/doi/full/10.1177/23333928211053965; RETRACTED: *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, https://journals.sagepub.com/doi/10.1177/23333928221103107.

92 Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event* 1 (2025), https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf.

experienced a serious adverse event following taking mifepristone.[93] EPPC's retrospective, non-peer-reviewed study has already been widely rejected as biased and scientifically flawed, including by abortion opponents.[94] FDA Director Makary testified before the Senate that he "ha[d] not seen the study, the data, or the underlying methodology" of the EPPC paper and, in an exchange with a different Senator, noted that the dataset "is not available" but that FDA would "take a hard look" when it becomes available.[95] Even EPPC acknowledges FDA should not simply accept their findings, stating they "are asking the FDA to conduct its own review of this data."[96]

Retrospective studies are known to have several limitations, as they depend on the review of information in charts and files not designed to collect data for research, may be poorly standardized resulting in information bias, and may be prone to classification bias.[97] Vital information is likely to be missing. For example, the reasons for differences in treatment between patients may not be explained and lack of follow up information creates voids in the dataset, which raises serious questions about any conclusions.[98] FDA cited these concerns in its Real-World Evidence Program, highlighting the ease with which electronic datasets can be misused. FDA stated:

> The potential lack of up-front transparency, especially in retrospective observational study design and conduct, coupled with the fact that retrospective analyses in electronic datasets can be conducted multiple times relatively inexpensively with varying study design elements, makes it possible to conduct numerous retrospective studies until the desired result is obtained and then submit only favorable results as if they were the result of a single study with a prespecified protocol.[99]

FDA also flagged the use of medical claims data as particularly problematic, citing several limitations, including the following:

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93 *Id*.

94 *See generally* Kimberly Heatherington, *Experts flag concerns over EPPC study on dangers of pill used in miscarriage care, abortion*, Catholic Review (May 21, 2025), https://catholicreview.org/experts-flag-concerns-over-eppc-study-on-dangers-of-pill-used-in-miscarriage-care-abortion/.

95 Testimony of Martin Makary before Senate Appropriations Subcommittee (May 22, 2025) at 48:50, 1:05:57, https://www.c-span.org/program/senate-committee/fda-commissioner-testifies-on-fiscal-year-2026-budget-request/660256?utm_source=substack&utm_medium=email, https://www.appropriations.senate.gov/hearings/a-review-of-the-presidents-fiscal-year-2026-budget-request-for-the-food-and-drug-administration.

96 Jamie Bryan Hall & Ryan T. Anderson, *Frequently Asked Questions About the Largest Study on Chemical Abortion*, Ethics & Pub. Pol'y Ctr (May 7, 2025), https://eppc.org/wp-content/uploads/2025/05/Frequently-Asked-Questions-About-the-Largest-Study-on-Chemical-Abortion-1.pdf.

97 Jerome Lambert, *Statistics in brief: how to assess bias in clinical studies?*, 469 Clinical Orthopaedics & Related Rsch. 1794, 1794-96 (2010).

98 Keerthi Talari & Mohit Goyal, *Retrospective studies – utility and caveats*, 50 J. Royal Coll. Physicians Edinburgh 398, 398-401 (2020).

99 FDA, *Framework for FDA's Real-World Evidence Program* 22 (December 2019, https://www.fda.gov/media/120060/download?attachment.

> The purpose of medical claims data is to support payment for care; claims may not accurately reflect a particular disease or the comprehensive management of a disease (e.g., the transcription and classification practices of clinical coders may differ), or a patient may have a particular disease or condition that is not reflected or well-reflected in claims data. In addition, medical claims data can change during the run-off period and claims adjudication process, as initial submissions may be adjusted or corrected, leading to variations in reported diagnoses and procedures over time.[100]

Beyond the flaws in using retrospective claims data, the additional flaws inherent in the EPPC paper are glaring. *First*, EPPC's mission establishes an inherent bias. EPPC is a staunch advocate against abortion and as part of its "Life and Family Initiative" touts its commitment "both to ensuring the equal protection of unborn children in the law and to providing concrete support to families by advancing a pro-life, pro-family agenda that takes our duties in justice to the unborn and to families seriously."[101] The organization's website states "[t]he Life and Family Initiative works nationwide to advance pro-life policies that protect unborn children by restricting abortion at the state and federal levels, via legislation, regulation, and litigation."[102] The only two disclosed authors of the paper are EPPC employees, neither of whom are medical doctors and one of whom has no medical or scientific background at all.[103]

Second, the purported data source, an all-payer medical claims database, was not intended for research or for evaluating adverse events generally, much less specifically to mifepristone. Uniform terminology and criteria do not exist in the database for identifying or evaluating adverse events. To the extent any terms are defined, they are plainly to advance the goals of making medical coverage decisions.

Third, the insurance database does not contain a complete medical profile of each patient, as an Electronic Health Record (EHR) might contain. Therefore, relevant confounding conditions or treatments may not be recorded or well-reflected. *Fourth*, EPPC did not publish its protocol before conducting the study or provide definitions of the terms it applied to evaluate information from the database to reach its conclusion. There is no indication that EPPC applied any methodology to mitigate the inherent biases in conducting a retrospective study. In addition, the EPPC paper uses vague or undefined terms that make drawing any conclusions based on those terms inherently unscientific. For example, "other abortion-specific complications", which encompasses nearly half of the serious adverse events counted by EPPC, is not clearly defined and the EPPC paper is not transparent as to what falls within that category.

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100 FDA, *Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products: Guidance for Industry* 4 (July 2024).

101 *Life and Family Initiative*, Ethics & Pub. Pol'y Ctr., https://eppc.org/program/life-and-family-initiative/ (last visited June 2, 2025).

102 *Id.*

103 *Ryan T. Anderson*, Ethics & Pub. Pol'y Ctr., https://eppc.org/author/ryan_anderson/ (last visited June 2, 2025); *Jamie Bryan Hall*, Ethics & Pub. Pol'y Ctr., https://eppc.org/author/jhall/ (last visited June 2, 2025).

Additional methodological flaws in the paper have been outlined by the Society of Family Planning (SFP).[104] In addition to some of the flaws cited above, SFP notes that the paper "incorrectly counts emergency room visits as serious adverse events, which contradicts FDA guidance."[105] FDA's guidance states: "Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event)."[106] Similarly, SFP points out that EPPC's analysis treated ectopic pregnancy as a complication of medication abortion.[107] This is misleading and incorrect, because ectopic pregnancy is a risk arising from pregnancy itself; medication abortion cannot cause ectopic pregnancy.

SFP also notes that the EPPC paper improperly classified subsequent procedures required to complete an abortion as a "serious adverse event," which is inappropriate because it is a known and expected outcome in approximately 3-5% of cases.[108] Incomplete abortion is not a serious or urgent complication, but an expected one. This category inappropriately accounts for 24,563 of the 94,605 "serious adverse events" in the EPPC paper.[109]

Similarly, the authors provide no definition of "hemorrhage" as a serious adverse event included in the paper, leaving open the possibility that EPPC treated all occurrences of bleeding as a serious adverse event.[110] But because a medication abortion necessarily induces bleeding when a patient presents with bleeding without further specification as to the severity, it is unclear whether that is truly a serious adverse event or just the expected bleeding corresponding to a medication abortion. The reader thus has no indication as to whether EPPC treated all patients presenting with bleeding in the emergency room—whether routine or not— as having a hemorrhage, thus meeting the study's definition of a serious adverse event.

SFP also notes that the EPPC paper "[c]onflates abortion with miscarriage and other uses of mifepristone, which leads to an inflated rate of complications."[111] This ignores that mifepristone is used for other purposes, including miscarriage management and labor induction.[112] Significantly, if the EPPC authors counted any emergency room visit that occurred on the day mifepristone was prescribed, any person who was miscarrying and received

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104 Letter from Soc'y Family Planning to Martin Markary, Comm'r, FDA 1-2 (May 2, 2025), https://societyfp.org/wp-content/uploads/2025/05/SFP-Letter-to-Commissioner-Makary_5.2.2025.pdf.

105 *Id*. at 1.

106 FDA, *What is a Serious Adverse Event?* (May 18, 2023), https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

107 Letter from Soc'y Family Planning to Martin Markary, Comm'r, FDA, *supra* note 104, at 2.

108 *Id*. at 1.

109 Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, *supra* note 92, at 2.

110 Letter from Soc'y Family Planning to Martin Markary, Comm'r, FDA, *supra* note 104, at 2.

111 *Id*.

112 Elise W. Boos et al., *Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020*, 330 JAMA 766, 766 – 68 (2023) (noting that a regimen of mifepristone with misoprostol is now recommended by the American College of Gynecologists for medical management of miscarriage); Jessica Tarleton et al., *Society of Family Planning Clinical Recommendation: Medication management for early pregnancy loss*, 144 Contraception (2025); Jenna Nobles et al., *Abortion Restrictions Threaten Miscarriage Management In The United States*, 43 Health Affairs 1219-24 (2024).

mifepristone at an emergency room would have been mistakenly included in this study as a serious adverse event.

A May 21, 2025 article by OSV News, a Catholic news service, identified "concerns" about the EPPC paper raised by five experts, all "doctoral-level faculty in both public health and research evaluation programs at three Jesuit-run Catholic universities," after "review[ing] and assess[ing] the methodological framework" of the EPPC paper.[113] The experts identified a number of concerns, including (1) the lack of statistical analyses, including correlations or randomized control trial; "necessary to establish causation or even strong associations;" (2) a lack of evidence that "this research has undergone external scientific review, which is the standard for validating this type of research and to minimize bias;" (3) the possibility of counting events multiple times through the "combined use of multiple methods to define 'adverse event'" without "explanation as to how this was done;" (4) the lack of verification "whether the data are truly nationally representative in a way that would meet research standards;" and (5) the lack of named researchers beyond the named authors.[114] One of the experts noted that it is "potentially misleading to suggest, as the report does, that the data in the report are more representative than a clinical trial."[115]

In a subsequently posted "Fact Sheet" and "Frequently Asked Questions,"[116] EPPC attempts to address some of these flaws and claims to have excluded women who were having a miscarriage based on "a Z332 code (an encounter for elective termination of pregnancy)" in the insurance database, but EPPC is not able to verify whether that code was correctly used.[117] Similarly, EPPC claims to have relied only on "codes related to hemorrhage or serious bleeding (according to the FDA definition) were included" and not "[t]ypical expected bleeding," but EPPC cannot demonstrate that the codes were correctly applied by the reporter, or that the definitions were consistently applied in each claim across the nation.[118] And EPPC failed to disclose all the diagnoses or codes it considered "medically serious" or the medical and scientific basis for that determination. A database used to determine payment coverage is simply an unreliable database for evaluating adverse events much less for reaching the conclusions EPPC has formulated.[119]

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113 Kimberly Heatherington, *Experts flag concerns over EPPC study on dangers of pill used in miscarriage care, abortion*, Catholic Review (May 21, 2025), https://catholicreview.org/experts-flag-concerns-over-eppc-study-on-dangers-of-pill-used-in-miscarriage-care-abortion/.

114 *Id.*

115 *Id.*

116 Jamie Bryan Hall & Ryan T. Anderson, *FACT SHEET: Excluded Adverse Events in Real-World Study of Mifepristone*, Ethics & Pub. Pol'y Ctr. (May 6, 2025), https://eppc.org/stop-harming-women/#4-fact-sheet-excluded-adverse-events-in-real-world-study-of-mifepristone; Jamie Bryan Hall & Ryan T. Anderson, *Frequently Asked Questions About the Largest Study on Chemical Abortion*, Ethics & Pub. Pol'y Ctr. (May 7, 2025), https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/.

117 Jamie Bryan Hall & Ryan T. Anderson, *FACT SHEET: Excluded Adverse Events in Real-World Study of Mifepristone*, *supra* note 116.

118 *Id.*

119 The experts from the OSV article were provided these new EPPC documents but uniformly responded that information in the documents did not alter their earlier assessments or concerns. *See* Kimberly Heatherington, *Experts flag concerns over EPPC study on dangers of pill used in miscarriage care, abortion*, *supra* note 101.

In sum, the above, deeply flawed "studies" are outliers whose methodologies fail to meet the rigorous scientific standards that form the backbone of FDA's gold-standard review process.[120] In any event, they are overshadowed by the overwhelming weight of scientific research and evidence-based postmarketing data demonstrating mifepristone's safety and confirming that its benefits outweigh any risks. Based on the totality of evidence, mifepristone does not warrant designation under a REMS program.

C. The Mifepristone REMS Program Imposes Unnecessary and Unduly Burdensome Restrictions on Prescribers, Patients, and Pharmacies

In addition to being medically unjustified, specific ETASU elements that currently comprise the Mifepristone REMS Program—the Prescriber Certification, Patient Agreement Form, and Pharmacy Certification—also impose unnecessary and burdensome hurdles on patients, prescribers, pharmacists, and the healthcare system, contrary to the statute. Under federal law, ETASU may be imposed only where "required . . . to mitigate a specific serious risk" of a "serious adverse drug experience," and only where the risk is sufficiently severe that FDA would not approve, or would withdraw approval of, the medication, absent ETASU. 21 U.S.C. § 355-1(f)(1). Moreover, ETASU must not be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system." *Id*. §§ 355-1(f)(2)(C)–(D). Here, the current regulatory requirements for prescribing and dispensing mifepristone—requiring patients to sign an agreement form and providers and pharmacies to obtain special certification—are unrelated to any "specific risk" of the drug, let alone required to mitigate any perceived risk.

As stated on the labeling, mifepristone does not pose any specific serious risks other than to the continuation of a pregnancy. Instead, the risks that arise when taking mifepristone are inherent with pregnancy termination regardless of how it comes to occur, and the health care system is well-aware of and well-equipped to address those risks.[121] For example, mifepristone itself does not cause serious infection.[122] Any risk of serious infection arises from the termination of pregnancy, not from mifepristone, and is present regardless of how the pregnancy termination occurs. Similarly, the risk of heavy bleeding is not caused by mifepristone; rather, it is the

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120 For an analysis of the numerous other instances in which authors of the EPPC study have been discredited, *see* Brief for ACLU et al. as Amici Curiae Supporting Petitioners, *FDA v. Alliance for Hippocratic Medicine*, 144 S. Ct. 1540 (2024), https://www.aclu.org/cases/danco-laboratories-llc-v-alliance-for-hippocratic-medicine-u-s-fda-v-alliance-for-hippocratic-medicine?document=ACLU-et-al-Amicus-Brief-AHM-v-FDA.

121 *See* Mifepristone 2023 Labeling and Medication Guide, *supra* note 7, at 2 ("Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. *No causal relationship between the use of MIFEPREX and misoprostol and these events has been established*.") (emphasis added); *id.* at 16 ("Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. *There is no information that use of Mifeprex and misoprostol caused these deaths*.") (emphasis added).

122 *See* Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 202107Orig1s000 Risk Assessment and Risk Mitigation Review(s) (Korlym)* 5–8 (Jan. 1, 2012) (the two risks of Korlym in the postmarketing context do not include serious infection).

pregnancy termination that may lead to heavier than normal bleeding in some patients. And ultimately, a pregnant person will face these risks regardless of whether they obtain an abortion, experience a pregnancy loss, or carry their pregnancy to term. These risks are not present with the use of mifepristone for other conditions, such as Cushing's syndrome, also known as hypercortisolism (when a body has too much of the hormone cortisol), where treating such conditions does not involve the evacuation of a pregnant uterus.[123] Indeed, Korlym, the formulation of mifepristone used to treat Cushing's syndrome (*see* p.39 *infra*), is prescribed without a REMS program.[124] Consequently, by limiting distribution of mifepristone through the 2023 REMS program, mifepristone's ETASU unduly burdens patients and imposes unnecessary burdens on the healthcare delivery system. For these reasons as well, FDA should remove mifepristone's burdensome ETASU elements.

The burdensome requirements of the REMS thus mean that clinicians who want to be able to provide medication abortion to their patients are unable to do so, restricting what they can offer in a way that is outside of the FDA's statutory authority.

1. The Mifepristone REMS Program interferes with the practice of medicine

The FDA is not authorized to regulate the practice of medicine. Among other categories, the FDA is authorized to regulate food, drugs, biologics, and medical devices,[125] but is not empowered to infringe on the practice of medicine or to "intrud[e] upon decisions statutorily committed to the discretion of health care professionals."[126] The FDA itself acknowledges this split in regulatory authority: "The FDA does not regulate the practice of medicine, medical services, the price or availability of medical products…."[127]

Yet, in the case of mifepristone, the REMS intrudes on the practice of medicine and involves the FDA in decisions that are best left to physicians and other licensed clinicians. At the heart of the goal for the Mifepristone REMS Program is mitigating serious complications related to pregnancy termination. But pregnancy termination arises in many contexts, not only in medication abortion. The risks of pregnancy termination complications may arise when a patient miscarries (which can be caused by a wide variety of reasons), has a medication or procedural abortion, or the body experiences other trauma. Such complications are not specific to the use of mifepristone.

Primary care providers, internists, family doctors, midwives, emergency care providers, as well as specialist OBGYNs, and in many states, advanced clinic practitioners such as nurse practitioners and physician's assistants, are capable of prescribing mifepristone, and regularly do so. Based on their individual training, hospital affiliations, scope of practice, and standards of

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123 *Id.* (discussing fetal loss or the intended termination of pregnancy as the risks associated with Korlym use).

124 *Id*. at 2.

125 FDA, *About FDA: Patient Q&A* (Nov. 2024), https://www.fda.gov/media/151975/download.

126 *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 350 (2001); *see also Piazza v. Myers*, 37 Pa. D. & C.4th 322, 326 ("Furthermore, the FDA does not regulate the practice of medicine.").

127 FDA, *About FDA: Patient Q&A*, *supra* note 125.

care in the practice of medicine, these healthcare providers are able to determine the best course of treatment for their patients.

The Mifepristone REMS Program discourages competent providers from adding medication abortion to their practice, puts patients at risk, burdens the healthcare system, and restricts access to healthcare. Illustrating this interference, a 2022 qualitative analysis of family medicine practitioners found 41% cited the REMS criteria as a "barrier" to providing medication abortion in primary care.[128] These family care physicians, who saw potential advantages to being able to offer mifepristone in a family care context as part of their broader provision of reproductive health care, saw the REMS requirements "as transforming the decision to provide mifepristone from being one between a physician and patient, to involving multiple levels of administration."[129] Another study of primary care physicians stated that the "FDA regulations that inhibit mifepristone provision in primary care create structural barriers to provision. This may result in physical, emotional, and financial burdens for patients."[130]

2. ETASU are Unduly Burdensome on Patient Access to Mifepristone.

a) Prescriber Certification (ETASU A)

The Prescriber Certification ETASU mandates, among other things, that mifepristone can only be prescribed by "certified" prescribers, who must attest to their qualifications in a written form and send their certification form to every pharmacy to which they send a mifepristone prescription.

(1) The Prescriber Certification deters otherwise qualified providers from prescribing mifepristone

The Prescriber Certification ETASU deters otherwise qualified providers from offering mifepristone in at least three respects. One survey of obstetrician-gynecologists (OB-GYNs) found that the Prescriber Certification ETASU prevents nearly 1 in 10 OB-GYNs from prescribing mifepristone.[131] The same is true in the primary care and family medicine practices.[132]

First, this ETASU "deters many qualified clinicians from becoming mifepristone prescribers," in part due to fear that registration could expose them to threats and violence by

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128 Na'amah Razon et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, 109 Contraception 19, 1 (May 2022).

129 *Id*. at 23.

130 Silpa Srinivasulu et al., *US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care*, 104 Contraception 92, 92 (April 10, 2021).

131 Daniel Grossman et al., *Induced Abortion Provision Among a National Sample of Obstetrician–Gynecologists*, 133 Obstetrics & Gynecology 477, 482 (Mar. 2019) (nine percent of OBGYN respondents cited the Prescriber Certification requirement as the reason they did not provide medication abortion).

132 *See generally* Silpa Srinivasulu et al., *supra* note 130; Danielle Calloway et al., *Mifepristone Restrictions and Primary Care: Breaking the Cycle of Stigma Through a Learning Collaborative Model in the United States*, 104 Contraception 24, 25 (Apr. 4, 2021); Kayla N. Rasmussen et al., *Expanding Access to Medication Abortion Through Pharmacy Dispensing of Mifepristone: Primary Care Perspectives from Illinois*, 104 Contraception 98, 100 (Mar. 21, 2021).

anti-abortion extremists if their registrations became public.[133] To become "certified," a provider must send the completed Prescriber Certification to the FDA-regulated drug sponsor and to every pharmacy their patients visit to obtain mifepristone. This requires that these clinicians are named on both national and local lists of certified abortion providers, raising significant safety concerns for the provider, the provider's family, and for employees and patients at any clinic, office, or facility where the provider works should such lists be leaked or compromised. Indeed, in light of the well-documented history of violence and harassment against abortion providers and clinics, this step involves significant risk.[134] This history of violence and harassment includes instances where "[a]bortion providers have been murdered, threatened, and physically attacked . . . and their clinics have been bombed, broken into, and defaced."[135] Notably, these fears have only mounted following *Dobbs*, as there has been a sharp increase in violence and disruption in states that are protective of abortion rights as anti-abortion extremists have been emboldened to travel to states where abortion remains legal to target clinics there.[136] Given that recent statistics on violence against abortion practitioners show increases in "major incidents" such as arson, burglaries, death threats, and invasions, there is good reason that clinicians may ultimately decide this risk is not worth taking at all.[137]

The dangers associated with being a "certified" abortion provider are all the more prevalent now given the number of states that have criminalized abortion and are seeking to punish providers who have facilitated medication abortions for patients who reside in other states.[138] For example, in California, 31% of providers reported trespassing and 7% reported threats in 2024.[139]

Second, the Prescriber Certification perpetuates the stigma associated with prescribing mifepristone, which can discourage clinicians from offering it.[140] This ETASU is an extremely unusual prerequisite for prescribing a drug as safe as mifepristone. Indeed, the FDA has only

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133 *See* Citizen Petition from ACOG (Jan. 2025), *supra* note 8; Letter from Dr. Graham Chelius, *supra* note 65; Citizen Petition from Dr. Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, et al. to Lauren Roth, Assoc. Comm'n for Pol'y, FDA 13-14 (Oct. 4, 2022) [hereinafter Citizen Petition from ACOG (Oct. 4, 2022)]; *see also* infra nn.199-200 (highlighting declarations from clinicians on this issue submitted in *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.)).

134 Feminist Majority Found., *2022 National Clinic Violence Survey Report* 2 (2022), https://feminist.org/wp-content/uploads/2023/07/2022-national-clinic-violence-survey.pdf; Press Release, Nat'l Abortion Fed., Violence Against Abortion Providers Continues to Rise Following Roe Reversal, New Report Finds (May 11, 2023), https://prochoice.org/violence-against-abortion-providers-continues-to-rise-following-roe-reversal-new-report-finds/.

135 Greer Donley, *Medication Abortion Exceptionalism*, 107 Cornell L. Rev. 627, 692 (June 2022).

136 Nat'l Abortion Fed., *2024 Violence & Disruption Report* (2025), https://prochoice.org/our-work/provider-security/2024-naf-violence-disruption/; Nat'l Abortion Fed., *2022 Violence & Disruption Statistics Report*, at 2, 8, https://prochoice.org/wp-content/uploads/2022-VD-Report-FINAL.pdf.

137 Nat'l Abortion Fed., 2022 *Violence & Disruption Statistics Report*, *supra* note 136, at 2.

138 *See, e.g.*, Madeline Halpert, *New York doctor indicted for prescribing Louisiana teen abortion pill*, BBC News (Jan. 31, 2025), https://www.bbc.com/news/articles/cjr8jv2yjz9o; Jack Queen, *Texas judge fines NY doctor at least $100,000 for prescribing abortion pills*, Reuters (Feb. 13, 2025), https://www.reuters.com/legal/texas-judge-fines-ny-doctor-least-100000-prescribing-abortion-pills-2025-02-14/.

139 Nat'l. Abortion Fed., *2024 Violence & Disruption Report* (2024), https://prochoice.org/our-work/provider-security/2024-naf-violence-disruption/.

140 *See* Sara Neill et al., *Management of early pregnancy loss among obstetrician-gynecologists in Massachusetts and barriers to mifepristone use*, 126 Contraception 110108, at 4 (2023).

imposed ETASU for approximately 71 of the more than 20,000 drugs it regulates, and generally has only required prescriber certification for drugs that are teratogenic (meaning they may cause birth defects) or that are known to cause serious adverse events such as anaphylaxis, stroke, coma, death.[141] That the FDA lumps in mifepristone with such drugs naturally contributes to misconceptions about its use and safety. One study, for instance, explained that the mifepristone REMS "reinforc[e] the perception that abortion is a tainted and undesirable service that should remain marginalized in specialty settings."[142] This stigma deters even providers who intend to prescribe mifepristone solely for management of early pregnancy loss or other therapies.[143] Yet as practitioners in primary care settings "regularly prescribe medications with far more complicated regimens and with more significant side effects than mifepristone," this stigma is wholly unfounded.[144] After all, as discussed below, when mifepristone is prescribed as Korlym for Cushing's syndrome, the FDA does not require a REMS at all—despite Korlym being prescribed at higher doses and frequency than mifepristone (a 300 mg tablet taken one to four times daily, compared to Mifeprex, which is prescribed as a 200 mg tablet taken just once).

Third, the Prescriber Certification ETASU imposes bureaucratic hurdles that prevent providers from offering mifepristone. It takes valuable time and effort to understand what the Prescriber Certification entails and the ongoing duties it requires of providers, including the numerous continuing administrative obligations it imposes in conjunction with the Patient Agreement Form and Pharmacy Certification.[145] Research has shown that "simply requiring an affirmative opt-in can discourage behavior."[146] Many providers have cited uncertainty with how to comply with the REMS as the main barrier to mifepristone use.[147] This is particularly relevant for primary care physicians, who may view the complexity of navigating these ETASU "as not worth the effort, since [medication abortion] is only a small component of services offered in primary care."[148] According to one recent study, approximately 40% of "family physicians interviewed . . . either named or described the [mifepristone] REMS criteria as a barrier to providing medication abortion."[149] These family physicians explained that "the REMS impede their ability to provide medication abortion within primary care" because they "require substantial involvement of clinic administration, who can be unsupportive," and because "[t]he complexity of navigating the REMS results in physicians and clinic administration . . . viewing medication abortion as not worth the effort, since it is only a small component of services offered

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141 *See* FDA, Approved Risk Evaluation and Mitigation Strategies (REMS), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last visited June 3, 2025).

142 Danielle Calloway et al., *Mifepristone restrictions and primary care*, *supra* note 132, at 24.

143 *See* Mugdha Mokashi et al., *"There's only one use for it": Stigma as a Barrier to Mifepristone Use for Early Pregnancy Loss (Abstract)*, 139 Obstetrics & Gynecology 9S-10S (May 2022).

144 Charlotte M. Lee et al., *Barriers to abortion provision in primary care in New England, 2019-2020: A qualitative study*, 117 Contraception 39, 43 (2023).

145 *See* Na'amah Razon et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, *supra* note 128, at 5-6.

146 Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 134, at 644.

147 Sara Neill et al., *Medication Management of Early Pregnancy Loss: The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy* [A289] [abstract], 139 Obstetrics & Gynecology 83S (May 2022).

148 Na'amah Razon et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, *supra* note 128, at 1-2.

149 *Id.* at 5.

in primary care."[150] And yet, as addressed below, prescription of mifepristone by primary care clinicians is a crucial component of improving safe access to medication abortion for people who need it.

By deterring providers from offering mifepristone, the Prescriber Certification necessarily reduces access to early and safe abortion. Reduced access, in turn, delays patients from obtaining this essential healthcare, which can cause them physical, mental, and emotional harm.[151] Although this result impacts individuals across Petitioner States—particularly as mounting abortion bans in neighboring states have caused an influx in the demand for abortion care in Petitioner States—the brunt is suffered by those in rural and medically underserved areas where providers are already scarce.

Because the Mifepristone REMS Program discourages family practitioners from prescribing mifepristone, medication abortion care has largely been segregated outside of primary care settings.[152] Indeed, approximately **only 1%** of medication abortions occur in the primary care setting.[153] And an overwhelming majority of abortions (approximately 96%) are obtained in specialty clinics.[154] Yet in 2020, 89% of counties in the United States—home to 38%of women ages 15 to 44—had no clinic that provided abortion care.[155] This disparity exists even in Petitioner States, where abortion access is valued and protected. As of 2020, in Massachusetts, 50% of counties did not have a clinic that provided abortion care; in California, that figure is 38%; in New Jersey, 29%; and in New York, 37%.[156] In California, for instance, most of the residents of Inyo County, a rural and medically underserved area in the Eastern Sierra, live over 200 miles from the nearest abortion provider.[157] And in Yreka, California—the largest city in the predominantly rural and medically underserved County of Siskiyou—the nearest abortion provider is almost 100 miles away.

A key measure of access to abortion is how far people have to travel to reach an abortion clinic.[158] Research has shown that the further someone lives from an abortion provider, the less

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150 *Id.*; *see also* Danielle Calloway et al., *Mifepristone restrictions and primary care*, *supra* note 132; Sara Neill et al., *Mifepristone use for early pregnancy loss: A qualitative study of barriers and facilitators among OB/GYNS in Massachusetts, USA,* 55 Persps. on Sexual & Reprod. Health 210, 210 (2023) (finding "the most common barriers" to incorporating mifepristone into early pregnancy loss care "were related to the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program imposed by the US Food and Drug Administration (FDA)").

151 Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 651, 655.

152 *Id.* at 656.

153 Danielle Calloway et al., *Mifepristone restrictions and primary care*, *supra* note 132, at 24; *see also* Alice F. Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. E186 (May 2018).

154 Rachel K. Jones et al., *Abortion incidence and service availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 136 (2022).

155 *Id.* at 134, 135 (Table 4).

156 *Id.* at 135 (Table 4).

157 Lauren DeLaunay Miller, *Many Rural Californians Still Lack Abortion Access. Here Are Solutions*, Cal. Health Rep. (Oct. 28, 2024), https://www.calhealthreport.org/2024/10/28/many-rural-californians-still-lack-abortion-access-here-are-solutions/.

158 Jonathan M. Bearak, Kristen Lagasse Burke, & Rachel K. Jones, *Disparities and change over time in distance a woman would need to travel to have an abortion in the USA: a spatial analysis*, 2 Lancet Pub. Health e493, e493 (2017).

likely they are to obtain an abortion.[159] Moreover, the presence of one nearby clinic does not mean that the demand for abortion care is met in those areas.[160] Patients may still have to wait weeks or longer to obtain treatment, at which point medication abortion may no longer be an option.[161] Unnecessary delays in obtaining abortion care are directly associated with significant reductions in patient access and safety.[162] Delay, for instance, increases the rates of second-trimester and procedural abortions, which although safe, have increased complication rates as compared to medication abortion.[163] Delay can also result in "increased and perhaps prohibitive cost and access barriers, as second trimester abortions are more expensive, may require more time (2-3 days), and have fewer providers who are trained to perform them."[164] This is particularly concerning for low-income residents, as well as for rural communities that are less likely to have access to an OB-GYN provider able to provide procedural abortion care.[165]

The integration of medication abortion into primary care practices could increase access to such care, including in such places where access to abortion may otherwise be limited.[166] Yet, REMS such as the Prescriber Certification ETASU unnecessarily impede access without providing any countervailing safety interest.[167] Removing the Provider Certification ETASU will improve access by expanding the number of providers offering mifepristone as well as reducing the burden on existing abortion providers.[168] Given the increasing expansion of maternity care deserts across the country, including in rural areas of many Petitioner States, FDA must consider the impact that the Mifepristone REMS Program is having on patients' ability to access needed care in rural and medically underserved areas.[169] Indeed, if a patient delays or has difficulty

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159 *Id.*

160 *Id.* at 498; *see also* Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 656.

161 Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 657; Lauren DeLaunay Miller, *For Many Rural Californians, Abortion Isn't Accessible. Here's What Can Be Done*, Cal. Health Rep. (Dec. 21, 2022), https://www.calhealthreport.org/2022/12/21/for-many-rural-californians-abortion-isnt-accessible-heres-what-can-be-done/.

162 *Increasing Access to Abortion, Committee Statement No. 16*, Am. College Obstetricians & Gynecologists (Feb. 2025), https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2025/02/increasing-access-to-abortion.

163 *See* David A. Moss et al., *Options for Women with Unintended Pregnancy*, 91 Am. Family Physician 544, 547 (2015); Congress of Delegates, Am. Acad. Of Fam. Physicians, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* 2 (May 24, 2018) ("REMS classification contributes to delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates").

164 Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 657.

165 *See* William F. Rayburn et al., *Distribution of American Congress of Obstetricians and Gynecologists fellows and junior fellows in practice in the United States*, 119 Obstetrics & Gynecology 1017, 1020 – 21 (May 2012); *Health Disparities in Rural Women, Committee Opinion No. 586*, Am. College Obstetricians & Gynecologists (Feb. 2014), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/02/health-disparities-in-rural-women.

166 Na'amah Razon et al., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, *supra* note 128, at 7-8, 9.

167 *See id.* at 6.

168 Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 701-02.

169 March of Dimes, *Nowhere to Go: Maternity Care Deserts Across the US* 8 (2024) (explaining how "[o]ver one third (35.1%) of the 3,142 US counties are considered maternity care deserts, areas without a single . . . obstetric clinician," and that "[a]pproximately, 6 in 10 maternity care deserts are rural, less populated areas"); *see*

finding a certified prescriber, they may miss the very limited window in which to have a safe and effective medication abortion.[170]

(2) The FDA's previous rationales for maintaining the Prescriber Certification do not overcome the enormous burden it imposes.

In reassessing the Prescriber Certification in 2023 and deciding to continue it, FDA provided three rationales—(i) its July 2021 literature review, (ii) its concerns about the increased number of prescribers following the removal of in-person dispensing ETASU, and (iii) the requirement to report patient deaths. But none of these rationales supports a continuation of this burdensome ETASU. *First*, FDA justified maintaining Prescriber Certification because its 2021 literature review "did not identify any studies comparing providers who met these qualifications with providers who did not."[171] FDA explained that "[i]n the absence of such studies, there is no evidence to contradict our previous finding that prescribers' ability to accurately date pregnancies, diagnose ectopic pregnancies, and provide surgical intervention or arrange for such care through others if needed, is necessary to mitigate the serious risks associated with the use of mifepristone in a regimen with misoprostol."[172] The Petitioner States have a strong interest in ensuring that patients in their states are only treated by qualified providers. However, these important interests are well-served by existing state statutes and regulations which ensure patients are protected and given the highest quality of care.

Notably, FDA's rationale is not consistent with existing practice. FDA does not require prescriber certification for 99% of prescription drugs; rather, prescribers self-determine their qualifications to treat a particular condition or prescribe a specific medication based on their education and training. Given the standard scope-of-practice limitations and rigorous regulatory and ethical frameworks that govern healthcare prescribers, FDA's assumption that it has to regulate provider qualifications through a certification is both evidentiarily unsupported and unwarranted. *See infra* Section III. (discussing state regulations and medical ethics rules that provide guardrails for prescribers). The fact that there are no studies identifying *unqualified* providers prescribing mifepristone has no bearing on whether this ETASU is necessary to ensure only *qualified* providers prescribe it. Indeed, if an unqualified provider were to prescribe mifepristone and fail to accurately date a pregnancy or other risk, they would be subject to discipline and other repercussions within the Petitioner States. *See id.* (discussing state laws and regulations governing the practice of medicine).

Second, FDA decided to maintain Prescriber Certification in its last REMS review given "the potential addition of new prescribers" because it was lifting the in-person dispensing

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also Silpa Srinivasulu et al., *US clinicians' Perspectives on How Mifepristone Regulations Affect Access to Medication Abortion and Early Pregnancy Loss Care in Primary Care*, 104 Contraception 92, 95 (Apr. 19, 2021) (explaining that when mifepristone is unavailable in primary care, patients suffer the consequences: "disrupted continuity of care, additional medically-unnecessary appointments, and undesired aspiration procedures").

170 *See, e.g.*, Declaration of Dr. Emily Godfrey, M.D., M.P.H., *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 100 (Feb. 24, 2023).

171 FDA Mifepristone REMS Modification Rationale Review (Dec. 2021), *supra* note 68, at 13.

172 *Id.*

ETASU.[173] But, again, this concern only makes sense if *unqualified* prescribers would begin prescribing mifepristone absent certification, which state protections already sufficiently guard against. *See infra* Section III.A.1. Indeed, the study on which FDA relied for the potential doubling of the number of prescribers in its last REMS review[174] was a survey of OB-GYNs who were characterized as "well situated to provide timely abortion care."[175] As ACOG previously explained to FDA, the Provider Certification ETASU "serves no benefit to patient safety" because providers *already* possess the skills necessary to prescribe any given medication.[176]

Third, FDA explained that the Prescriber Certification ETASU was needed to ensure that the manufacturers receive all reports of patient deaths.[177] But, as noted above, mifepristone's "associated" fatality rate is a miniscule 0.00048% for the 25-years it has been on the U.S. market and not a single death has been "causally attributed to mifepristone," as opposed to a patient's underlying pregnancy or other factors.[178] Given mifepristone's well-established safety record, FDA provides no reason for continuing to single out mifepristone for this reporting requirement, while not applying it to other drugs with much higher death rates, including, for instance, Penicillin, Viagra, and Tylenol.[179] *Contra* 21 U.S.C. § 355-1(f)(2)(A) (ETASU must be "commensurate" with the specific risk); *see infra* Section II.D. (discussing FDA's differential treatment of mifepristone compared to other drugs with higher death rates without ETASU elements).

In sum, by artificially depressing the number of mifepristone prescribers, the Prescriber Certification ETASU is unduly burdening patient access to mifepristone without furthering patient safety and should be removed. 21 U.S.C. § 355-1(f)(2)(C).

b) Patient Agreement Form (ETASU D)

ETASU D requires patients being prescribed mifepristone to sign an agreement form that goes in their medical file, certifying that "I have decided to take mifepristone and misoprostol to end my pregnancy. . ."[180] Patients must sign this agreement form, even if they are taking the

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173 *Id.* at 14.

174 *Id.*

175 Sara Daniel, Jay Schulkin, & Daniel Grossman, *Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone*, 104 Contraception 73, 73 (Apr. 1, 2021).

176 *See* Citizen Petition from ACOG (Oct. 2022), *supra* note 133, at 13; *see* Letter from Dr. Graham Chelius, Soc'y Family Planning, to Dr. Janet Woodcock, Acting Comm'r, FDA 2 (Sept. 29, 2021), https://societyfp.org/wp-content/uploads/2022/08/Letter-to-FDA_Mifepristone-REMS.pdf.

177 FDA Mifepristone REMS Modification Rationale Review (Dec. 2021), *supra* note 68, at 14.

178 FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024, *supra* note 2, at 1 (36 deaths from approximately 7.5 million uses, 13 of which were associated with sepsis and 22 of which involved homicide, drug intoxication/overdose, ruptured ectopic pregnancy, suicide, toxic shock-like syndrome, probable anaphylactic medication reaction, undetermined etiology, and natural death due to severe pulmonary emphysema); Mifepristone 2023 Labeling and Medication Guide, *supra* note 7, at 16 ("Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifeprex and misoprostol caused these deaths.").

179 Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone US Post-Marketing Adverse Events Summary through 6/30/2021"* 3 (Nov. 2022).

180 FDA, *Patient Agreement Form: Mifepristone Tablets, 200 mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf [hereinafter FDA Mifepristone Patient Agreement Form].

medication for miscarriage management, making it inaccurate in these instances. The Patient Agreement Form ETASU similarly burdens abortion patients without offering any countervailing safety benefits. Expert reviewers with the FDA have confirmed as much—recommending in 2016 that the Patient Agreement Form be removed because it "does not add to safe use conditions for the patient for this REMS and is a burden for patients."[181] Specifically, they found this ETASU is "duplicative of information in [mifepristone's] Medication Guide and of information and counseling provided to patients under standard informed consent practices for medical care and under professional practice guidelines."[182] Indeed, FDA experts recognized that the "FDA has removed REMS requirements in other programs based on the integration of the REMS safe use condition into clinical practice" and acknowledged that, with respect to mifepristone, the information covered in the Patient Agreement Form is already part of well-established clinical practice.[183]

Yet the FDA continues to treat mifepristone differently from other medications by imposing this ETASU. As of 2023, the "FDA currently requires 31 of 62 products subject to REMS to include documented patient agreement" and the "vast majority of those . . . are due to serious risks to an unborn fetus, significant toxicity levels, potential for addiction or abuse, or dangerous drug interactions."[184] But "mifepristone does not raise any of those risks."[185] This exceptionalism perpetuates stigma[186] surrounding mifepristone—stigma that alone threatens access and can result in patients avoiding needed abortion care.[187] Abortion stigma also harms patients by "increas[ing] the risk of poor psychological and physical health outcomes among pregnant individuals."[188]

In support of its 2023 decision to continue maintaining this ETASU, FDA explained that its literature search "yielded no publications which directly addressed this element of the

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181 Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Origls020, Mifeprex Summary Review* 25 (Mar. 29, 2016) [hereinafter FDA Mifeprex Summary Review (Mar. 29, 2016)]; Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Origls020, Cross Discipline Team Leader Review* 30 (Mar. 29, 2016).

182 Letter from Dr. Graham Chelius, Soc'y Family Planning, to Dr. Janet Woodcock, Acting Comm'r, FDA 2 (Sept. 29, 2021) (citing FDA Mifeprex Summary Review (Mar. 29, 2016), *supra* note 181, at 25), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf; Ctr. for Drug Eval. & Rsch., FDA, *Application Number 020687Orig1s020: Risk Assessment and Risk Mitigation Review(s)* 2 (Mar. 29, 2016).

183 Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Origls020, Cross Discipline Team Leader Review* 25 (Mar. 29, 2016); FDA Mifeprex Summary Review (Mar. 29, 2016), *supra* note 181, at 24 ("Established clinical practice includes patient counseling and Informed Consent, and, more specifically with Mifeprex, includes counseling on all options for termination of pregnancy, access to pain management and emergency services if needed."; "Medical abortion with Mifeprex is provided by a well-established group of organizations and their associated providers who are knowledgeable in this area of women's health. Their documents and guidelines cover all the safety information that also appears in the Patient Agreement.").

184 Jordan Paradise, *Mifepristone Paternalism at the FDA*, 51 J. Law, Med. & Ethics 554, 558 (Dec. 2023).

185 *Id.*

186 *See* Greer Donley, *Medication Abortion Exceptionalism*, *supra* note 135, at 642-43; *see also* Jaclyn J. Serpico, *Abortion Exceptionalism and the Mifepristone REMS*, 104 Contraception 8, 9-10 (2021).

187 *Increasing Access to Abortion, Committee Statement No. 16*, Am. College Obstetricians & Gynecologists (Feb. 2025), https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2025/02/increasing-access-to-abortion; Janet M. Turan & Henna Budhwani, *Restrictive Abortion Laws Exacerbate Stigma, Resulting in Harm to Patients and Providers*, 111 Am. J. Pub. Health 37, 38 (Jan. 2021).

188 Janet M. Turan & Henna Budhwani, *Restrictive Abortion Laws Exacerbate Stigma, Resulting in Harm to Patients and Providers*, 111 Am. J. Pub. Health 37, 38 (Jan. 2021).

REMS,"[189] and therefore determined there was no evidence "that would support removing ETASU D."[190] And, as with Prescriber Certification, FDA pointed to the potential increase in the number of prescribers upon removal of the in-person dispensing requirement, explaining that "[t]he Patient Agreement Form is an important part of standardizing the medication information on the use of mifepristone that prescribers communicate to their patients, and also provides the information in a brief and understandable format for patients."[191] But this circular rationale does not explain why the Patient Agreement Form is "require[d] . . . to mitigate a specific serious risk."[192] Nor does this rationale identify any specific risk.

Indeed, in "conclud[ing] that maintaining the Patient Agreement Form remains necessary to assure safe use,"[193] FDA provided no explanation for why the medication's current Boxed Warning and Medication Guide, which provide the same information, are insufficient to standardize the medication information communicated to patients. Nor did FDA explain why or whether new mifepristone prescribers would be *unqualified* to explain the drug's risk to their patients. As FDA scientists determined back in 2016, the Patient Agreement Form is duplicative of informed consent, which is a well-established part of medical practice.[194] FDA also failed to explain why a Patient Agreement Form continues to be necessary for mifepristone given that adverse events associated with mifepristone are "extremely rare,"[195] particularly when a Patient Agreement Form is not required for much more dangerous and addictive drugs like fentanyl and Oxycontin. [196] In short, the lack of reasoned basis for this ETASU has long been apparent.

Beyond providing no utility, the Patient Agreement Form is "a burden for patients" as FDA previously acknowledged.[197] It needlessly subjects patients, and their providers, to increased risk of harassment and violence, as the Patient Agreement Form must be signed by a provider, kept in the patient's medical record, and given to the patient. Anyone with access to the medical record or to the patient's own copy will have evidence that the patient received abortion medication from the particular provider "to end [their] pregnancy."[198] This subjects both patient and provider to increased risk of being targeted with violence or threatened with legal liability, even if the mifepristone was lawfully obtained in Petitioner States.

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189 FDA Mifepristone REMS Modification Rationale Review (Dec. 2021), *supra* note 68, at 16.

190 *Id*. at 17 (emphasis added).

191 *Id*. at 18.

192 21 U.S.C. § 355-1(f)(1)(A).

193 Ctr. for Drug Evaluation & Rsch., *supra* note 181, at 37.

194 *See also* Nat'l Abortion Fed., *Clinical Policy Guidelines for Abortion Care* 4 (2024) (describing how, at a minimum, patient must be informed of the risks of hemorrhage, infection, continuing pregnancy and death); Committee on Ethics, Am. Coll. of Obstetricians & Gynecologists, *Opinion No. 819 – Informed Consent and Shared Decision Making in Obstetrics and Gynecology*, 137 Obstetrics & Gynecology e34, e35 – e36 (2021); *see also* FDA Mifepristone REMS Modification Rationale Review (Dec. 2021), *supra* note 68, at 17 (acknowledging "strong adherence to evidence-based guidelines" by clinicians who provide abortion care); s*ee also infra* Section III.A.2 (discussing clinician's responsibility to obtain a patient's informed consent)

195 FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 12.

196 FDA, *Introduction FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain*, https://www.fda.gov/media/173774/download?attachment (last visited June 4, 2025); *contra* 21 U.S.C. § 355-1(f)(2)(A) (ETASU must be "commensurate" with the specific risk); *see also infra* Section II.D. (discussing FDA's differential treatment of mifepristone).

197 FDA Mifeprex Summary Review (Mar. 29, 2016), *supra* note 181, at 25.

198 FDA Mifepristone Patient Agreement Form, *supra* note 180.

But requiring ETASU D is also unduly burdensome on the healthcare system. For instance, telehealth providers must find a means by which to obtain dual signatures in a remote setting while still ensuring provider-patient confidentiality. This, in turn, may require health care systems to develop expensive custom-built technology processes.[199] This ETASU also unduly burdens prescribers by making patient counseling more difficult by, for instance, suggesting to a patient that mifepristone is unsafe, when it is not, which may cause additional patient stress.[200] And it likewise can inflict harm and emotional distress on miscarriage patients, who "must attest that they are ending [their] pregnancy," when they did not choose to do so.[201] Consideration of these burdens compels the removal of this ETASU consistent with the recommendation of FDA scientists nearly a decade ago.

c) Pharmacy Certification (ETASU B)

ETASU B requires pharmacies that dispense mifepristone to also be specially certified, which necessitates the development and implementation of a *sui generis* system to track Prescriber Certifications forms confidentially before pharmacies can fill a mifepristone prescription. In adding this requirement in 2023, FDA stated: "Adding pharmacy certification ensures that ETASU A [Prescriber Certification] is met prior to dispensing the product to a patient; certified prescribers, in turn, have agreed to meet all the conditions of the REMS, including ensuring that the *Patient Agreement Form* (ETASU D) is completed."[202] In short, ETASU B simply ensures compliance with ETASUs A and D, which, as explained, are no longer needed.

The Pharmacy Certification ETASU, accordingly, imposes undue burden with no associated medical benefit.[203] Indeed, FDA experts have recognized that the Pharmacy Certification "will likely limit the types of pharmacies that will choose to certify in the REMS."[204] *First*, the Pharmacy Certification results only in additional cost and administrative

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199 The declarations filed in the *Washington v. FDA* litigation discuss these burdens. *See State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 at 380-81 (Declaration of Angad Singh, M.D.); *id*. at 329-330 (Declaration of Brian Reed); *id*. at 343-344 (Declaration of Grace Shih, MD, MAS) (Feb. 24, 2023).

200 The declarations filed in the *Washington v. FDA* litigation likewise discuss these burdens. *See id.* at 82-83 (Declaration of Emily Godfrey, M.D., M.P.H.) (noting that the Patient Agreement Form harms the patient experience and makes patient counseling more difficult because it suggests mifepristone is unsafe, when it is not); *id*. at 269 (Declaration of Sarah W. Prager, MD, MAS) (Feb. 24, 2023) ("The Patient Agreement Form can also make counseling more difficult in many circumstances. Some patients, for instance, are confused as to why I am asking them to sign an agreement form for a drug that I am explaining to them is very safe. In those instances, the Patient Agreement Form acts to unnecessarily heighten patient worry and stress."); *id.* at 233 (Declaration of Dr. Mark D. Nichols, M.D.) (discussing the "look of concern" on the faces of patients when reviewing the Patient Agreement Form and how he "frequently need[s] to explain to patients that it is an FDA-required process, and that the medical literature is replete with documentation of mifepristone's safety); *id*. at 342-43 (Declaration of Dr. Grace Shih, MD, MAS) (noting the added burden of the form on an "already complex visit" as well as the additional administrative time ensuring the forms are signed and properly saved).

201 Citizen Petition from ACOG (Oct. 4, 2022), *supra* note 133, at 12.

202 FDA Mifepristone REMS Modification Rationale Review (Dec. 2021), *supra* note 68, at 40 (Dec. 16, 2021).

203 *See* Citizen Petition from ACOG (Oct. 4, 2022), *supra* note 133, at 15-17.

204 Ctr. for Drug Evaluation & Rsch., FDA, *Application No. 020687Orig1s025 Mifepristone Summary Review* 14 (Jan. 3, 2023) [hereinafter FDA Mifepristone Summary Review (Jan. 3, 2023)].

burdens on pharmacies that become certified. For instance, the Pharmacy Certification mandates that pharmacies either ensure delivery to the patient within four days or contact the prescriber for permission to ship the drug beyond four days, as well as that pharmacies track and verify receipt of each shipment.[205] As one declarant in litigation with FDA explained, small chain and family-owned pharmacies—which most often serve rural communities and lower populated areas—"are often ill equipped to meet the additional burden that the REMS create, because they are not large enough to absorb the extra staffing, training, administrative, and recordkeeping burdens of the REMS—all of which the pharmacy must undertake without compensation."[206] This, in turn, directly impacts patients who live in rural and less populated areas who will need to travel long distances to find a certified pharmacy who carries mifepristone.[207]

Second, as with the Prescriber Certification discussed above, the Pharmacy Certification makes pharmacies an ideological target susceptible to intimidation. For instance, following an announcement by two large pharmacy chains that they planned to seek REMS certification to distribute mifepristone, these pharmacies received threats from anti-abortion activists and conservative states.[208] As a result, one of the chains subsequently decided that, in an abundance of caution, it would not dispense mifepristone in 20 states, including in several states where abortion remains legal.[209] Six of these states border Tennessee—whose Attorney General publicly objected to the pharmacy's initial decision to seek certification.[210] Ideological pressure stemming from a pharmacy's choice to become certified could be exerted on pharmacy chains large and small with respect to mifepristone.[211]

Nor has FDA addressed the ongoing burden this ETASU imposes on prescribers, as prescribers are required to submit their Prescriber Certification to *every* pharmacy they prescribe to in order for the medication to be dispensed to a patient.[212] Requiring prescribers "[t]o track which pharmacies are 'certified' or not, and whether clinicians have 'submitted' their form to

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205 *See* FDA, *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* 3 (2023).

206 Declaration of Donald Downing, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 67 (discussing burdens associated with Pharmacy Certification ETASU, particularly for small or family-owned pharmacies) (Feb. 24, 2023).

207 *Id.*

208 Press Release, Tennessee Office of the Attorney General, *Attorney General Skrmetti Cautions Pharmacies Not to Distribute Abortion-Inducing Pills in Tennessee* (Mar. 23, 2023), https://www.tn.gov/content/dam/tn/attorneygeneral/documents/pr/2023/ma23-15.pdf; Kaitlyn Radde & Sarah McCammon, *Abortion pills are legal in Kansas, but Walgreens won't sell there after attorney general's threat*, NPR (Mar. 6, 2023), https://www.kcur.org/health/2023-03-06/abortion-pills-are-legal-in-kansas-but-walgreens-wont-sell-there-after-attorney-generals-threat.

209 Alice Miranda Ollstein, *Walgreens won't distribute abortion pills in states where GOP AGs object*, POLITICO (Mar. 2, 2023), https://www.politico.com/news/2023/03/02/walgreens-abortion-pills-00085325; Press Release, Tennessee Office of the Attorney General, *supra* note 208.

210 Press Release, Tennessee Office of the Attorney General, *supra* note 208.

211 *See* Olafimihan Oshin, *20 GOP attorneys general tell CVS, Walgreens plans to dispense abortion pills 'both unsafe and illegal*, The Hill (Feb. 1, 2023), https://thehill.com/policy/healthcare/3840332-20-gop-attorneys-general-tell-cvs-walgreens-plans-to-dispense-abortion-pills-both-unsafe-and-illegal/.

212 Declaration of Dr. Emily Godfrey, M.D., M.P.H., *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 97 (Feb. 24, 2023).

each potential 'certified' pharmacy is out of the scope of any mainstream clinic or provider."[213] All of these burdens compound to limit patient access to mifepristone and drive up costs for already over-burdened healthcare systems.

Further, in concluding that this new ETASU B was necessary, FDA ignored that pharmacies dispensed mifepristone with no pharmacy certification requirement for more than a year during the COVID-19 pandemic with no increase in adverse events.[214] This was no outlier. Data from Canada confirms and that patient safety has remained stable without any pharmacy certification requirement.[215] Because this costly ETASU unduly burdens patients, prescribers, and the healthcare system, while not mitigating a specific risk, it is unlawful and should be removed. 21 U.S.C. §§ 355-1(f)(1)(A), (2)(C)(ii), 2(D)(ii).

Notwithstanding its limited purpose, the Pharmacy Certification requirement imposes enormous new burdens on pharmacies, patients, and prescribers. For instance, as the State of Washington explained in litigation with FDA, in order to begin dispensing mifepristone, its state pharmacies had to create costly new systems that required hundreds of personnel hours to develop and implement.[216] Notably, the Pharmacy Certification requirement adopted by FDA for mifepristone is unique to that drug alone because it is the only REMS that requires individual pharmacies to independently create a secure system to verify prescriber certification (and, moreover, only applies when the drug is used for abortion or miscarriage care, not when a higher and more frequent dose is used to treat Cushing's disease).[217] This distinction is crucial in terms of the burdens it imposes on patient access and the healthcare delivery system. *See* 21 U.S.C. §§ 355-1(f)(2)(C)-(D) (providing that ETASU must not be "unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system.").[218]

For other drugs with pharmacy certification and prescriber certification ETASUs, certified pharmacies may generally look up the certified prescriber and/or the enrolled patient in a centralized database, which is maintained by the drug's sponsor, to verify the provider's certification and/or the patient's enrollment in the REMS program.[219] This, in turn, allows pharmacists nationwide to quickly and easily check the centralized database when dispensing a

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213 *Id*.; *see* Declaration of Dr. Grace Shih, MD, MAS, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 349-350 (Feb. 24, 2023).

214 *See* Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians and Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. 2 (Apr. 12, 2021); *see also* Daniel Grossman, et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology, 613, 620 (Apr. 2021).

215 *See infra* pp.15-16 (discussing Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57, 57 (2022)).

216 *See* Declaration of Sumona DasGupta, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 46-47 (Feb. 24, 2023); *see also* Declaration of Angad Singh, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 380-382 (Feb. 24, 2023).

217 *See State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 72-1 72-2-72-3 (Mar. 30, 2023) (listing drugs for which a pharmacy certification ETASU is required along with a description for how they work differently from the mifepristone REMS).

218 *Id.* at 72-2.

219 *Id.* at 72-4-72-5.

prescription.[220] Here, the Mifepristone REMS Program imposes the entire administrative burden solely on each individual certified pharmacy to create its own secure, dynamic system for tracking and storing providers' certification information. Thus, unlike other drugs with Prescriber Certification and Pharmacy Certification ETASUs, the Mifepristone REMS Program is uniquely onerous because: (1) each provider must separately send their certification information to *each and every* certified pharmacy dispensing a prescription written by the provider; (2) each pharmacy must ensure it receives certification information from each prescriber on every mifepristone prescription; and (3) each pharmacy must separately track this information by creating its own secure, dynamic database of certified prescribers.[221] This is far more time-consuming and burdensome than for the high-risk drugs on which these ETASUs are usually imposed.[222]

This decentralized, patchwork process negatively impacts patients, as well. Whereas the centralized systems that are in place for other REMS-restricted drugs allow *any* certified pharmacy to dispense a prescription written by *any* certified prescriber, the mifepristone REMS only allows a certified pharmacy to dispense a prescription written by a provider who has sent their certification to *that particular pharmacy*.[223] This piles onto the complex and confusing requirements that patients already have to navigate to obtain a prescription for mifepristone in the first place, further delaying and blocking access to care to this time-sensitive medication.[224] To be sure, a centralized database is not the answer for mifepristone, as the existence of any database poses threats to provider safety.[225] The point is that the Pharmacy Certification is uniquely onerous and apply to a drug for which the imposition of *any* REMS is unlawful.

If pharmacies are discouraged from becoming certified, whether due to administrative and cost burdens or political pressure, patient access to mifepristone will necessarily be reduced. Again, this will have a disproportionate impact on rural and medically underserved individuals. For instance, residents of Inyo County, California, noted above, live over 200 miles from the

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220 *Id.*

221 Declaration of Dr. Emily Godfrey, M.D., M.P.H., *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 97 (Feb. 24, 2023); Declaration of Dr. Grace Shih, MD, MAS, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 349-350 (Feb. 24, 2023).

222 Pharmacy-certification ETASU are generally imposed only on drugs with significant risk profiles that require additional safeguards at the point of dispensing to ensure patient safety. For instance, serious liver injury and severe birth defects (Tracleer); heart failure (Camzyos); sudden death (Caprelsa); rapidly lifethreatening and fatal infections (empaveli); liver toxicity, liver failure, and severe birth defects (Filspari); pulmonary embolisms (Sublocade); and valvular heart disease and pulmonary arterial hypertension (Fintepla), among others. *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 72-1 (listing drugs for which a pharmacy certification ETASU is required along with a description for how they work differently from the mifepristone REMS).

223 *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 72-1 72-5 (Mar. 30, 2023); *See* Declaration of Dr. Grace Shih, MD, MAS, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 348 (Feb. 24, 2023).

224 *State of Washington et al. v. U.S. Food & Drug Admin. et al.* at 72-5.

225 Declaration of Brian Reed, *State of Washington et al. v. U.S. Food & Drug Admin. et al.,* No. 1:23-cv-03026 (E.D. Wash.), Dkt. # 4-1 328-329 (Feb. 24, 2023).

closest certified pharmacy, a large pharmacy chain that was willing to obtain certification.[226] Although obtaining the medication by mail may lessen the disparity in some cases, as discussed above, this is not always an option for rural and medically underserved residents.

3. The Mifepristone REMS Program imposes an undue burden on patients in need of emergency abortion or miscarriage.

The Mifepristone REMS Program also imposes an undue burden on pregnant patients experiencing miscarriage and early pregnancy loss who seek treatment at emergency departments. Data suggest that miscarriage and early pregnancy loss account for approximately 900,000 emergency department visits annually.[227] As emergency departments often serve as a safety net for rural and underinsured communities, patients who present to the emergency department with these conditions are often those who have difficulty accessing health care.[228]

As previously stated, the standard of care for treating miscarriage and early pregnancy loss is the combined regimen of mifepristone and misoprostol.[229] The mifepristone ETASUs, however, significantly impede mifepristone's use in emergency departments.[230] Emergency medicine physicians, for example, are unlikely to be "certified" to provide mifepristone.[231] And the Patient Agreement Form and Pharmacy Certification ETASU reduce access in emergency departments in the same manner as discussed above. For instance, the administrative requirements imposed by the REMS can effectively discourage emergency departments from carrying mifepristone in their pharmacies.[232]

As a result, these requirements reduce access to mifepristone in emergency departments—particularly for rural and medically underserved patients—contrary to the REMS statutory requirements.[233] In such cases, they also prevent patients from receiving the evidence-based standard of care, thereby increasing the risk that these patients will only have the option to take a misoprostol-only regimen, which is more likely to require additional procedural interventions,

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226 Lauren DeLaunay Miller, *Many Rural Californians Still Lack Abortion Access. Here Are Solutions*, Cal. Health Rep. (Oct. 28, 2024), https://www.calhealthreport.org/2024/10/28/many-rural-californians-still-lack-abortion-access-here-are-solutions/.

227 Maryann Mazer-Amirshahi & Peggy Ye, *Mifepristone in the emergency department: "RU" ready?*, 65 Am. J. Emergency Med. 202, 202 (Mar. 2023).

228 *See* Anne N. Flynn et al., *The burden of the Risk Evaluation and Mitigation Strategy (REMS) on providers and patients experiencing early pregnancy loss*, 104 Contraception 29, 30 (Apr. 2022).

229 Anne N. Flynn et al., *The burden of the Risk Evaluation and Mitigation Strategy (REMS) on providers and patients experiencing early pregnancy loss*, *supra* note 228, at 29 ("[T]he combined mifepristone-misoprostol regimen has become the standard of care for medical management of EPL.").

230 Maryann Mazer-Amirshahi & Peggy Ye, *Mifepristone in the emergency department: "RU" ready?*, *supra* note 224, at 202; Anne N. Flynn et al., *The burden of the Risk Evaluation and Mitigation Strategy (REMS) on providers and patients experiencing early pregnancy loss*, *supra* note 227, at 30.

231 Anne N. Flynn et al., *The burden of the Risk Evaluation and Mitigation Strategy (REMS) on providers and patients experiencing early pregnancy loss*, *supra* note 227, at 30.

232 *University of Washington School of Medicine: Mifepristone Underutilized in Early Pregnancy Loss*, UW Medicine (Nov. 14, 2024), https://newsroom.uw.edu/news-releases/mifepristone-underutilized-in-early-pregnancy-loss.

233 21 U.S.C. § 355-1(f)(2)(C).

such as vacuum aspiration.[234] Alternatively, the REMS may delay care in cases where another provider must be called in to prescribe the mifepristone regimen or where the patient chooses to go elsewhere for care in order to receive for more efficacious treatment.[235] As discussed above, delayed miscarriage management is directly associated with significant reductions in patient access and safety.[236]

4. There is no evidence of misuse or coercion that would justify these burdens on the prescribing of mifepristone

Mifepristone is not classified as a controlled substance by the federal Drug Enforcement Administration (DEA) or similar agencies outside of the United States.[237] Indeed, Schedule IV medications (which include benzodiazepines and certain opioid analgesics) are classified as such because they have some potential for abuse or dependence.[238] Mifepristone has no misuse or addiction potential.[239] There is no evidence of mifepristone misuse that might support the burdens of continuing the REMS.[240]

There is also no evidence that mifepristone carries a serious risk of being used to coerce pregnancy termination. In fact, researchers at the University of California San Francisco found that approximately 95 percent of women report that having an abortion was the right decision for them, while women denied a wanted abortion were more likely to suffer adverse outcomes such as anxiety, poor physical health, and complications from the end of pregnancy including eclampsia and death.[241] Reproductive coercion is simply not related to mifepristone. As discussed above, Petitioner States have robust informed consent and ethics laws, which carry significant penalties for violations. To be sure, some abortions may be coerced—just as some

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234 Maryann Mazer-Amirshahi & Peggy Ye, *Mifepristone in the emergency department: "RU" ready?*, *supra* note 227, at 202-03.

235 *Id*. (noting Emergency Department physicians may be unfamiliar with mifepristone and the barriers caused by the REMS may limit adoption of the mifepristone-misoprostol regimen for miscarriage care).

236 *See Increasing Access to Abortion, Committee Statement No. 16*, Am. College Obstetricians & Gynecologists (Feb. 2025), https://www.acog.org/clinical/clinical-guidance/committee-statement/articles/2025/02/increasing-access-to-abortion ("[D]elays in care are directly associated with significant reductions in patient access and safety.").

237 Maryann Mazer-Amirshahi et al., Am. Coll. of Med. Toxicology, *AMCT Position Statement: Mifepristone and Misoprostol are not "Controlled Dangerous Substances"* 2 (Sept. 30, 2024), https://www.acmt.net/wp-content/uploads/2024/09/PS_240930_Mifepristone-and-Misoprostol-are-Not-Controlled-Dangerous-Substances.pdf.

238 *Id.*

239 *Id.*

240 Although the state of Louisiana recently reclassified mifepristone as a Schedule IV "controlled substance," and other anti-abortion states seek to do the same, decades of scientific research demonstrate that mifepristone does not meet the definition of a controlled substance or match the intent of what a controlled substance should be. *See* Linda Li et al., *Classifying Misoprostol and Mifepristone as Controlled Substances: Implications for the Management of Non-Abortion Related Conditions*, KFF (Apr. 3, 2025), https://www.kff.org/womens-health-policy/issue-brief/classifying-misoprostol-and-mifepristone-as-controlled-substances-implications-for-the-management-of-non-abortion-related-conditions/; Mazer-Amirshahi et al., Am. College of Med. Toxicology, *AMCT Position Statement: Mifepristone and Misoprostol are not "Controlled Dangerous Substances"* 2 (Sept. 30, 2024), https://www.acmt.net/wp-content/uploads/2024/09/PS_240930_Mifepristone-and-Misoprostol-are-Not-Controlled-Dangerous-Substances.pdf.

241 Diana Greene Foster et al., *The Turnaway Study*, Univ. Cal. S.F., https://www.ansirh.org/research/ongoing/turnaway-study (last visited May 7, 2025).

people may be coerced to carry their pregnancies to term.[242] Studies have described women whose partners threatened to harm or kill them if they had abortions, while another study described women whose partners threatened to use violence to cause the abortions themselves.[243]

One pair of studies funded by the Charlotte Lozier Institute—the same nonprofit anti-abortion research entity whose studies on mifepristone's safety were retracted by an academic publisher[244]—have claimed that abortion coercion is prevalent.[245] But like the mifepristone safety studies, these studies are deeply flawed. As a threshold matter, both of these coercion studies combine a host of varied response options into single statistics, summarily characterized as representing "pressured" or "unwanted/coerced" abortions.[246] Moreover, neither study addressed whether participants' associations with their abortions were due to financial, medical, or other factors—as opposed to coercion from an individual.[247] A prominent researcher at the Bixby Center for Global Reproductive Health has further noted that both studies are problematic because they are retrospective and therefore are based on biased samples.[248] Further, neither study links mifepristone to abortion coercion.

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In sum, by unnecessarily reducing the number of providers who can prescribe and dispense mifepristone, the mifepristone ETASU elements decrease access to and increases burdens on patients. This, in turn, disproportionately harms patients already facing challenges accessing healthcare, particularly patients in rural and medically underserved communities in the Petitioner States. The Mifepristone REMS Program also unduly burdens the healthcare system, by imposing unnecessary, burdensome, and expensive-to-implement ETASU elements on prescribers, pharmacists, and their employers, for no noted benefit.

D. Continuing the Mifepristone REMS Program is Inconsistent with the Lack of Similar Regulation of Comparably Risky and Deadlier Drugs

FDA guidance states that, "[w]hen considering this burden on patient access . . . FDA takes into account existing REMS elements for other drugs with similar risks."[249] Yet many

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242 Karen Trister Grace & Jocelyn C. Anderson, *Reproductive Coercion: A Systematic Review*, 19 Trauma, Violence, & Abuse 371, 372, 379 – 40 (Oct. 2018); *see* Amy G. Bryant & Jonas J. Swartz, *Why Crisis Pregnancy Centers are Legal but Unethical*, 20 AMA J. Ethics 269, 270, 272 – 73 (Mar. 2018).

243 Karen Trister Grace & Jocelyn C. Anderson, *Reproductive Coercion: A Systematic Review*, 19 Trauma, Violence, & Abuse 371, 381 (Oct. 2018).

244 Sherman Smith, *Kansas abortion 'coercion' bill touted by out-of-state think tank that produced retracted research*, Kansas Reflector (Mar. 19, 2024), https://kansasreflector.com/2024/03/19/kansas-abortion-coercion-bill-touted-by-out-of-state-think-tank-that-produced-retracted-research/.

245 David C. Reardon & Tessa Longbons, *Effects of Pressure to Abort on Women's Emotional Responses and Mental Health*, 15 Cureus 1, 1 – 9 (Jan. 2023); David C. Reardon et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, 15 Cureus 1 (May 2023).

246 *Id.*

247 *Id.*

248 Sherman Smith, *Kansas abortion 'coercion' bill touted by out-of-state think tank that produced retracted research*, *supra* note 244.

249 FDA, Health & Hum. Servs., *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary – Guidance for Industry* 9 (April 2019).

drugs with similar or more serious risks are not under a REMS.[250] In light of mifepristone's well-established safety profile over the last quarter century, there is no reason for FDA to continue treating mifepristone differently from the other 20,000 prescription drugs, many of which have comparable or more serious risks, that do not have a REMS with ETASU elements. Other than the fact that mifepristone is prescribed for a "controversial use," [251] the continued imposition of restrictive ETASU elements on mifepristone is unwarranted, particularly when the FDA does not impose them on other, more dangerous prescription medications that carry similar or greater risks.

For instance, despite acknowledging that serious complications associated with mifepristone are "extremely rare," inherent to pregnancy, and not causally linked to the use of mifepristone, *see, e.g., supra* p. 2, FDA regulates mifepristone much more strictly than the vast majority of opioid products, which have claimed a staggering number of lives in the Petitioner States. Further examples follow below.

Korlym. Korlym, which is the identical chemical compound of mifepristone, does not have a REMS when used to treat Cushing's syndrome even though it is prescribed for daily use and in a much higher dose. And Korlym has remained without a REMS even though its long-term use and higher dosage has had significantly higher rates of adverse events.[252] Korlym does carry a Boxed Warning, but it is only specific to the unwanted termination of pregnancy, not for any other adverse event or complication. And despite the potential for the same serious events associated with pregnancy termination, should a pregnant woman take Korlym to treat Cushing's syndrome, there is no REMS requirement.

Botox Cosmetic and Jeuveau. Other examples of commonly-used drugs that pose a much more serious risk than mifepristone include Botox® Cosmetic and Jeuveau®—FDA-approved medications derived from botulinum toxin-type A and used for purely cosmetic purposes, such as improving the appearance of "wrinkles between the eyebrows." These biological drugs have no REMS even though they are toxins by definition. They carry Boxed Warnings for the uncontrolled spread of botulinum toxin in the body that can cause "life-threatening" conditions like difficulty "[s]wallowing and difficulty breathing that could lead to death."[253]

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[250] Jaclyn J. Serpico, *Abortion exceptionalism and the mifepristone REMS*, *supra* note 186; Congress of Delegates, Am. Acad. Of Fam. Physicians, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* (May 24, 2018).

[251] Ctr. for Drug Evaluation and Rsch., FDA, *Application Number: 202107Orig1s000, Summary Review (Korlym)* 3 (Feb. 17, 2012).

[252] FDA Mifepristone Post-Marketing Adverse Events Summary Through 12/31/2024, *supra* note 2; Ctr. for Drug Evaluation & Rsch., FDA, *All Adverse Events (Mifepristone 200mg)* (Dec. 22, 2022); *see also* FDA Mifeprex Medical Review(s) March 29, 2016, *supra* note 6, at 10 ("Adverse reactions noted in >20% of patients in clinical trials with Korlym included nausea, fatigue, headache, hypokalemia, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite and endometrial hypertrophy.").

[253] *Drug Trials Snapshots: JEUVEAU*, FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots-jeuveau (last updated Jan. 31, 2020); FDA, *JEUVEAU: Highlights of Prescribing Information* (Feb. 2019).

Coumadin. Common anticoagulants like Coumadin® (warfarin), carry only a Boxed Warning that the drug "can cause major or fatal bleeding."[254] Coumadin does not have any REMS restrictions even though its use also raises specific pregnancy risks, including risks to the fetus. The labeling specifically states, "[i]f this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential harm to the fetus."

Sildenafil drugs. There is no REMS for sildenafil drugs (including Viagra® and its generic versions), which are commonly used to treat erectile dysfunction, even though cumulatively they have a much higher fatality rate than mifepristone.[255] The same is true with respect to penicillin, which causes a fatal anaphylactic reaction at a rate of 2 deaths per 100,000 patients administered the drug, yet has no REMS.[256]

Opioids. As previously discussed, while FDA prohibits providers or pharmacies from prescribing or dispensing mifepristone without first being certified, there is no such precondition to prescribing or dispensing fentanyl or Oxycontin. Instead, the Opioid Analgesic REMS merely makes optional educational materials available.[257] Nor does FDA require patients receiving opioids to sign a Patient Agreement ETASU, notwithstanding the highly addictive and potentially deadly nature of opioids.

As FDA explains to the public, "REMS are not designed to mitigate all the adverse events of a medication, [as] these are communicated to health care providers in the medication's prescribing information"; "[r]ather, REMS focus on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."[258] But, the Mifepristone REMS Program accomplishes no such purpose as the risks associated with mifepristone relate to pregnancy termination—not the medication itself.[259] Since the frequency or severity of an event associated with pregnancy

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254 FDA, *Coumadin 2011 Labeling and Medication Guide* (Oct. 2011).

255 *See* Abdullah H. Al Ibrahim et al., *A Systematic Review of Sildenafil Mortality Through the Years,* 14 Cureus e32179, 3 (Dec. 4, 2022) ("Reviewing and analyzing the adverse effects of PDE5 inhibitors that have been reported to the FDA in a period of 10 years showed a total of 26,451 adverse events, of which death reports represent 8.3%. A total of 14,818 adverse events were reported with sildenafil used to treat erectile dysfunction and were associated with the highest number of death reports among the PDE5 inhibitors group, at 12.3%."); *see also* Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report*, *supra* note 7, at 3 ("Phosphodiesterase type-5 inhibitors, which are used for erectile dysfunction and include Viagra, have a fatality rate of 4 deaths per 100,000 users." (citing Gregory Lowe & Raymond A. Costabile, *10-Year analysis of adverse event reports to the FDA for phosphodiesterase type-5 inhibitors*, 9 J. Sex Med. 265, 265 – 70 (2012)).

256 Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report*, *supra* note 7, at 3.

257 *See* FDA, *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)* (Mar. 31, 2025), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

258 FDA, *Risk Evaluation and Mitigation Strategies (REMS)*, https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems (last visited June 3, 2025).

259 *See* FDA, *Mifepristone 2023 Labeling and Medication Guide*, at 2 ("Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use*. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established*.") (emphasis added); *id.* at 16 ("Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur

termination is not directly affected by the drug, but rather by the termination process, the Mifepristone REMS Program requirements cannot actually mitigate the risks. Other than ensure that prescribers and patients are aware of the risks associated with terminating a pregnancy—which are already adequately communicated through the medication's labeling and Medication Guide—the mifepristone REMS requirements do nothing to prevent, monitor, or manage the risks associated with pregnancy termination. There is simply no other way to reconcile mifepristone's disproportionately restrictive REMS program and its burdensome ETASU elements with FDA's more lenient treatment of riskier and deadlier medications, other than mifepristone's purpose as an abortion medication. For this reason, too, the Mifepristone REMS Program should be removed.

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Given mifepristone's well-established safety record in the United States over the last 25 years, its critical importance for women's healthcare in states where abortion is legal, and the significant burdens the Mifepristone REMS Program places on patient access and the healthcare system, the Mifepristone REMS Program should be removed in its entirety.

III. In the Alternative, FDA Should Decline to Enforce the REMS ETASU Requirements for Prescriber Certification, Patient Agreement Form, or the Pharmacy Certification in Petitioner States.

If FDA declines to lift the Mifepristone REMS Program in its entirety, FDA should exercise enforcement discretion and not enforce the Mifepristone REMS ETASU within the Petitioner States because the Petitioner States already impose robust protections designed to ensure patient safety. The goals of the Prescriber Certification, Patient Agreement Form, and Pharmacy Certification of Mifepristone REMS ETASU are addressed by state-level regulations that ensure patient safety without the undue administrative burden imposed by those components of the ETASU. FDA has authority to exercise enforcement discretion as to these aspects of the mifepristone REMS in Petitioner States and has done so in analogous circumstances.

A. Petitioner States have enacted robust protections that render the ETASU Patient Agreement Form, Prescriber Certification Form, and Pharmacy Certification Forms Duplicative and Unnecessary.

Under our federalist system, States enjoy general authority to enact laws and policies aimed at protecting the health and welfare of their residents. Regulation of the practice of medicine lies at the heart of that established power. At the most fundamental level, states regulate the practice of medicine by defining the scope and contours of medical practice and requiring medical licenses for practitioners,[260] by imposing stringent requirements for informed consent, and by regulating the prescribing and distribution of prescription medications within their

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following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. *There is no information that use of Mifeprex and misoprostol caused these deaths*.") (emphasis added).

[260] Federation of State Medical Boards, *Assessing Scope of Practice in Health Care Delivery: Critical Questions in Assuring Public Access and Safety* (2005), https://www.fsmb.org/siteassets/advocacy/policies/assessing-scope-of-practice-in-health-care-delivery.pdf.

borders. Petitioner States have exercised that authority by enacting a variety of laws and regulations of the healthcare delivery system specifically designed to maximize patient safety. The ETASU elements are duplicative of those robust protections in place in Petitioner States, and wholly unjustified in light of mifepristone's long-standing and extensive safety record discussed above. FDA should accordingly decline to enforce them in Petitioner States.

1. The Prescriber Certification ETASU is duplicative of existing state licensure regimes in Petitioner States.

The Prescriber Certification ETASU, which requires prescribers to certify that they are operating within their scope of practice and meet applicable standards of care within their field, is duplicative of long-standing physician and advance practice clinician professional licensing requirements in the Petitioner States.

The Mifepristone REMS Program requires that mifepristone "be prescribed by a health care provider that meets certain qualifications and is certified under the Mifepristone REMS Program" and that "[i]n order to become certified to prescribe mifepristone, health care providers must complete a Prescriber Agreement Form."[261] The Prescriber Certification ETASU was originally imposed with the purpose of ensuring that mifepristone is "prescribed by a certified prescriber who has certain qualifications and agrees to follow certain guidelines for use."[262] Per FDA, health care providers who seek to become certified to prescribe mifepristone must "have the ability to date pregnancies accurately and the ability to diagnose ectopic pregnancies."[263] They must also "be able to provide any necessary surgical intervention or have made arrangements for others to provide for such care," must ensure that patients have access to medical facilities for emergency care, and, among other things, must agree to review and sign the Patient Agreement Form with the patient.[264] Recognizing that the states have regulations in place related to prescribing of medications, FDA acknowledges that some states permit health care providers other than physicians to prescribe medication and notes that health care providers should check individual state laws.[265]

Each of these requirements has long been extensively regulated in Petitioner States. Indeed, one of the most important functions of the nation's state medical boards is to regulate physicians and other clinicians. States have long held this responsibility; indeed, "[s]tate licensing laws enacted in the 19th century established medical boards to license and discipline physicians within each state and territory."[266] Universal requirements for obtaining a medical license across states include graduation from an accredited medical school, completing one or

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261 *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification.

262 *Id.*

263 *Id.*

264 *Id.*

265 *Id.*

266 Federation of State Medical Boards, *History*, https://www.fsmb.org/about-fsmb/history/ (last visited June 4, 2025).

more years of residency or fellowship, and passing a licensing examination.[267] Additional requirements can include interviews, a documented lack of criminal history, and malpractice insurance coverage documentation.[268]

State boards further regulate medical practice by disciplining licensees who act illegally or unethically and by reporting and disclosing when licensees are disciplined.[269] "Through licensing and disciplinary investigations, state licensing boards ensure that all practicing clinicians have appropriate education and training, that they are operating within their scope of practice, and that they abide by recognized standards of professional conduct while serving their patients."[270]

In Massachusetts, for example, "[a]ll healthcare practitioners . . . are subject to professional discipline for the failure to comply with recognized standard of practice."[271] Practitioners will be subject to professional discipline, up to and including license revocation, for failing to comply with those standards.[272] The Board of Registration in Medicine (BORIM) is responsible for licensing, regulation, and discipline of Massachusetts physicians, specifically, and incorporates those standards.[273]

In addition, as part of the review of the mental, moral, and physical fitness to safely practice medicine, each state imposes ethical obligations on physicians who are licensed by that state. This means considering "questions about the personal history and background of the applicant, including work history, physical and/or mental conditions that might impact their ability to safely practice medicine. Criminal background checks at the time of license application are also conducted by many boards."[274] Parallel regulatory schemes and requirements are in place for other types of clinicians, such as nurse practitioners, physician assistants, nurse midwives, and midwives.[275]

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267 Federation of State Medical Boards, *About Physician Licensure*, https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-licensure/#:~:text=In%20the%20United%20States%2C%20medicine%20is%20a,of%20professional%20conduct%20while%20serving%20their%20patients (last visited June 4, 2025).

268 *Id*.

269 Federation of State Medical Boards, *About Physician Discipline*, https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-discipline/ (last visited June 4, 2025).

270 Federation of State Medical Boards, *About Physician Licensure*, https://www.fsmb.org/u.s.-medical-regulatory-trends-and-actions/guide-to-medical-regulation-in-the-united-states/about-physician-licensure/#:~:text=In%20the%20United%20States%2C%20medicine%20is%20a,of%20professional%20conduct%20while%20serving%20their%20patients (last visited June 4, 2025).

271 Memorandum from Dr. Robert Goldstein, Comm'r of Mass. Dep't of Pub. Health, to Mass. licensed physicians, physician assistants, nurses, pharmacists, pharmacies, hospitals, and clinics (Jan. 3, 2024).

272 *Id.*

273 *Board of Registration in Medicine (BORIM)*, Mass.gov, https://www.mass.gov/orgs/board-of-registration-in-medicine (last visited June 3, 2025).

274 Federation of State Medical Boards, *supra* note 264.

275 *See generally* 130 Mass. Code Regs. 433.000; 244 Mass. Code Regs. 4.00; 263 Mass. Code Regs. 5.00; Mass. Gen. Laws c. 112 § 291-297.

Additionally, states impose continuing obligations on clinicians to provide care only when the provider is qualified to do so.[276] For example, in Massachusetts, a provider's scope of practice is defined by BORIM: "Medical services requiring licensure are services which fall within the definition of the practice of medicine, which may only be performed by licensed physicians, and other licensed health care professionals to the extent that the services also fall within the scope of practice of the license held."[277] As discussed further in Section III.B. below, such regulations ensure that providers are qualified and able to provide the care they offer exist in all Petitioner States.

The Prescriber Certification ETASU serves precisely the same function as the statutes and regulations outlined above—ensuring that the provider is competent to prescribe the medication— but in a manner specific to mifepristone. This is unnecessary, as state regulations on licensure and professional discipline are in place to ensure that practitioners are competent to prescribe all the medications they might prescribe. As previously discussed, there is no basis for the FDA to set this specific medication apart for additional certification by providers as to their training and qualifications, given mifepristone's extensive safety record and its decades of clinical use. Petitioner States' medical licensure regimes ably serve the function of ensuring providers are qualified; FDA's Prescriber Certification requirement simply interferes with the Petitioner States' regulation of the practice of medicine by subjecting providers to duplicative and unnecessary burdens that limit their ability to prescribe, and patients' ability to access, this essential drug.

2. The Patient Agreement Form ETASU is duplicative of state protections for informed consent in Petitioner States.

The Patient Agreement Form ETASU is duplicative of not only the information in mifepristone's medication guide and information provided on the drug label, but also of information already required under state laws and regulations and providers ethical obligations governing informed consent.

As described in Section II.C.2 *supra*, under ETASU D, The Patient Agreement Form, the Mifepristone REMS Program requires that the "Patient Agreement Form must be reviewed with and signed by the patient and the health care provider, and the risks of the mifepristone treatment regimen must be fully explained to the patient before prescribing mifepristone."[278] The REMS Program requires that the patient "be provided with a copy of the Patient Agreement Form and the mifepristone Medication Guide."[279] The purpose of this requirement is to ensure "that patients be informed of the risks of the treatment regimen."[280]

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276 Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, American Medical Association (Policy Forum) (Apr. 2005).

277 Memorandum from Dr. Robert Goldstein, Comm'r of Mass. Dep't of Pub. Health, *supra* note 271; 243 Mass. Code Regs. § 2.01(4).

278 *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification.

279 *Id.*

280 *Id.*

This is unnecessary and duplicative of the established statutory and regulatory protections in place to safeguard informed consent. As the FDA has previously acknowledged, it is the responsibility of the individual states to ensure their laws protect patient autonomy.[281] Accordingly, individual states have codified and interpreted informed consent nationwide, enacting robust regulatory schemes to ensure patients are appropriately informed of risks and can confer their voluntary informed consent before undergoing any medical procedures or taking any medication.

Two primary standards for informed consent have emerged: physician-based and patient-based.[282] Taking first the physician-based standard, which is adopted by Petitioner State New York: "Under the modern version of the physician standard, physicians are commonly required to inform a patient of the dangers of, possible negative consequences of, and alternatives to a proposed treatment or procedure to the same degree that a reasonably prudent practitioner in the same field of practice or specialty would."[283] Alternatively, "[u]nder the patient-based approach, physicians must disclose to patients any material risk, generally defined as those risks that a reasonable person in the patient's position would attach significance to in deciding whether or not to forego the proposed therapy."[284] States that have adopted the patient-based approach include California, Massachusetts, and New Jersey.[285]

Regardless of whether a state follows the physician-based or patient-based approach to informed consent, each state has its own standards and regulations to ensure patients understand the relative risks and benefits of each procedure, medication, or test they choose to undergo.[286] These protections are sufficient to ensure patients enter into medical procedures or begin new medications with their eyes open to potential side effects and impacts.

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281 *See* Noah Lars, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 Am. J.L. & Med. 361, 361 (2002); *cf.* 21 U.S.C. § 393 (FDA authorizing statute containing no direction to the FDA to ensure regulations protect patient autonomy).

282 *Medical Treatment and Informed Consent State Law Survey*, LexisNexis Practical Guidance 2 (2025).

283 *Id.*; *see also Tashman v. Gibbs*, 263 Va. 65, 73 (Va. 2002).

284 *Medical Treatment and Informed Consent State Law Survey*, LexisNexis Practical Guidance 2 (2025); *see also Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972)*.

285 *Medical Treatment and Informed Consent State Law Survey*, LexisNexis Practical Guidance 4, 9, 11 (2025).

286 *See, e.g.* 243 Mass. Code Regs. § 2.07(26) ("Informed Consent. A physician has the obligation to obtain and record a patient's written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments. Informed consent means that the physician has disclosed and explained to the patient's satisfaction the process used to arrive at the medically reasonable and recommended procedure, intervention or treatment, based on reliable evidence of the expected benefit and risk of each alternative, free from any impermissible bias. Written informed consent means that the patient, who has demonstrated capacity, or the patient's representative, has been given ample opportunity to ask questions, with all questions having been answered to the patient's or representative's satisfaction, and with the patient or representative giving consent in writing to the procedure, intervention or treatment."); *See also* NY Pub. Health § 2803 (hospital patients' bill of rights, including right to "all the information that [a patient would] need to give informed consent for any proposed procedure or treatment [including] the possible risks and benefits of the procedure or treatment"); N.Y. Pub. Health § 2805-d (cause of action for lack of informed consent); N.J. Stat. Ann. § 26:2H-12.8 (statutory right of informed consent while being treated in hospital); N.J. Stat. Ann. § 26:14-4 (statutory right to informed consent when serving as subject of medical research).

In Massachusetts, for example, BORIM requires "a patient's written informed consent before diagnostic, therapeutic or invasive procedures, medical interventions or treatments."[287] The physician must disclose and explain "to the patient's satisfaction the process used to arrive at the medically reasonable and recommended procedure, intervention or treatment, based on reliable evidence of the expected benefit and risk of each alternative, free from any impermissible bias" and the patient must have been given the opportunity to ask questions, which all must be answered to the patient's satisfaction.[288]

Practitioners have an obligation to convey information to their patients within the practice of medicine, and to exercise their medical judgment for each specific patient within the doctor-patient relationship in accord with the state laws of each Petitioner State. FDA should exercise enforcement discretion and not enforce the Patient Agreement Form ETASU for mifepristone, which adds an undue burden on the doctor-patient relationship, may inappropriately elevate the safety concerns of mifepristone (as discussed above), and unduly burden the health care delivery systems in Petitioner States. Practitioners also may have obligations to report unsafe practice of medicine.[289]

3. The Pharmacy Certification ETASU is duplicative of regulations governing the practice of pharmacy in Petitioner States.

Under the Mifepristone REMS Program, "[m]ifepristone may only be dispensed by or under the supervision of a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber" and to become certified to dispense, pharmacies must complete the Pharmacy Agreement Form.[290] Per FDA, the Pharmacy Certification ETASU was imposed to ensure that pharmacies agree to follow the REMS requirements and to ensure that "mifepristone is only dispensed pursuant to prescriptions that are written by certified prescribers."[291] As noted in Section II.C. *supra*, because the Prescriber Certification and Patient Agreement are both unnecessary, so, too, is the Pharmacy Certification.

As described in Section II.C. *supra*, the Pharmacy Certification ETASU unduly burdens patients, prescribers, and the healthcare system, is unrelated to patient safety and does not mitigate any specific risk. It is duplicative of licensing requirements and pharmacy regulation in the Petitioner States. In Massachusetts, for example, the Board of Registration in Pharmacy regulates the practice of pharmacy, the operation of pharmacies, and the distribution of

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287 243 Mass. Code Regs. § 2.07(26).

288 *Id.*

289 *See, e.g.*, N.J. Stat. Ann. § 45:1-37 (2024); N.J. Stat. Ann. § 26:2H-12.25 (2024) (mandatory reporting obligation for medical practitioners to the New Jersey Board of Medical Examiners of information that reasonably indicates another practitioner has engaged in conduct that would present imminent danger to the patient or to the public and to report incidents relating to adverse patient outcomes).

290 *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification.

291 *Id.*

prescription drugs.[292] Furthermore, there are robust requirements related to Massachusetts Controlled Substances Registration, and all practitioners must comply with the controlled substance requirements set forth in the Massachusetts Controlled Substances Act.[293] A Massachusetts Controlled Substances Registration "is required for any practitioner or entity to purchase, store, or dispense any controlled substance, *which includes any prescription medication in Massachusetts.*"[294]

The Petitioner States have robust systems that regulate prescription drugs. While having no relation to patient safety, the Pharmacy Certification ETASU adds significant burdens and precludes access for those who need Mifepristone, ultimately undermining the safety and efficacy of the drug because those who need it often cannot get it. As explained at Section II.C.2(c) *supra*, there are considerable burdens imposed on particularly smaller pharmacies that will restrict access in more remote and medically underserved areas.

B. Specific regulations in place in each Petitioner State for ensuring provider competence, patient informed consent, and pharmacy oversight render the ETASU elements duplicative and unnecessarily burdensome.

As described fully in Section II.C. above, contrary to the REMS statute, 21 U.S.C. 355-1(f)(2)(C), the Prescriber Certification, Patient Agreement Form, and Pharmacy Certification ETASUs each unduly burden patient access to mifepristone in Petitioner States. Not only are they medically unnecessary, but they also obstruct and hinder access to the medication—particularly in rural and medically underserved areas. FDA's exercise of enforcement discretion to not enforce the ETASU requirements would help ensure patient access while Petitioner States ensure that providers and pharmacies are compliant with state law that governs their professional conduct.

1. Massachusetts:

Prescriber certification: The Massachusetts BORIM achieves what the Prescriber Certification allegedly accomplishes, as both ensure that prescribers of Mifepristone protect patient safety. FDA's proposed Prescriber Certification form requires that prescribers meet certain qualifications and send the certification to every pharmacy to which they send a prescription.[295] The Massachusetts BORIM has already issued comparable regulations governing patient safety. Namely, BORIM's Licensing and the Practice of Medicine regulations lay out guidelines for prescribers and set limitations on the circumstances under which medication such as Mifepristone can be prescribed.[296] As discussed above, the Prescriber Certification ETASU adds unnecessary administrative burdens, which discourages qualified providers, including

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[292] *Board of Registration in Pharmacy*, Mass.gov, https://www.mass.gov/orgs/board-of-registration-in-pharmacy (last visited June 3, 2025).

[293] *See* Mass. Gen. Laws c. 94C §7.

[294] Memorandum from Dr. Robert Goldstein, Comm'r of Mass. Dep't of Pub. Health, *supra* note 268 (emphasis added).

[295] Danco, *Prescriber Agreement Form: Mifepristone Tablets, 200mg* (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf; GenBioPro, *Prescriber Agreement Form: Mifepristone Tablets, 200mg* (Jan. 2023), https://genbiopro.com/wp-content/uploads/2024/09/GBP-MIF-715-Prescriber-Agreement_2023-01-26.pdf.

[296] 243 Mass. Code Regs. §§ 2.07, 2.08 (2025).

Emergency Room physicians and rural family practice physicians, from seeking certification. This undue burden unnecessarily limits access to mifepristone.

Patient Agreement Form: Likewise, the Patient Agreement Form duplicates what the Massachusetts BORIM's informed consent regulations currently accomplish. The FDA's Patient Agreement Form requires the signatures of both provider and patient, attesting to the provider's explanation and the patient's understanding of the risks of taking Mifepristone.[297] Essentially, this Patient Agreement Form achieves the same result as the Massachusetts informed consent regulations which include requirements that physicians obtain and record a patient's understanding of the risks and benefits prior to receiving medical treatment.[298] Because Massachusetts has generally applicable regulations, these informed consent rules govern prescribers of mifepristone and render the REMS redundant and unduly burdensome.

Pharmacy Agreement Form: The Pharmacy Agreement Form is unnecessary in light of regulations issued by the Massachusetts Board of Registration in Pharmacy. The FDA's proposed Pharmacy Certification mandates that dispensing pharmacies design and implement a system that confidentially tracks prescriber certifications and filled prescriptions.[299] This system imposes significant burdens on pharmacies as a condition of dispensing mifepristone.[300] Although Massachusetts lacks regulations specific to mifepristone, the regulations of Massachusetts pharmacies sufficiently ensure that patients receive the right dosage, proper warnings, and other information necessary to safeguard patients. For instance, the Massachusetts Board of Registration in Pharmacy has issued regulations regarding general practice standards, requirements for dispensing and refilling prescriptions, and patient counseling.[301] Other relevant Massachusetts-specific regulations include personal registration renewal and continuing education rules.[302] Accordingly, the additional Pharmacy Certification imposes a documentation and tracking burden that is unnecessary to ensure patient safety and unduly burdens the health care delivery system in Massachusetts.

2. California

Provider Certification: In California, any person who practices, attempts to practice, or holds themselves as practicing, any care or treatment for which they are not properly qualified—including by prescribing drugs to another person—may be held criminally liable.[303] Moreover, California has specific statutory licensure requirements for performing medication abortion,[304] as well as for prescribing medications generally.[305] These protections ensure that only qualified

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297 FDA Mifepristone Patient Agreement Form, *supra* note 180.

298 243 Mass. Code Regs. § 2.07 (2025).

299 Danco, *Pharmacy Agreement Form: Mifeprex (Mifepristone) Tablets, 200mg* (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Pharmacy_Agreement_Form_Danco_Laboratories.pdf; GenBioPro, *Pharmacy Agreement Form: Mifepristone Tablets, 200mg* (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Pharmacy_Agreement_Form_for_GenBioPro_Inc.pdf.

300 *See id.*

301 247 Mass. Code Regs. §§ 9.01, 9.04, 9.18 (2024).

302 247 Mass. Code Regs. §§ 4.01-.02 (2017).

303 Cal. Bus. & Prof. Code §§ 2052, 2053.5(a)(3) (2024).

304 Cal. Bus. & Prof. Code § 2253 (2024).

305 Cal. Health & Saf. Code § 11150 *et seq*.

providers can prescribe mifepristone, making the Prescriber Certification redundant and unnecessary in the state.

Patient Certification: California also has robust protections for patients' rights[306] and requirements for informed consent, [307] which similarly nullify the need for a separate Patient Agreement Form.

Pharmacy Certification: This is true for the Pharmacy Certification as well, as California's statutory requirements for pharmacists' scope of practice, prescription labeling, and drug containers ensure patients receive directions for use of the drug and other information necessary for patient safety.[308]

3. New Jersey

Prescriber Certification: New Jersey's regulations emphasize the redundancy of the FDA's Prescriber Certification for prescribers in the state. New Jersey's Board of Medical Examiners already ensures prescribers of mifepristone protect patient safety by ensuring that prescribers are qualified in storage, handling, security, counseling, labeling, packing, dispensing and record keeping requirements.[309] State law also requires all prescribers ensure that a prescription is based on a thorough evaluation of the patient's medical history and clinical need.[310] All prescriptions must be within the practitioner's scope of practice.[311] And all prescribers of any prescription drug must comply with the drug's prescription requirements .[312]

Patient Agreement Form: Further, during medical examination, all New Jersey practitioners must discuss with each patient the risks and benefits of any treatment.[313] Additionally, New Jersey patients have a common law right to informed consent,[314] and a

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306 Cal. Health & Saf. Code § 1262.6; 22 Cal. Code Regs. §§ 70707, 73523.

307 In California, under the doctrine of informed consent, a provider has a duty to disclose to the patient all material information that is necessary to make an informed decision about a proposed treatment. *Hahn v. Mirda*, 147 Cal. App. 4th 740, 754 (App. 1 Dist. 2007). Material information for a patient's informed consent is that which the provider knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the procedure, including the potential of death, serious harm, complications associated with the procedure, and any information pertaining to a patient's unique concerns. *Wilson v. Merritt*, 142 Cal. App. 4th 1125 (App. 4 Dist. 2006). Patients may bring a negligence claim for lack of informed consent against providers who breach this duty. *Jameson v. Desta*, 215 Cal. App. 4th 1144 (App. 4 Dist. 2013). Additionally, withholding a material risk or material information may give rise to a claim for fraud, conversion, or intentional infliction of emotional distress. *Hahn v. Mirda*, 147 Cal. App. 4th 740 (App. 1 Dist. 2007). Finally, patients may bring a claim for medical battery if a procedure is performed without consent or if the patient gives permission to perform one type of procedure and the doctor performs another. *See Dennis v. Southard*, 174 Cal. App. 4th 540 (App. 3 Dist. 2009).

308 Cal. Bus. & Prof. Code §§ 4050 et seq., 4076, 4076.5; 16 Cal. Code Regs. § 1707.5.

309 N.J. Stat. Ann. § 45:9-1 et seq.

310 N.J. Admin. Code § 13:35-7.1A.

311 N.J. Admin. Code §§ 13:35-7.2(a), 7.4(a), 7.4A(a).

312 N.J. Stat. Ann. § 24:21-15.

313 N.J. Admin. Code § 13:35-7.1A(a)(3).

314 S*ee Perna v. Pirozzi*, 457 A.2d 431, 438 (N.J. 1983) (recognition of duty to disclose information that will allow patient to "evaluate knowledgeably the options available and the risks attendant upon each" before treatment);

statutory right to informed consent when being treated in a hospital.[315] Because the state's required informed consent practice accomplishes what the Patient Agreement Form purports to do, the Patient Agreement Form is unnecessary and duplicative.

Pharmacy Agreement Form: The Pharmacy Agreement Form also imposes an unnecessary burden on New Jersey as the state's Board of Pharmacy already regulates "the practice of pharmacy, the licensure of pharmacists and the permitting, control and regulation of all pharmacy practice sites" in the state.[316] New Jersey pharmacists must conduct a drug utilization review before dispensing or delivering medication and must ultimately exercise independent professional judgment as to whether to dispense or refill a prescription,[317] demonstrating the deliberate analysis of patient safety already required without the Pharmacy Agreement Form.

4. New York

Provider Certification Form: The New York state board for medicine regulates physicians' qualifications for licensure, NY Educ. Law § 6524, and its state board for professional misconduct enforces detailed statutes and regulations as to what constitutes physician misconduct, including a pattern of inappropriate prescribing, NY Pub. Health Law § 230 10 (D) (iv) (A), as well as threats to patient safety, *id.* § 230 10 (D); NY Educ. Law § 6530-6532; 8 NYCRR § 17.9.a.b., d., § 18.5, and sets forth a detailed process by which such misconduct is determined.[318] Requirements for licensure, practice and disciplinary processes for misconduct for nurse practitioners, physician assistances, and certified nurse midwives, are similarly regulated under New York law.[319]

Patient Agreement Form: New York State law protects patients' rights to informed consent to medical care, which includes a right to information about the proposed treatment or diagnosis as well as alternatives, along with "the reasonably foreseeable risks and benefits involved as a reasonable . . . practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation."[320]

Pharmacy Certification Form: New York's regulates pharmacist licensing and professional conduct, including imposing stringent requirements for licensure, NY Educ. Law § 6805, and overseeing through its state board of pharmacy the sale, distribution, character, and

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Matthies v. Mastromonaco, 733 A.2d 456, 460-61 (N.J. 1999) (disclosure must include both medically reasonable invasive and noninvasive alternatives, risks, and likely outcomes of both); *Teilhaber v. Greene*, 727 A.2d 518, 524 (N.J. Super. Ct. App. Div. 1999) (explaining prima facie test for medical negligence via lack of informed consent).

315 N.J. Stat. Ann. § 26:2H-12.8.

316 N.J. Stat. Ann. § 45:14-40.

317 N.J. Stat. Ann. § 45:14-66.

318 N.Y. Pub. Health Law § 230(10).

319 N.Y. Comp. Codes R. & Regs. tit. 8, §§ 17, 18, 24, 28, 64.4-64.6, 64.8, 79.5. *See also* N.Y. Comp. Codes R. & Regs. tit. 8, §§ 28 (Determination of Good Moral Character in the Professions); 28-1 (Determination of Good Moral Character for Authorization to Practice the Licensed Profession); 29 (Unprofessional Conduct); 31 (Proceedings Relating to the Unauthorized Practice of the Professions or the Unauthorized Use of a Professional Title).

320 N.Y. Pub. Health Law §§ 2805-d, 2803(1)(g) (statutory cause of action for medical malpractice based on lack of informed consent); N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7, 405.7(a)(1), 405.7(c).

standard of drugs, and investigations of violations of the regulations, *id.* § 6804. It also requires pharmacies to be registered, meeting required elements, and regulates the conduct of pharmacies. *Id.* § 6808. Pharmacies that ship to New York also must be registered. *Id.* § 6808-b. New York also has specific requirements for dispensing and filling prescriptions, *id.* § 6810, along with requirements for certain drugs to be clearly marked or labelled. *Id.* § 6811-a. New York further regulates the standardization of data elements, labelling, dispensing and recording of prescription drugs.[321]

C. FDA has authority to exercise enforcement discretion regarding the mifepristone REMS.

Finally, the FDA has authority to exercise enforcement discretion. *Heckler v. Chaney*, 470 U.S. 821 (1985) (holding that "FDA's decision not to take the enforcement actions […] is […] not subject to judicial review under the APA"); *Hoffmann-LaRoche, Inc. v. Weinberger***,** 425 F. Supp. 890 (D.D.C. 1975) ("the FDA is to be given the administrative flexibility to make regulations and to determine the new drug status of individual drugs or classes of drugs"); *Cook v. Food and Drug Administration,* 733 F.3d 1, 10 (2013) (affirming that FDA may use enforcement discretion for drugs that are made in a registered establishment). *MediNatura, Inc. v. Food & Drug Admin.*, 496 F. Supp. 3d 416, 462 (D.D.C. 2020), *aff'd*, 998 F.3d 931 (D.C. Cir. 2021) (highlighting the importance of FDA having flexibility in enforcement actions). It should exercise that discretion here as to Petitioner states.

When exercising enforcement discretion in the regulation of pharmaceuticals, FDA applies a risk-based approach. FDA considers, among other things, the safety of a drug or class of drugs, the circumstances surrounding its marketing, the regulatory goals of the agency, and agency resources.[322] FDA also considers whether the exercise of enforcement discretion will adversely affect public health, impose undue burdens on consumers, or unnecessarily disrupt the market.[323]

FDA has previously applied its enforcement discretion to the Mifepristone REMS Program when it did not enforce the in-person dispensing requirement during the COVID-19 Public Health Emergency. FDA then found that when the in-person dispensing requirement was not enforced, the rate of adverse events remained the same. On April 12, 2021, the agency stated its intent to exercise enforcement discretion with respect to the in-person dispensing requirement during the COVID-19 public health emergency.[324] The FDA analyzed postmarketing data to determine if there was a difference in adverse events between periods when in-person dispensing

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321 N.Y. Pub. Health Law § 6830; N.Y. Comp. Codes R. & Regs. tit. 8, § 29.7.

322 *See* FDA, *Guidance for FDA Staff and Industry: Marketed Unapproved Drugs — Compliance Policy Guide (Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs)* 2 – 3 (June 2006).

323 *See id.*

324 *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification.

was and was not enforced.[325] Based on this review, the agency concluded that there did not appear to be a difference in adverse events between periods when in-person dispensing was and was not enforced.[326] The exercise of enforcement discretion with respect to the in-person dispensing requirement thus provided FDA the data that confirmed that this REMS element was unnecessary to mitigate the potential for serious adverse events.

Similarly, in November 2021 and November 2022, FDA exercised enforcement discretion with respect to certain Clozapine REMS requirements and collected information to confirm that the REMS requirements were unnecessary.[327] Specifically, FDA applied its enforcement discretion to address patient access issues and ensure continuity of care.[328] Subsequently, FDA concluded that the REMS imposed undue burden on patients and prescribers, and that the REMS program was not needed to ensure the benefits of the drug outweigh the risks.[329] Compared to mifepristone, clozapine bears significantly more safety concerns and involves specialty training to address very specific serious risks directly caused by the drug. Nevertheless, FDA responded quickly and appropriately to provider and patient concerns in exercising its enforcement discretion. FDA now relies on labeling and communication with providers to ensure the drug's safe use, without the burden of the ETASU requirements.

FDA has also exercised enforcement discretion for products regulated by specific states. For example, FDA has recognized the regulatory oversight provided by the New York State Clinical Laboratory Evaluation Program (NYS CLEP). FDA is temporarily exercising enforcement discretion with respect to its final rule on laboratory developed tests (LDTs) and generally not enforcing premarket review requirements when an LDT is "approved, conditionally

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325 FDA Mifepristone Summary Review (Jan. 3, 2023), *supra* note 204.

326 *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (updated Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation#:~:text=The%20January%202023%20modification%20to,Program%20is%20eligible%20for%20certification.

327 *See FDA is Temporarily Exercising Enforcement Discretion with Respect to Certain Clozapine REMS Program Requirements to Ensure Continuity of Care for Patients Taking Clozapine*, FDA, https://www.fda.gov/drugs/drug-safety-and-availability/fda-temporarily-exercising-enforcement-discretion-respect-certain-clozapine-rems-program?_hsenc=p2ANqtz-8jfa0LvjO2Zf1MEnzTux1Hp_dQL7NLc1DziMUNuiPbi0nKqdWZg-afj95gyBjB48f9-e2D (last updated Nov. 2, 2022).

328 *Id*.

329 *Frequently Asked Questions: Clozapine REMS Modification*, FDA, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/frequently-asked-questions-clozapine-rems-modification (last updated Feb. 24, 2025).[330] *Phaseout Policy and Enforcement Discretion Policies: Laboratory Developed Tests FAQs*, FDA, https://www.fda.gov/medical-devices/laboratory-developed-tests-faqs/phaseout-policy-and-enforcement-discretion-policies-laboratory-developed-tests-faqs (last updated Jan. 15, 2025).

approved, or within an approved exemption from full technical documentation by NYS CLEP."[330]

The safety of mifepristone, described above, as well as the considerable protections already in place in Petitioner States, make it an appropriate exercise of enforcement discretion on the part of FDA.

ENVIRONMENTAL IMPACT

The proposed action is exempt from the requirement of an environmental impact statement under 21 C.F.R. § 25.30, 25.31, 25.32, 25.33, or § 25.34 or an environmental assessment under 21 C.F.R. § 25.40.

ECONOMIC IMPACT

Petitioner States will submit an economic impact statement should the Commissioner request such information following review of this petition.

CERTIFICATION

The Petitioner States certify that, to the best of our knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Respectfully,

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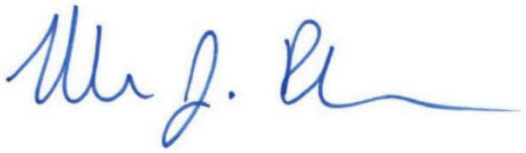

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