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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

No. 1:23-cv-3026-TOR

BRIEF OF AMICI CURIAE MEDICAL AND PUBLIC HEALTH SOCIETIES IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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I. INTERESTS OF *AMICI CURIAE*

Amici curiae are leading medical and public health societies representing physicians, clinicians, and public health professionals who serve patients in Washington and nationwide. Among other organizations, they include the American College of Obstetricians and Gynecologists ("ACOG"), the nation's leading organization of physicians who provide health services unique to people seeking obstetric or gynecologic care; the American Medical Association ("AMA"), the largest professional association of physicians, residents, and medical students in the country; and the Society for Maternal-Fetal Medicine ("SMFM"), the professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies.[1]

Amici believe that all patients are entitled to prompt, complete, and unbiased healthcare that is medically and scientifically sound. Ensuring access to evidence-based healthcare and promoting policy that improves patient health are central to *amici*'s missions. *Amici* submit this brief to explain that mifepristone is exceedingly safe and effective and that the Risk Evaluation and

[1] Additional *amici* are described in the Motion for Leave.

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Mitigation Strategy's ("REMS") restrictions on mifepristone currently in place, described *infra*, are medically unnecessary.

Continuing to unnecessarily restrict access to mifepristone will deprive patients of lifesaving care and set healthcare back by decades. Mifepristone has undergone rigorous testing and review and has been approved for use in the United States for over 20 years. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is understood and access to this critical medication is not unduly restricted.

II. PRELIMINARY STATEMENT

Medication abortion including mifepristone is safe and effective—as evidenced by over two decades of medical studies and vast data collection. The Food & Drug Administration ("FDA") based its initial approval in 2000 on robust evidence that showed mifepristone was extremely safe. The evidence collected and studies performed since then have only confirmed mifepristone's safety. Serious side effects occur in ***less than 1%*** of patients, and major adverse events—significant infection, blood loss, or hospitalization—occur in ***less than 0.3%*** of patients. The risk of death is almost non-existent. Medication abortion also offers advantages over

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procedural abortion because it is less invasive and more accessible, particularly to underserved patient populations.

Mifepristone is also frequently used for the safe and effective management of miscarriage, which can be dangerous and life threatening if left untreated. Recent research has shown that use of mifepristone, in conjunction with misoprostol, improves safety outcomes for patients experiencing pregnancy loss who are treated through medication abortion.

While some progress has been made to increase mifepristone's availability, the FDA continues to limit its accessibility through the REMS without justification. The REMS includes: (1) provider-certification restrictions, mandating that providers be specially certified to prescribe mifepristone; (2) authorization forms requiring the patient to recognize they are "end[ing]" their pregnancy by taking mifepristone; and (3) regulations requiring special pharmacy certification. REMS programs do not apply by default and are used only where necessary to keep patients safe—circumstances not present here. The REMS at issue is only a barrier to access and does nothing to protect patients given mifepristone's proven safety. The relief sought in the Amended Complaint should be granted.

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A. Mifepristone Is Safe and Effective.

The most common method of medication abortion in the United States is a two-drug regimen: mifepristone is taken in conjunction with misoprostol to end an early pregnancy by emptying the contents of the uterus.[2] Mifepristone followed by misoprostol is used both to induce abortion and to manage miscarriage or early pregnancy loss, which can be life threatening.[3]

There is overwhelming scientific evidence supporting mifepristone's safety and efficacy. The REMS creates medically unnecessary burdens for providers and patients seeking abortion or miscarriage management, particularly in areas where care is already limited.

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[2] Mifepristone-misoprostol regimens are more effective than misoprostol-only regimens. ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation*, at 4 (Oct. 2020).

[3] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021).

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1. Mifepristone Has Been Thoroughly Studied and Is Conclusively Safe.

Decades of evidence demonstrate that medication abortion is safe and effective, with exceptionally low rates of major adverse events. Mifepristone's safety profile is on par with, or safer than, over-the-counter painkillers like ibuprofen, which more than 30 million Americans take in any given day.[4] Viagra—which is widely prescribed and *not* subject to a comparable REMS program—carries a substantially higher risk of death than mifepristone.[5]

The FDA first approved the use of mifepristone over 20 years ago after determining, based on extensive clinical trials and sound research, that mifepristone is safe, effective, and that the health benefits outweighed the known risks.[6] In the decades since, hundreds of systemic reviews, trials, and

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[4] *See* R. Morgan Griffin, *Making the Decision on NSAIDs*, WEBMD (Oct. 17 2005), https://www.webmd.com/arthritis/features/making-decision-on-nsaids.

[5] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA 590, 590–93 (Feb. 2, 2000).

[6] *See* 2000 FDA Approval Memo, Compl. Ex. D, ECF No. 1-5; Development & Approval Process: Drugs, FDA (Aug. 8, 2008).

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observational studies have confirmed the safety and effectiveness of mifepristone up to the 10-week gestational period.[7] As a result, medication abortion is a commonly preferred form of abortion care,[8] accounting for most abortions in the U.S. as of 2020,[9] while maintaining an exceptionally low rate of complications.

Studies have repeatedly concluded that even minor complications arising from medication abortion are rare—yet the REMS inexplicably remains in place without compelling medical justification.[10] Major adverse

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[7] *See* 2016 FDA Mifeprex Summary Review, Compl. Ex. J, ECF No. 1-11, at 6; ACOG Practice Bulletin No. 225, *supra* note 2.

[8] *See* ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 6/30/2021*, UNIV. OF CAL., S.F. 1, 1–3 (Nov. 2022).

[9] *See* Rachel Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Dec. 21, 2022).

[10] *See* Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States*, NAT'L ACADS. PRESS 45, 58 (2018); Dina

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events—which include hospitalization and serious infection or bleeding—are "exceedingly rare," occurring in approximately 0.3% of cases.[11] Studies have shown an even smaller number, between 0.014% and 0.07% of patients, experience serious infection.[12] The FDA has made clear that the same

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Abbas et al., *Outpatient Medical Abortion Is Safe and Effective through 70 Days Gestation*, 92 CONTRACEPTION 197 (2015).

[11] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications after Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 175–83 (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)); *see also* Compl. Ex. J, *supra* note 7; FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 56 (Mar. 29, 2016) ("2016 FDA Medical Review"); ANSIRH, *U.S. Studies on Medication Abortion without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. (Oct. 2021); Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 CONTRACEPTION 26, 30 (2013).

[12] 2016 FDA Medical Review, *supra* note 11, at 53–54.

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complications can be observed following a miscarriage, procedural abortion, or medication abortion—i.e., any time a pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections, bleeding, or death] has been established."[13]

The risk of death from medication abortion is near zero.[14] A 2019 analysis of FDA data by the University of San Francisco Medical Center over an 18-year period found only 13 deaths possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00035%.[15] Indeed, there is a greater risk of complications or mortality for procedures like wisdom tooth removals, tonsillectomies, colonoscopies, or from the use of

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[13] Mifeprex Labeling, Compl. Ex. M, ECF No. 1-14 at 2, 5.

[14] *See* Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, 70 CDC MORBIDITY & MORTALITY WKLY. REP. 1, 7, 29 tbl.15 (Nov. 26, 2021); Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998–2010*, 126 OBSTETRICS & GYNECOLOGY 258, 261 (2015).

[15] ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, UNIV. OF CAL., S.F., 1, 1–2 (Apr. 2019).

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Viagra, than by any abortion method (medication or procedural).[16] Studies have associated Viagra with 4.9 deaths per 100,000 prescriptions,[17] demonstrated that death from colonoscopy occurs in about 0.03% of cases,[18] and found that the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[19] Put simply, medication abortion is among the safest medical interventions in any category, related to pregnancy or not.

Accordingly, mifepristone's use has only expanded since its initial approval. It is now used for a variety of other health purposes, including to

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[16] ANSIRH, *Safety of Abortion in the United States*, UNIV. OF CAL., S.F. 1, 1–2 (Dec. 2014); ASGE Standards of Practice Committee, *Complications of Colonoscopy*, 74 AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY 745, 745 (2011).

[17] Mitka, *supra* note 5.

[18] ASGE Standards of Practice Committee, *supra* note 16, at 747.

[19] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216 (2012).

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treat uterine fibroids and endometriosis,[20] to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications,[21] to and treat patients with Cushing's Syndrome.[22]

Mifepristone's safety was evident when it was first approved and has not changed for decades after rigorous and ongoing scientific study, testing, and monitoring of post-market data.[23] There is no compelling medical basis to justify continuing its REMS.

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[20] *See* Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYST. REV. (Aug. 2012); Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, CLIN. & EXP. OBSTETRICS & GYNECOLOGY 350, 350–53 (2016).

[21] *See, e.g.*, Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on Coagulation Function*, 13 INT. J. CLIN. EXP. MED. 2234, 2234–40 (2020).

[22] *See* Farah H. Morgan & Marc J. Laufgraben, *Mifepristone for Management of Cushing's Syndrome*, 33 PHARMACOTHERAPHY 319, 319–29 (2013).

[23] *See* 2016 FDA Medical Review, *supra* note 11, at 8.

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2. Medication Abortion Offers Comparative Benefits Against Other Forms of Abortion.

Procedural abortion (sometimes referred to as a "surgical abortion," though it does not involve "surgery" as that term is generally understood) is not an adequate substitute for medication abortion. While both methods are exceedingly safe, procedural abortion and medication abortion are not equivalent in terms of patient care—procedural abortion can be intrusive in a way that medication abortion is not. In *amici*'s experience, patients choose medication over procedural abortion for many reasons, including a desire to avoid physical contact or the distress of having instruments inserted into the vagina due to prior sexual assault or trauma; a desire to be able to have the abortion in the company of loved ones; or simply a desire for privacy. Patients experiencing miscarriage may choose a mifepristone-misoprostol regimen for the same reasons, rather than an in-clinic procedure.

Additionally, medication abortion may be the only option reasonably accessible to patients given the lack of available reproductive care and restrictions many states have imposed or seek to impose on procedural abortion. This is especially true for patients who are from historically marginalized populations, are low income, or are living in rural areas that are

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long distances from medical facilities or otherwise lack trained clinicians.[24] Even when medical facilities are reasonably accessible to patients, a significant number that provide abortion care offer only medication abortion.[25] For patients with certain medical conditions, disabilities, or other extenuating circumstances (such as a lack of access to child care or the inability to take time off work or travel long distances), medication abortion is the safest and most accessible option. Unnecessarily restricting access to mifepristone through the REMS only exacerbates these issues—without reason—for the most vulnerable populations.

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[24] *See* March of Dimes, *Maternity Care Deserts Report* (Oct. 2022), https://www.marchofdimes.org/maternity-care-deserts-report; Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. C. EMERGENCY PHYSICIANS OPEN e12549 (2021); Anthony Mazzeo et al., *Delivery of Emergency Care in Rural Settings,* ACEP EMERGENCY MEDICINE PRAC. COMM. (July 2017).

[25] *See* Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017–2021*, ANSIRH, UNIV. OF CAL., S.F. (2022).

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B. Restricting Mifepristone Access without Justification Harms Patients.

Unnecessarily restricting access to mifepristone has profound impacts on patients, providers, and our healthcare system on a macro-level in ways that are both related and unrelated to abortion.

For instance, mifepristone is frequently used in the management of miscarriages. Worldwide, one in six recognized pregnancies ends in miscarriage,[26] and when accounting for unrecognized pregnancies (e.g., where the patient is not aware they are pregnant), that number rises to 25%.[27] Without proper care and intervention when needed, miscarriage carries risks of

[26] Siobhan Quenby et al., *Miscarriage Matters: The Epidemiological, Physical, Psychological, and Economic Costs of Early Pregnancy Loss*, 397 LANCET 1658, 1658–67 (2021).

[27] Xiaobin Wang et al., *Conception, Early Pregnancy Loss, and Time to Clinical Pregnancy: A Population-Based Prospective Study*, 79 FERTILITY & STERILITY 577, 577–84 (2003).

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hemorrhage, sepsis, and death.[28] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage.[29] Restricting the use and availability of mifepristone for miscarriage management deprives patients, including a disproportionate amount of patients of color, of the ability to receive prompt, effective, and critical medical care.

The same is true for induced medication abortions. Abortion care can be lifesaving, especially for people suffering from serious health conditions or complications related to pregnancy. Medication abortion's relative availability makes it more accessible to patients who otherwise face challenges accessing medical care, including low-income patients, rural patients, and patients of color[30]—the very people who are most likely to experience

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[28] Robin R. Wallace et al., *Counseling Women with Early Pregnancy Failure: Utilizing Evidence, Preserving Preference*, 81 PATIENT ED. & COUNSELING 454, 454–61 (2010).

[29] *See* Benson et al., *supra* note 24.

[30] *See* Christine Dehlendorf & Tracy Weitz, *Access to Abortion Services: A Neglected Health Disparity*, 22 J. HEALTH CARE FOR THE POOR & UNDERSERVED 415, 418 (2011); Rachel Jones et al., *COVID-19 Abortion Bans*

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maternal morbidity and more likely to die from pregnancy-related complications.[31]

Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying preexisting conditions and can severely compromise health, sometimes permanently.[32] Pregnancy, particularly when coupled with a preexisting condition, can

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and Their Implications for Public Health, 52 PERSPS. ON SEXUAL AND REPROD. HEALTH 65, 66–67 (2020); Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, GUTTMACHER INST. (May 2016); Ctr. for Medicare & Medicaid Serv., *CMS Rural Health Strategy*, at 2 (2018).

[31] *See* Ctr. for Medicare & Medicaid Serv., *Advancing Rural Maternal Health Equity*, at 1 (2022); Juanita Chinn et al., *Health Equity among Black Women in the United States*, 30 J. WOMEN'S HEALTH 212, 215 (2021).

[32] *See, e.g.*, ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017); Alison G. Cahill et al., *Obstetric Care Consensus: Placenta Accreta Spectrum*, 132 OBSTETRICS & GYNECOLOGY e259 (2018).

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quickly evolve into a life-threatening situation necessitating critical care, including abortion. This phenomenon is particularly apparent in the U.S., which has the highest maternal mortality rate among developed countries, with rates increasing the most for Black and Hispanic patients.[33]

The harms of unnecessarily restricting mifepristone access disproportionately impact these underserved patient populations. For instance, though people of all races and ethnicities take mifepristone for miscarriage management, Black patients are more likely to need such care. Miscarriage is more common among groups impacted by social inequities, such as pregnant people who are Black, poor, or exposed to environmental pollutants.[34] Black patients are also at an increased risk of experiencing major depression

[33] Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, COMMONWEALTH FUND (Nov. 18, 2020).

[34] *See generally* Quenby et al., *supra* note 26.

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following a miscarriage,[35] the negative outcomes for which are mitigated by providers who empower patient autonomy by offering management strategies, like mifepristone, that are safe and effective. Restricting mifepristone imposes unnecessary burdens on access to essential reproductive healthcare, particularly for the country's most vulnerable patient populations.

C. The REMS at Issue Harms Patients.

The REMS harms patients by imposing logistical and administrative hurdles to health care without any compelling reason. First, the Patient Agreement Form is medically unnecessary and duplicative of informed consent. Such forms are particularly burdensome when compared to protocols for alternative, less-preferred forms of miscarriage management—i.e., misoprostol-alone management—which have a similar safety profile but do *not* require patients to sign any form. Patients are, confusingly, required to jump through this additional, repetitive, and unnecessary administrative hurdle to receive the same treatment via a more effective regimen (involving

[35] *See* Jade Shorter et al., *Racial Disparities in Mental Health Outcomes Among Women with Early Pregnancy Loss*, 137 OBSTETRICS & GYNECOLOGY 156 (2021).

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mifepristone). At minimum, any mandatory forms should be amended to be tailored to the specific medical needs of the patient. The present form requires patients to attest that they "have decided to take mifepristone and misoprostol to *end* [their] pregnancy,"[36] which is not accurate in all circumstances. During miscarriage, pregnancy loss is already in process or has already occurred in many cases. Requiring miscarriage patients to attest to terminating a pregnancy is confusing, at best, and harmful, at worst, due to the prevalence of abortion stigma.[37] It could also put patients who seek miscarriage care in jurisdictions hostile to reproductive care and abortion access in legal jeopardy.

Second, the clinician "Certified Provider Requirement" does not meaningfully benefit patients. Clinicians who commonly provide early pregnancy care, such as emergency medicine specialists, obstetrician-gynecologists, family physicians, women's health nurse practitioners, and

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[36] *See* Mifepristone Patient Agreement Form, Compl. Ex. Q, ECF No. 1-18 (emphasis added).

[37] *See generally* Alison Norris et al., *Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences*, 21 WOMEN'S HEALTH ISSUES S49 (2011).

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certified nurse midwives are already trained in pregnancy dating, ectopic risk factors, and general care, rendering the additional certification redundant and unnecessary. This requirement does nothing to improve care, creating yet another administrative burden discouraging clinicians from using mifepristone and complicating their ability to do so.[38] Clinicians may also be wary of undergoing the mifepristone certification process due to the stigma and potential legal ramifications associated with providing abortions and the violence and harassment they risk as a result,[39] even if those clinicians prescribe mifepristone solely for miscarriage management.[40] It is not surprising that providers have described the REMS as a barrier to integrating

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[38] *See* Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 644 (2022).

[39] *See id.*; *see also* 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 (2021).

[40] *See* Donley, *supra* note 38.

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mifepristone in their practice,[41] whether for induced abortion, miscarriage, or other treatments.

Finally, *amici* expect that the "Pharmacy Certification" requirement is harmful for the same reasons as provider certification requirements. Pharmacies are already well-equipped to dispense mifepristone without special certification.[42] Certification will force retail pharmacies to make business decisions weighing the value of distributing mifepristone against the risks—including potential unfounded litigation from anti-abortion groups and unwanted public attention, protests, or boycotts for that same reason.[43] For example, national pharmacy chain Walgreens has already indicated that it will not seek certification, and other large retail pharmacies may follow suit (again,

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[41] *See*, *e.g.*, Calloway et al., *supra* note 39; 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 (2022).

[42] *Cf.* Daniel Grossman et al., *Medication abortion with pharmacist dispensing of mifepristone*, 137 OBSTETRICS & GYNECOLOGY 613 (2021).

[43] *See* Donley, *supra* note 38, at 646.

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with rural patients feeling the heaviest impact).[44] Given that the misoprostol-only alternative can be accessed at *any* pharmacy regardless of certification status, this certification requirement actually incentivizes pharmacies to carry the *less preferred* regimen that offers no safety benefit to patients. Pharmacies that do not seek certification (after weighing the considerations above) will be unable to provide their customers the more effective regimen for medication abortion and will be limited in the types of miscarriage management they can offer—ultimately harming patients by restricting the availability of a safe medication.

In sum, eliminating the REMS expands access to a safe and effective drug with virtually no other impact. Removing unnecessary barriers to access this safe, effective, and commonly-used drug will only serve to help patients and the providers who care for them in the long term.

III. CONCLUSION

For these reasons and those articulated in Plaintiffs' Brief, we strongly urge the Court to grant the relief sought in the Amended Complaint.

[44] *Cf. id.* at 665.

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DATED this 24th day of March 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receives CM/ECF notification.

DATED this 24th day of March, 2023.

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