IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH OF THE TWIN CITIES, LLC, on behalf of itself, its staff, and its patients; BLUE MOUNTAIN CLINIC, on behalf of itself, its staff, and its patients; HELEN WEEMS, APRN-FNP on behalf of herself and her patients; ALL FAMILIES HEALTHCARE, on behalf of itself, its staff, and its patients; and TRUST WOMEN FOUNDATION, on behalf of itself, its staff, and its patients, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, Defendants.	Case No. 3:23-cv-00019-NKM

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

PRELIMINARY STATEMENT

Plaintiffs Whole Woman's Health Alliance, Whole Woman's Health, Whole Woman's Health of the Twin Cities, LLC, Blue Mountain Clinic, Helen Weems, All Families Healthcare, and Trust Women Foundation ("Plaintiffs") are abortion providers respectively operating in Virginia, Montana, and Kansas, where abortion remains legal notwithstanding the reversal of *Roe v. Wade*. In this case, Plaintiffs ask the Court to lift the unjustified cloud of fear and apprehension over mifepristone—one of two drugs used in the most common protocol for medication abortion in the United States—created and perpetuated by the U.S. Food and Drug Administration ("FDA") and exploited by anti-abortion politicians and activists. FDA's imposition of a "Risk Evaluation and Mitigation Strategy" in January 2023 (the "2023 REMS") for mifepristone exceeds FDA's statutory authority, is arbitrary and capricious, and contrary to the Constitution. Compl. ¶¶ 144–58. The medically baseless REMS harms patients and providers by imposing unnecessary restrictions on mifepristone. At the same time, anti-abortion activists have weaponized both the 2023 REMS and prior REMS against abortion providers around the country.

This motion for a preliminary injunction seeks to protect Plaintiffs' continued ability to prescribe and dispense mifepristone to their patients during the pendency of this litigation. Such relief is needed because a host of threats have encircled the provision of medication abortion, including pending federal litigations to which Plaintiffs are not party, *Alliance for Hippocratic Medicine v. FDA*, No. 2:22-CV-00223-Z (N.D. Tex.) (the "*Alliance* Case"), and *State of Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash.) (the "*Washington* Case"), along with a new citizen petition to FDA seeking to have mifepristone's approval revoked.[1]

[1] Alice Miranda Ollstein, *Anti-Abortion Group Launches New Pill Challenge as SCOTUS Mulls Sweeping Restrictions*, Politico (Apr. 20, 2023, 9:48 A.M.), https://www.politico.com/news/2023/04/19/students-for-life-abortion-scotus-00092771.

On April 7, 2023, a federal district court judge in Amarillo, Texas (a state that has already banned abortion)[2] effectively ordered mifepristone off the market by purporting to stay FDA's regulatory actions approving the drug on the spurious ground that FDA had not adequately considered mifepristone's safety and efficacy. *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-00223-Z, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023). Five days later, on applications for an emergency stay pending appeal, the United States Court of Appeals for the Fifth Circuit stayed the *Alliance* Case injunction with respect to FDA's initial approval of mifepristone in 2000, but not with respect to its actions regarding mifepristone from 2016 through 2023, purporting to reinstate the REMS in effect prior to 2016. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *1, *17, *21 (5th Cir. Apr. 12, 2023) (per curiam). Although the Supreme Court entered a preliminary stay that averts some of the devastating harms that were about to occur due to the trial court decision in the *Alliance* Case, *see Danco Lab'ys, LLC v. All. for Hippocratic Med.*, No. 22A901, 2023 WL 3033177 (U.S. Apr. 21, 2023) (mem.), threats to mifepristone continue to proliferate—prompting a growing number of states to stockpile large amounts of mifepristone even after the Supreme Court's stay.[3]

[2] Caroline Kitchener & Ann E. Marimow, *The Texas Judge Who Could Take Down The Abortion Pill*, Wash. Post (Feb. 25, 2023, 6:00 A.M.), https://www.washingtonpost.com/politics/2023/02/25/texas-judge-abortion-pill-decision ("The lead plaintiff in the . . . case, the Alliance for Hippocratic Medicine, incorporated in Texas—with a 'registered agent' in Amarillo—several months before the lawsuit was filed. While the group's website does not include any location or contact information, records filed with the Texas secretary of state's office show that the group's mailing address is in Tennessee.").

[3] *See, e.g.*, Reis Thebault et al., *Democratic States Stockpile Abortion Pills as Access Rests in Courts*, Wash. Post (Apr. 21, 2023), https://www.washingtonpost.com/nation/2023/04/21/blue-state-abortion-pill-access (describing six states, representing a quarter of the U.S. population, that "have publicly pledged to stockpile abortion drugs"); Jen Christensen, *Concerned About the Courts, Some States and Universities are Stockpiling Abortion Drugs*, CNN (Apr. 12, 2023, 5:49 P.M.), https://www.cnn.com/2023/04/12/health/abortion-drugs-stockpile/index.html (University of Massachusetts and University of Washington stockpiling mifepristone; New York and California stockpiling misoprostol).

Plaintiffs—independent abortion providers doing all they can to care for an ever-increasing number of patients in the post-*Roe* world—are caught in the middle. The preliminary injunction and ensuing orders in the *Alliance* Case unleashed chaos and confusion at Plaintiffs' clinics. Plaintiffs expended significant resources preparing their practices for the possibility that they would be unable to offer mifepristone entirely. Declaration of Rebecca Tong, attached as Exhibit 1 ("Tong Decl.") ¶ 24; Declaration of Nicole Smith, PhD, MPH, attached as Exhibit 2 ("Smith Decl.") ¶ 23; Declaration of Helen Weems, MSP, APRN-FNP, attached as Exhibit 3 ("Weems Decl.") ¶ 19; Declaration of Amy Hagstrom-Miller, attached as Exhibit 4 ("Hagstrom-Miller Decl.") ¶¶ 28, 30. Then, days later, they had to pivot to determining how to provide medication abortion as if it were 2015 and the outdated restrictions imposed under a prior REMS were still in place. Tong Decl. ¶ 27; Smith Decl. ¶ 24; Weems Decl. ¶ 19; Hagstrom-Miller Decl. ¶ 29. Further, they were unsure about whether they could use the generic mifepristone approved in 2019. Tong Decl. ¶¶ 27–28; Smith Decl. ¶ 24; Weems Decl. ¶ 19.

Although the Supreme Court's stay maintains the status quo for the time being, Plaintiffs remain vulnerable to repetition of the same chaotic scenario. The pending appeal in the Fifth Circuit will be argued on May 17, 2023, and the stay remains through the Fifth Circuit decision and a petition for certiorari that may or may not be filed—neither of which Plaintiffs can control. Further, as the case proceeds, new orders could arise not subject to the stay, and, taking past as prologue, any appeals of those orders would once again thrust abortion providers and their patients into the same chaos and uncertainty.[4]

[4] *See, e.g.*, Christine Fernando & Jeanine Santucci, *Dueling Federal Rulings Plunge Future of Abortion Pill into Legal Uncertainty*, USA Today (Apr. 8, 2023, 2:32 P.M.), https://www.usatoday.com/story/news/nation/2023/04/07/judge-revokes-fda-approval-key-abortion-drug-nationwide/11203402002 (describing providers' rush to shift to misoprostol-only protocols due to legal uncertainty); C.A. Bridges, *What is Mifepristone? Are Abortion Pills Legal in Florida?*, Gainesville Sun (Apr. 17, 2023, 2:22 P.M.), https://www.gainesville.com/story/news/healthcare/2023/04/14/abortion-pills-florida-mifepristone-misoprostol-what-they-are-how-get-them/7766021001 (describing confusion as "patients

Not all abortion providers in the states where abortion remains legal are exposed to the same risks and uncertainty that Plaintiffs face. In the *Washington* Case, the district court issued an order that maintains the status quo for abortion providers in 17 states and the District of Columbia, all of which protect access to abortion as an essential part of reproductive healthcare.[5] That lawsuit challenges the same 2023 REMS at issue here. There, the district court held that the plaintiff states had raised "serious issues going to the merits of" their challenge to the 2023 REMS. *Washington v. FDA*, No. 1:23-CV-03026-TOR, 2023 WL 2825861, at *8 (E.D. Wash. Apr. 7, 2023). The district court enjoined FDA from altering the status quo on mifepristone's availability in the plaintiff states "irrespective of" the rulings in the *Alliance* Case. *Washington v. FDA*, No. 1:23-CV-03026-TOR, 2023 WL 2941567, at *2 (E.D. Wash. Apr. 13, 2023). The injunction in the *Washington* Case, however, does not protect Plaintiffs here from the devastating consequences of any rulings in the *Alliance* Case or others because the states of Virginia, Montana, and Kansas are not parties to it—indeed, the Attorney General of Montana unsuccessfully sought to intervene to *oppose* the relief sought, *see Washington v. FDA*, No. 1:23-CV-03026-TOR, 2023 WL 3035380, at *3 (E.D. Wash. Apr. 21, 2023)—and the district court declined to issue a nationwide injunction, *Washington*, 2023 WL 2825861, at *10.

Plaintiffs ask this Court to halt this uncertainty by enjoining FDA from deviating from the status quo in the states in which they provide care. Plaintiffs ask for the same relief as was granted to Washington State and its co-plaintiff States: maintenance of the status quo so their continued

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and providers try to understand the new and shifting laws, lawsuits and court rulings"); Jan Johnson & Michael Martin, *Supreme Court Ruling on Mifepristone Causes Uncertainty for Advocates*, NPR (Apr. 21, 2023, 11:30 A.M.), https://www.npr.org/2023/04/21/1171202676/abortion-pill-supreme-court (citing Michigan provider saying that "conflicting legal rulings and the wait for answers is complicating care and making it difficult to help patients").

[5] Plaintiffs in the *Washington* Case are the states of Washington, Arizona, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, Oregon, Pennsylvania, Rhode Island, Vermont, and the District of Columbia.

provision of mifepristone is not repeatedly under threat while their challenge to the REMS proceeds.

Plaintiffs' application satisfies all of the required elements for preliminary relief: they are likely to prevail on the merits (as the district court held in the *Washington* Case); they and their patients would be irreparably injured if their ability to prescribe and dispense mifepristone were proscribed or constrained during the pendency of this litigation; and the public interest favors equal treatment under federal law for providers and patients who work and live in states where abortion, including medication abortion, is legal. Indeed, equity requires this result; otherwise, Plaintiffs and their patients will be gravely prejudiced merely because they happen to work or reside in states where medication abortion is legal, but whose state officials nonetheless opted not to protect their interests by joining the *Washington* Case as plaintiffs.

STATEMENT OF FACTS

A. The Plaintiff Providers

Plaintiffs are independent abortion providers who provide care in Virginia, Montana, and Kansas. Each brings this case on behalf of themselves, their providers, and their patients. All Plaintiffs provide medication abortion using the FDA-approved regimen of mifepristone followed by misoprostol. They use both Danco's Mifeprex and Genbiopro's generic mifepristone, which was approved in 2019. Compl. ¶ 60; Smith Decl. ¶ 23; Weems Decl. ¶ 19; Tong Decl. ¶¶ 27–28. Plaintiffs' continued prescription of medication abortion under the status quo is essential to their patients. If Plaintiffs and their clinicians are unable to prescribe mifepristone, or if they must prescribe mifepristone with outdated restrictions, their patients will be delayed in obtaining or outright denied access to medication abortion with mifepristone or abortion generally.

Whole Woman's Health. Whole Woman's Health Alliance is a nonprofit organization committed to providing holistic reproductive care for its patients that operates Whole Woman's

Health of Charlottesville ("WWH of Charlottesville"), which has provided medication abortion since 2017. Whole Woman's Health also operates Whole Woman's Health of Alexandria ("WWH of Alexandria"), a licensed healthcare facility in Alexandria, Virginia, which currently has a nurse practitioner on staff who provides medication abortion to patients in-clinic. And, since August 2021, Plaintiff Whole Woman's Health of the Twin Cities, LLC ("WWH of the Twin Cities") has operated a virtual healthcare program that provides telehealth services for medication abortion in Virginia and other states. As part of its telehealth abortion services, WWH of the Twin Cities provides medication abortion by mail ("direct to patient telehealth").

Blue Mountain Clinic. Plaintiff Blue Mountain Clinic ("Blue Mountain") is a family practice in Missoula, Montana. When it opened in 1977, Blue Mountain was the first and only abortion clinic in the state of Montana; its services now include comprehensive family medical care to better serve its community. Blue Mountain's primary physician and two physician assistants provide medication abortion both in person and via direct to patient telehealth to patients with Montana addresses.

All Families Healthcare and Helen Weems. Plaintiff Helen Weems is a nurse practitioner licensed to practice in Montana with over 20 years of clinical experience. She owns and is the only clinician at All Families Healthcare, a sexual and reproductive health clinic located in Whitefish, Montana. All Families provides medication abortion, both in-person and by direct to patient telehealth. Ms. Weems is the clinic's only certified mifepristone prescriber, and the only provider of abortion care in the Flathead Valley.

Trust Women. Trust Women operates clinics in Wichita, Kansas, and Oklahoma City, Oklahoma. In Wichita, Trust Women provides reproductive healthcare, including both procedural and medication abortion. Trust Women has provided medication abortion since it opened its

Wichita clinic in 2013. Trust Women was in the process of organizing a telehealth program that would include direct to patient telehealth when mifepristone's approval came under fire.

B. FDA's Repeated Acknowledgments of Mifepristone's Safety

To date, mifepristone has been used by over 5 million patients in the United States. Under the branded name "Mifeprex," the drug was first approved by FDA in September 2000 for use in a two-drug regimen: administration of mifepristone, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, followed by misoprostol, which causes uterine contractions that expel the pregnancy from the uterus.[6] Shortly after taking the two drugs, a patient experiences bleeding akin to a heavy period or a miscarriage.[7]

FDA's initial approval of mifepristone was the result of a thorough, nearly five-year scientific review that determined mifepristone was safe for use in the United States. Compl. ¶ 43. After over 15 years of widespread use, a multidisciplinary FDA review team conducted a medical review based on the 2.5 million uses of Mifeprex for medication abortion in the U.S. that had occurred since the drug's 2000 approval. Its 2016 report concluded that "[Mifeprex] has been increasingly used as its efficacy and safety have become well established by both research and experience, and serious complications have proven to be extremely rare," and "that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely."[8] FDA has

[6] U.S. Food & Drug Admin., NDA 20-687 Mifeprex Approval Memo, Sept. 28, 2000, Compl. Ex. A.

[7] *See* U.S. Gov't Accountability Office, GAO-08-751, Food and Drug Administration Approval and Oversight of the Drug Mifeprex (2008), https://www.gao.gov/assets/gao-08-751.pdf (hereinafter FDA Approval and Oversight of Mifeprex), Compl. Ex. B.

[8] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Medical Review(s) 8, 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (hereinafter FDA 2016 Medical Review), Compl. Ex. E; *see also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Full Prescribing Information for Mifeprex 7–8, tbls.1 & 2 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf ("Mifeprex Labeling"), Compl. Ex. F.

further stated: "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[9] Still further, "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low."[10]

The FDA's 2016 review also concluded that the risk of death from mifepristone is near zero. The FDA review reflected that there are only 13 recorded deaths even possibly related to medication abortion—roughly 0.00000232%. The other deaths were included in the adverse events summary "regardless of causal attribution to mifepristone" and included cases of homicide and drug overdose.[11] FDA further noted that, as to rare, serious infections following use, "the critical risk factor" is not mifepristone but "pregnancy itself," as the very same complications can arise during a miscarriage or procedural abortion.[12] FDA found that mifepristone was just as safe when administered by an advanced practice clinician ("APC") as it was when administered by a physician, pointing to five studies demonstrating that "efficacy is the same with non-physician providers compared to physicians."[13]

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[9] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): REMS Modification Memorandum 3 (Mar. 29, 2016) (hereinafter 2016 REMS Modification Memorandum), Compl. Ex. G.

[10] Compl. Ex. E (FDA 2016 Medical Review) at 47.

[11] U.S. Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, at 1, https://www.fda.gov/media/164331/download (hereinafter Mifepristone U.S. Post-Marketing Adverse Events Summary), Compl. Ex. I.

[12] U.S. Food & Drug Admin., FDA-2002-P-0364-0002, Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Donna Harrison, Exec. Dir., Am. Assoc. of Pro Life Obstetricians & Gynecologists, Gene Rudd, Senior Vice President, Christian Med. & Dental Ass'n, and Penny Young Nance, CEO and President, Concerned Women for Am., denying Citizen Petition, Docket No. FDA-2002-P0364, at 25 n.69 (Mar. 29, 2016) (hereinafter Citizen Petition Denial), Compl. Ex. D.

[13] Compl. Ex. E (FDA 2016 Medical Review) at 43.

Leading scientific and medical organizations also recognize mifepristone's safety. In 2018, the National Academies of Sciences, Engineering, and Medicine ("National Academies"), a universally respected non-partisan advisory institution, reviewed all available scientific research and concluded that the risks of medication abortion are "similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications," such as "antibiotics and NSAIDS"[14] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications that millions of people take daily.[15]

In 2019, relying on the data supporting Mifeprex, FDA approved an abbreviated new drug application for a generic version of mifepristone produced by GenBioPro.

C. FDA's Promulgation of the Medically Unnecessary and Harmful REMS

Notwithstanding the mountains of evidence demonstrating mifepristone's safety, and its own repeated conclusions about mifepristone, FDA has mystifyingly persisted in subjecting the drug to uniquely burdensome restrictions.

FDA may impose a "Risk Evaluation and Mitigation Strategy" ("REMS") as a condition to approval, but only when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). The most burdensome form of REMS is "Elements to Assure Safe Use" ("ETASU"), which FDA may impose if medically necessary due to a drug's "inherent toxicity or potential harmfulness." *Id*. § 355-1(f)(1). By statute, REMS with ETASU is only appropriate for drugs with serious side effects such as death, incapacity, or birth defects, and even then, only where that risk is so severe that approval could not be granted without the restriction.

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[14] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 56, 79 (2018) (hereinafter National Academies Report), http://nap.edu/24950.

[15] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, 41 U.S. Pharmacist 24 (Mar. 2016), http://bit.ly/3YLbw3x.

Id. §§ 355-1(b)(4), (f)(1)(A). Among the 20,000 prescription drug products approved by FDA, there are only 60 REMS programs, 56 of which include ETASU. Compl. ¶ 82.

Currently, FDA continues to impose the REMS with the following ETASU on mifepristone, none of which accord with FDA's determinations about mifepristone's safety and efficacy:

- **A Prescriber Certification requirement,** requiring clinicians who prescribe mifepristone to attest to their clinical abilities in a signed form kept on file by the manufacturer, and to agree to comply with reporting and other REMS requirements. Under the prior REMS, only physicians could be certified as mifepristone prescribers, although APCs (nurse practitioners, nurse midwives, and physician assistants) could dispense mifepristone under the supervision of a physician. Compl. ¶ 83.
- **A Patient Agreement requirement,** mandating that the prescriber and patient review and sign a special form with information about the mifepristone regimen and risks, and requiring the prescriber to provide the patient with a copy and place a copy in the patient's medical record. *Id.*
- **A Pharmacy Certification requirement,** mandating that pharmacies wishing to dispense mifepristone be "specially certified" by the manufacturer. This requirement took effect in January 2023, when FDA ended the in-person dispensing requirement and first allowed retail pharmacies to dispense mifepristone. *Id.*

FDA's continued adherence to these restrictions has no justification. In 2016, preeminent reproductive health, rights, and justice organizations, including the Society of Family Planning ("SFP"), urged FDA to lift the REMS in their entirety, arguing that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the

drug."[16] The organizations emphasized that: "[e]xtensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients.[17]

Specifically as to the ETASU that remain in place today, the organizations pressed FDA to "[e]liminate the Prescriber Agreement certification requirement," because it was not necessary for the safe distribution of mifepristone—especially considering the "many laws, policies, and ordinary standards of care" to which health professionals and drugs are already subject.[18] With respect to the "confusing and unnecessary" Patient Agreement Form, the organizations urged that it was "medically unnecessary and interferes with the clinician-patient relationship."[19] An internal FDA review concurred with this assessment, and unanimously recommended eliminating the Patient Agreement Form because it "contains duplicative information already provided by each healthcare provider or clinic," "does not add to safe use conditions," and "is a burden for patients."[20] Nonetheless, in 2016 FDA retained the Patient Agreement Form, overruling the internal recommendation of its own staff for no apparent reason.[21]

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[16] Letter from Soc'y of Fam. Plan. et al., to Stephen Ostroff, Acting Comm'r of Food & Drugs, Robert M. Califf, Deputy Comm'r for Med. Prods. & Tobacco & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin. 5 (Feb. 4, 2016) (hereinafter SFP Letter to FDA), Compl. Ex. K.

[17] *Id.* at 6.

[18] *Id.* at 3.

[19] *Id.* at 4.

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

[21] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Re: NDA 020687, Supp 20, at 1 (Mar. 28, 2016) (hereinafter "Woodcock Patient Agreement Memo"), Compl. Ex. L.

Considering FDA's repeated, and eminently correct, recognition of mifepristone's safety and efficacy, and the conclusion that it could be made more accessible without sacrificing safety or efficacy, FDA has relaxed *some* of the REMS over the years. In 2016, it expanded the types of healthcare providers who could be certified prescribers to include APCs, including nurse practitioners, nurse midwives, and physician assistants.[22] Restricting APCs from prescribing mifepristone limits access to abortion, especially in rural and underserved areas.[23] FDA concluded that extensive evidence and experience demonstrate that APCs provide medication and aspiration abortion with the same safety, efficacy, and patient satisfaction as their physician counterparts.[24]

In addition, FDA has removed the in-person dispensing requirement, paving the way for access to mifepristone via direct to patient telehealth and in brick-and-mortar pharmacies. In July 2020, a court ordered FDA to suspend the in-person dispensing requirement for mifepristone due to the constraints on in-person healthcare during the COVID-19 pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.). In April 2021, FDA itself suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-person dispensing requirement had been enjoined, the availability of direct to patient telehealth showed no increases in serious

[22] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex REMS (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf (hereinafter 2016 REMS).

[23] *See* National Academies Report, *supra* n.14, at 114–19.

[24] Compl. Ex. E (FDA 2016 Medical Review) at 78–80; *see also* National Academies Report, *supra* n.14, at 103–05; Tracy A. Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am. J. Pub. Health 454 (Mar. 2013).

patient safety concerns.[25] In January 2023, FDA permanently removed the in-person dispensing requirement, enabling patients to access medication abortion by mail and opening the door for brick-and-mortar pharmacies to dispense mifepristone.[26] However, without basis, FDA imposed a new mandate that pharmacies, like prescribers, be "certified." FDA refused to remove the requirements mandating the unnecessary agreements.[27]

The imposition of the REMS has influenced and emboldened anti-abortion actors who leverage FDA's history of overregulation against providers and patients. For example, the Montana Legislature enacted a statute in 2021 that prohibited telehealth medication abortion, identifying the REMS as evidence of FDA's view that mifepristone is dangerous. The Legislature referred to FDA's use of the "only FDA approval process that allows for postmarketing restrictions" and the resulting restrictions to justify medically unnecessary barriers to accessing mifepristone. H.B. 171, 67th Leg., 1st Reg. Sess. (Mont. 2021). And, ongoing litigation continuously threatens to reinstate restrictions FDA removed; specifically, requiring in-person dispensing and restricting certified prescribers to physicians only. The Fifth Circuit's April 12 modified order would have done precisely that. Although widely reported as a compromise, that order was no such thing. It would have propelled providers and patients backward years and deprived them of significant service-delivery advancements—eliminating highly qualified and much needed providers as certified

[25] Letter from Janet Woodcock, Acting Comm'r, U.S. Food & Drug Admin., to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Of Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) (hereinafter Woodcock Letter), Compl. Ex. J.

[26] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf (hereinafter 2023 REMS).

[27] *See id.*

prescribers and upending direct to patient telehealth, which has dramatically improved access to mifepristone. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *1–2.

In short, despite reimposing the REMS, FDA continuously and correctly concluded in 2016, 2019, 2021, and 2023 that mifepristone is one of the safest drugs available in the United States. And, when the safety of mifepristone was called into question by anti-abortion activists in the *Alliance* Case, FDA vigorously defended its approval of mifepristone by repeatedly emphasizing the proven safety record of mifepristone over the last 23 years, comparing its risk to that of ibuprofen. Emergency Mot. Under Cir. R. 27.3 for a Stay Pending Appeal at 1, 14–15, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023).

D. The Dueling Lawsuits Over Mifepristone

Ensuring medically sound, protected access to mifepristone is more important now than ever, with abortion rapidly becoming criminalized across large swaths of the nation, and with anti-abortion zealots seeking to deprive people *in any state* of access to mifepristone. Such idealogues have been emboldened by years of overregulation of mifepristone, which has culminated in an unprecedented challenge to the decades-old 2000 approval of the drug.

In the *Alliance* Case, filed on November 18, 2022, plaintiffs sought to enjoin FDA's 2000 approval of mifepristone. Relying on long-discredited junk science and purported experts who have been rejected by numerous courts,[28] the district court ordered an unprecedented stay of FDA's longstanding approval of mifepristone. *See All. for Hippocratic Med.*, 2023 WL 2825871, at *32.

[28] *See* Mot. for Leave to File Br. of Over 100 Reprod. Health, Rts. & Just. Orgs. as Amici Curiae in Support of Defs.-Appellants and the Mots. for Stay Pending Appeal at 6–9, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023); Unopposed Mot. for Leave to File Br. of Med. & Pub. Health Soc'ys as Amici Curiae in Support of Defs.-Appellants at 7, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023) (identifying the rejection of plaintiffs' experts by courts and concluding that "[t]he so-called studies on which the District Court relied are not scientifically tested or sound; they are produced by anti-abortion advocacy groups or contain serious (and often well-documented) methodological flaws—or both.").

The court maintained that FDA's 2000 approval of mifepristone ignored "safety concerns," suggesting that the agency acquiesced to "political pressure to forego its proposed safety precautions." *Id*. at *27. Even though the challenged approval has been in effect for over twenty years, with no safety concerns, the court—citing nothing more than plaintiffs' assertions in their brief—declared that medication abortion causes "physical and emotional trauma," "mental and monetary costs," and death. *Id*. at *29.

Rather than stay this erroneous decision in its entirety, on April 12, the Fifth Circuit compounded the problem, staying the decision only in limited part, and reimposing an older version of the REMS from prior to 2016. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *1. The Fifth Circuit stayed only the portion of the district court ruling that suspended FDA's 2000 approval of mifepristone, while declining to stay the district court's holdings essentially enjoining the 2016 and 2023 REMS. *Id*. at *21. On April 21, 2023, the Supreme Court stayed the *Alliance* Case injunction until it either (i) denied a petition for certiorari seeking review of the Fifth Circuit's decision on the merits of the *Alliance* Case injunction or, (ii) if certiorari were granted, issued its own ruling on the merits. *Danco Lab'ys*, 2023 WL 3033177, at *1.

Almost at the same time as the Texas court issued its injunction in the *Alliance* Case, the district court in the *Washington* Case enjoined FDA from deviating from the status quo—the 2023 REMS—concluding that Plaintiffs had a likelihood of success on their challenge to the REMS and faced irreparable injury. *Washington*, 2023 WL 2825861, at *8, *11. The court in the *Washington* Case emphasized that it is "precisely FDA's role" to make safety and efficacy determinations, however, based on the same record Plaintiffs present here, FDA "did not assess whether mifepristone qualifies for REMS and ETASU." *Id.* at *8. It noted FDA's repeated determinations that "[s]erious adverse events . . . are rare" and that mifepristone "is safe and effective through 70

days gestation." *Id.* Citing these factors, along with FDA's inexplicably inconsistent approval of mifepristone used for Cushing's syndrome without a REMS, the court found that FDA appears to have ignored an important aspect of the issue before it when it repeatedly imposed REMS requirements on mifepristone without scientific basis. *Id.*

Providers in states covered by the injunction in the *Washington* Case have the comfort of knowing that FDA cannot change the status quo during the pendency of that case, but Plaintiffs are left out, as are their patients.

E. The Irreparable Injury Caused by Rolling Back the Clock on Mifepristone

Plaintiffs all provide mifepristone as part of the two-drug regimen for medication abortion, and all have done so under multiple burdensome iterations of the REMS. Hagstrom-Miller Decl. ¶¶ 10, 17, 21; Smith Decl. ¶ 12; Weems Decl. ¶ 7; Tong Decl. ¶ 6.

Access to medication abortion with mifepristone is essential for patients. Weems Decl. ¶ 8; Tong Decl. ¶ 23. Decades of research and experience have shown that mifepristone is safe and effective. Hagstrom-Miller Decl. ¶ 45; Smith Decl. ¶ 17; Weems Decl. ¶ 8; Tong Decl. ¶¶ 7, 13, 23. It is also preferable for many patients. Hagstrom-Miller Decl. ¶ 45; Smith Decl. ¶ 34; Weems Decl. ¶ 8; Tong Decl. ¶ 35. Medication abortion is less medicalized, complex, and expensive than procedural abortion. Hagstrom-Miller Decl. ¶ 45; Tong Decl. ¶ 23. It is also medically indicated for some patients with particular conditions like fibroids, obesity, and certain kinds of cervixes. Hagstrom-Miller Decl. ¶ 45. Medication abortion with mifepristone is also more convenient and more private—patients can have an abortion on their own schedule and experience their abortion like a miscarriage. Hagstrom-Miller Decl. ¶ 45; Tong Decl. ¶ 35. The added privacy can be particularly important for certain people, including, for example, individuals experiencing intimate partner violence. Hagstrom-Miller Decl. ¶ 45; Tong Decl. ¶ 35. And, the lack of instrumentation avoids retraumatizing survivors of sexual assault. Hagstrom-Miller Decl. ¶ 45; Tong Decl. ¶ 35.

Although there is another safe and effective method of medication abortion using misoprostol alone, patients and providers have come to rely on mifepristone as a significant innovation in medication abortion care. Tong Decl. ¶ 23. Further, the inability to use mifepristone or the reinstatement of restrictions that would prohibit the use of APCs as certified prescribers and prevent direct to patient telehealth would gravely reduce patient access to medication abortion and to abortion generally. Hagstrom-Miller Decl. ¶¶ 36–43; Smith Decl. ¶¶ 28–33; Weems Decl. ¶¶ 25–36. At a minimum, it is critical to Plaintiffs' patients that the 2023 REMS be maintained while this and other litigation proceeds. Hagstrom-Miller Decl. ¶ 47; Smith Decl. ¶ 34; Weems Decl. ¶ 36; Tong Decl. ¶ 36.

Plaintiffs serve patients from their own states and the many patients traveling from states that have banned abortion, and they rely on mifepristone to do so. Hagstrom-Miller Decl. ¶¶ 10, 12, 17, 19, 22, 42–43; Smith Decl. ¶¶ 7, 9–10, 12; Weems Decl. ¶ 2. Whole Woman's Health's clinics in Charlottesville and Alexandria, and its virtual clinic, collectively provide care to nearly 5,000 patients a year, and most of those patients obtained a medication abortion with mifepristone. Hagstrom-Miller Decl. ¶¶ 10, 12, 17, 19, 21–22. Whole Woman's Health is seeing huge numbers of Texans and other out-of-state residents traveling to Virginia for care. Hagstrom-Miller Decl. ¶¶ 12, 19, 22. Nearly half of the patients who receive direct to patient telehealth from Whole Woman's Health are people traveling from other states. Hagstrom-Miller Decl. ¶ 22. Trust Women Wichita saw 1,500 patients in 2021, half of whom received medication abortion; in 2022, they saw approximately 3,500 patients; and in 2023, they are on pace to care for 6,000 patients. Tong Decl. ¶¶ 19, 35. On some days, Trust Women Wichita receives tens of thousands of calls—a call volume so high they would not be able to meet patient demand even if they operated 24 hours a day, 7 days a week. Tong Decl. ¶ 21. The availability of direct to patient telehealth is an essential option in a

vast, rural state like Montana where many patients must travel long distances and navigate significant logistical burdens to reach an abortion provider. Smith Decl. ¶¶ 10, 28–30. So far, in 2023, the vast majority of abortion care All Families provided was medication abortion using mifepristone, and half of those medication abortions were provided through direct to patient telehealth. Weems Decl. ¶¶ 6–7, 31.

Additionally, Plaintiffs rely on APCs to provide abortion care. Hagstrom-Miller Decl. ¶ 36; Smith Decl. ¶ 31; Weems Decl. ¶ 25. Ms. Weems is the sole clinician, sole certified mifepristone prescriber at All Families, and the only abortion provider in Northwest Montana. Weems Decl. ¶¶ 1–2, 25. Rolling back the clock nearly a decade and requiring compliance with the outdated REMS would mean Ms. Weems could no longer dispense mifepristone as a certified prescriber. The entire region would once again be without a mifepristone provider, and All Families' patients throughout Montana would lose a trusted, qualified provider. Weems Decl. ¶ 25.

In short, to meet the needs of their patients, Plaintiffs rely on the availability of mifepristone, the ability of APCs to prescribe it, and the ability to dispense it by direct to patient telehealth.

The REMS has always harmed patients and providers and been out of line with the extensive evidence that FDA itself has repeatedly concluded shows the safety and efficacy of mifepristone. The retained Prescriber and Patient Agreement and Pharmacy Certification requirements create barriers to entry to providers and pharmacies, compromise patient and provider confidentiality and safety, and sow confusion, especially for people taking mifepristone to manage a miscarriage. Hagstrom-Miller Decl. ¶ 44; Smith Decl. ¶¶ 18–20; Weems Decl. ¶¶ 13–15; Tong Decl. ¶¶ 11–12. At the same time, they are medically unjustified, given mifepristone's documented safety record. Hagstrom-Miller Decl. ¶¶ 44–46; Smith Decl. ¶ 17; Weems Decl. ¶¶

14–15; Tong Decl. ¶¶ 11–13. Further, maintaining the REMS has and will continue to stigmatize medication abortion and be a tool leveraged by anti-abortion activists against providers and patients. Smith Decl. ¶ 17; Weems Decl. ¶¶ 11, 13; Tong Decl. ¶ 12. As one recent study of clinicians and administrators put it: although mifepristone is safe and effective, the REMS is the "linchpin of a cycle of stigmatization that continues to keep mifepristone" out of reach for many.[29]

That "cycle of stigmatization" has come to include a revolving door of legal threats to Plaintiffs' ability to prescribe mifepristone. Throughout the last weeks, to say nothing of the last year, Plaintiffs have faced constant upheaval around whether and how they can prescribe medication abortion—causing massive disruption to their practices with no end in sight. Hagstrom-Miller Decl. ¶¶ 23–35; Smith Decl. ¶¶ 24–25; Weems Decl. ¶¶ 19–22; Tong Decl. ¶¶ 22–36. As healthcare providers, Plaintiffs require clarity around their provision of care, practice, and protocols in order to continue to meet the needs of their patients. Hagstrom-Miller Decl. ¶ 47; Smith Decl. ¶ 27; Weems Decl. ¶ 23; Tong Decl. ¶¶ 10, 31–32.

ARGUMENT

Plaintiffs meet all four requirements for a preliminary injunction because they can show: (1) "a likelihood of success on the merits," (2) "irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in [their] favor," and (4) "that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 236 (4th Cir. 2014). Further, "[t]he traditional office of a preliminary injunction is to protect the status quo and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment

[29] Danielle Calloway, Debra B. Stulberg & Elizabeth Janiak, *Mifepristone Restrictions and Primary Care: Breaking the Cycle of Stigma Through a Learning Collaborative Model in the United States*, 104 Contraception 24 (2021).

on the merits." *United States v. South Carolina*, 720 F.3d 518, 524 (4th Cir. 2013) (citation omitted).

Plaintiffs are facing an onslaught of threats to their provision of mifepristone around the country that are ongoing despite the Supreme Court's stay in the *Alliance* Case. Hagstrom-Miller Decl. ¶¶ 23, 28–33; Tong Decl. ¶¶ 22–32; Smith Decl. ¶¶ 23–25; Weems Decl. ¶¶ 19–21. These threats are part and parcel with FDA's continued imposition of the medically baseless and discriminatory REMS. *See supra* at **Error! Bookmark not defined.**19; Hagstrom-Miller Decl. ¶ 35; Tong Decl. ¶ 14; Smith Decl. ¶ 21. The REMS has always served to stigmatize and single out medication abortion, but now antiabortion activists and hostile enforcers are actively weaponizing the REMS against abortion providers around the country. *See supra* at **Error! Bookmark not defined.**–19; Weems Decl. ¶ 11; Tong Decl. ¶ 12; Smith Decl. ¶ 20. And, unlike abortion providers in the states that are party to the *Washington* Case, Plaintiffs expect day-to-day, week-to-week challenges to arise that will interfere with their prescription of essential medicine that allows them to best serve their patients. *See supra* at 19; Hagstrom-Miller Decl. ¶ 33; Tong Decl. ¶¶ 32, 36; Smith Decl. ¶ 27; Weems Decl. ¶ 21. Plaintiffs have met their burden in seeking a preliminary injunction that forestalls that chaos while this Court makes a determination on the merits of Plaintiffs' claims, by requiring FDA to maintain the status quo of the 2023 REMS in Plaintiffs' states. But, they have also demonstrated that an injunction blocking the imposition of the 2023 REMS is appropriate.

I. Plaintiffs' Claims Are Likely to Succeed on the Merits

This Court should find, as the federal district court in the *Washington* Case has already held based on an identical record, that "FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth in" the Food, Drug, and Cosmetic Act ("FDCA"). *Washington*, 2023 WL 2825861, at *8. The Court should also hold, as the *Washington* court did,

that "the record demonstrates potentially internally inconsistent FDA findings regarding mifepristone's safety profile." *Id*. Accordingly, like the *Washington* court, this Court should readily conclude that Plaintiffs have a "likelihood of success" on their claims to enjoin enforcement of the 2023 REMS. *Id*. at *4.

A. FDA's Persistence in Imposing the 2023 REMS Violates the APA

Under Section 706 of the Administrative Procedure Act ("APA"), a court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §§ 706(2)(A), (C). As FDA has repeatedly acknowledged, most recently in its filings in the *Alliance* lawsuit, mifepristone is extremely safe, with a safety profile comparable to drugs that are sold without a prescription, such as ibuprofen. *See supra* at *14*. Because mifepristone does not meet the FDCA's statutory requirements for imposing a REMS, much less ETASU, the REMS is likely contrary to law and in excess of FDA's statutory authority. Similarly, because there is no medical or scientific basis for restricting access to mifepristone, FDA's decision to impose the REMS and make mifepristone more difficult to access is also likely arbitrary and capricious.

1. The FDCA Does Not Authorize FDA to Impose the 2023 REMS for Mifepristone

Although FDA enjoys a significant degree of discretion in approving drugs, as a federal agency, its actions nonetheless "must be consistent with the statute under which they are promulgated." *United States v. Larionoff*, 431 U.S. 864, 873 (1977); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 638 n.1 (1973) (Powell, J., concurring) (acknowledging FDA's authority "to adopt reasonable regulations consistent with the statute"). The 2023 REMS with ETASU is inconsistent with the FDCA, which permits a REMS with ETASU to be applied

only in certain, limited circumstances. First, a medication must be associated with a "serious adverse drug experience," defined as "death," "immediate risk of death," "inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or where the medication "may jeopardize the patient and . . . require a medical or surgical intervention to prevent [such] an outcome." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4). Second, even where there is such an association with a "serious adverse drug experience," ETASU may be imposed only if the "specific serious risk listed in the labeling of the drug" is so great that FDA could not approve (or would have to withdraw approval of) the drug in the absence of an ETASU. *Id.* § 355-1(f)(1)(A). Third, ETASU must "not be unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must, to the extent practicable, "minimize the burden on the health care delivery system." *Id.* §§ 355-1(f)(2)(C)–(D).

The 2023 REMS with ETASU for mifepristone bears no relationship to these statutory requirements. *First*, far from being "associated with a serious adverse drug experience," *see id.* § 355-1(f)(1)(A), FDA itself has concluded that serious adverse events following mifepristone use are "exceedingly rare." Compl. ¶ 130. Indeed, serious adverse events occur in fewer than 1% of mifepristone uses. *Id.* ¶ 51. Mifepristone's *associated* fatality rate is *0.000005%* for the entire time it has been available in the U.S.[30]—and none of those deaths can "be causally attributed to mifepristone." *Id.* ¶ 54. Indeed, FDA found that the "critical risk factor" for deaths due to infection

[30] Compl. Ex. I (Mifepristone U.S. Post-Marketing Adverse Events Summary) (noting 28 total reported deaths in adverse events summary out of approximately 5.6 million users of mifepristone, "regardless of causal attribution to mifepristone," as reported deaths included instances of homicide, drug overdose, ruptured ectopic pregnancy, and sepsis).

is not mifepristone but "pregnancy itself." *Id.* ¶ 55. For these reasons, mifepristone is among the safest drugs on the market—demonstrably far safer than many drugs that are not subject to a REMS, including Viagra, which has an exponentially higher rate of death.[31]

Second, the restrictions imposed by the 2023 REMS with ETASU are not "required . . . to mitigate a specific serious risk" of a serious adverse drug experience. *Id.* §§ 355-1(b)(5), (f)(1)(A). FDA's own REMS review does not even pretend to assert that the required certifications are necessary to mitigate any specific risk.[32] To the contrary, the REMS with ETASU's burdensome administrative requirements—requiring patients to sign a form and providers and pharmacies to seek special certifications—are not related to any serious adverse drug experience, much less of any use in mitigating one. Weems Decl. ¶¶ 12–15; Tong Decl. ¶ 11; Smith Decl. ¶¶ 17–20; Hagstrom-Miller Decl. ¶ 44. Moreover, ETASU is appropriate only where the drug is so "inherent[ly] toxic[] or potential[ly] harmful[]" that—as a medical or scientific matter—FDA otherwise could not approve it. *See* 21 U.S.C. § 355-1(f)(1). FDA plainly does not consider mifepristone to be *inherently* toxic or harmful, as evidenced by its approval *without* any REMS of Korlym, a higher-dose form of mifepristone that is used for ongoing treatment of Cushing's syndrome, a chronic condition. Compl. ¶ 119.[33]

Finally, even where a drug meets the medical or scientific requirements for imposing a REMS with ETASU, Congress specifically required FDA to refrain from imposing one if it would

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[31] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA Network 590 (Feb. 2, 2000) (Viagra associated with 4.9 deaths per 100,000 prescriptions).

[32] *See* Compl. Ex. H (2016 Summary Review) at 26; Compl. Ex. E (FDA 2016 Medical Review).

[33] *See generally* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Korlym (mifepristone) Risk Assessment and Risk Mitigation Review(s) (Jan. 27, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf (hereinafter Korlym Review), Compl. Ex. M.

be "unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas." 21 U.S.C. § 355-1(f)(2)(C). Here, the ETASU creates a medically unnecessary burden, and that burden falls disproportionately on rural patients.[34]

Agency actions that are "inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement" are subject to vacatur under the APA. *Fed. Election Comm'n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 32 (1981). The REMS violates the FDCA's plain language and undermines the statute's goals of protecting public health without burdening patients' access to needed medications. By discouraging physicians and other healthcare professionals from prescribing mifepristone, the REMS makes abortion care harder to access for many patients without any discernible safety benefit. For these reasons, the 2023 REMS is likely invalid because it is squarely contrary to the FDCA.

2. The 2023 REMS is Arbitrary and Capricious

The 2023 REMS is also likely arbitrary and capricious. A regulation is arbitrary and capricious if the agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To comply with the APA, an agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions." *Michigan v. EPA*, 576 U.S. 743, 753 (2015). "An agency, although entitled to deference, cannot simply state it 'believes' something to be true—against the weight of all the evidence before it—without further support." *Mayor of Baltimore v. Azar*, 973 F.3d 258, 276 (4th Cir. 2020), *cert. dismissed* 141 S. Ct. 2170

[34] Compl. Ex. O (ACOG Citizen Petition) at 14–16; Compl. Ex. K (SFP Letter to FDA) at 2.

(2021). Rather, the agency must "offer an explanation why it made a certain decision, when 'every indication in the record points the other way.'" *Id.* (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 56–57).

The arbitrary and capricious nature of the 2023 REMS has at least three aspects: it is not grounded in science, it bears no demonstrated relationship to patient safety, and it reduces the availability of a safe and effective drug.

a. The 2023 REMS restrictions are not supported by science as attested by all mainstream medical organizations to have addressed them.

There has never been a scientific basis for subjecting mifepristone to additional burdens that are not applied to other, riskier medications, but this reality has only become more apparent with time. Since 2016, the preeminent, mainstream medical organizations in the United States, including the American College of Obstetricians and Gynecologists ("ACOG"), the American Public Health Association ("APHA"), the American Academy of Family Physicians ("AAFP"), and the American Medical Association ("AMA"), have *universally opposed* the imposition of the REMS in each of its iterations. Compl. ¶¶ 85–98, 120–27. And, in the face of this opposition, FDA has never been able to "satisfactorily explain its disagreement with the proliferation of negative comments from the medical community." *Mayor of Baltimore*, 973 F.3d at 281.

Most recently, the 2022 citizen petition submitted by the nation's leading healthcare professional organizations conclusively demonstrated that the 2023 REMS is not backed by science. Compl. ¶¶ 123–27. But, FDA continued to disregard these concerns with no explanation, and persisted in retaining certain REMS restrictions, even while it agreed that others were unnecessary. *See id.* ¶¶ 83, 128. FDA's decision to ignore the universal opinion of every mainstream medical organization and retain the REMS in 2023 matches the arbitrariness the Fourth Circuit found in the rule enjoined in *Mayor of Baltimore. See* 973 F.3d at 276. There, the

Fourth Circuit held that an agency "cannot easily brush off the swell of evidence in the record before the agency that the medical community finds [a] Rule to be repugnant." *Id.* at 278. Thus, by "merely" disagreeing with "every major medical organization in the country, without more," an agency fails to "examine the relevant data and articulate a satisfactory explanation for its action" and "offer[ ] an explanation for its decision that runs counter to the evidence before the agency." *Id.* (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43).

Science belies any assumption by FDA that the REMS is in any way responsible for the safety and efficacy of mifepristone. Data from countries without REMS-like restrictions—data FDA considered in 2016—show similarly low rates of complications. For example, "[a]fter Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug ('normal prescribing'), there was no increase in complications from mifepristone use."[35]

Even as mifepristone for pregnancy termination remains subject to the 2023 REMS, a higher-dose product of the same drug has been available to treat a chronic condition for over a decade without *any* comparable restrictions. In 2012, FDA approved Korlym (mifepristone) tablets, taken as one to four 300 mg pills daily, as treatment for Cushing's syndrome without a REMS. Compl. ¶ 119. FDA acknowledged that Korlym "is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex . . . [and] the rate of adverse events with Mifeprex is much lower."[36] FDA's decision to restrict 200 mg tablets of mifepristone more stringently than 300 mg tablets highlights the arbitrary and capricious nature of the REMS. *See,*

[35] Citizen Petition, Docket No. FDA-2022-P-2425, from Am. Coll. Of Obstetricians & Gynecologists et al. to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. Food & Drug Admin., at 17 (Oct. 4, 2022) (hereinafter ACOG Citizen Petition), Compl. Ex. O.

[36] Compl. Ex. E (FDA 2016 Medical Review) at 10.

e.g., *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015) ("[I]nternally inconsistent analysis is arbitrary and capricious.").

b. The 2023 REMS does not enhance patient safety.

The requirements of the 2023 REMS do not enhance patient safety. Indeed, as determined by FDA's *own* team of expert reviewers in 2016, the Patient Agreement should be eliminated because it duplicates informed consent laws and standards, "does not add to safe use conditions . . . and is a burden for patients."[37] Compl. ¶ 97; *see also id.* ¶ 125 (citing citizen petition stating that the Patient Agreement Form is "medically unnecessary and repetitive of informed consent," citing FDA's 2016 findings[38]). FDA's unexplained rejection of that recommendation is arbitrary and capricious. Since 2016, and especially in the last year of upheaval around the provision of abortion resulting from the reversal of *Roe v. Wade*, the burdens of the Patient Agreement Form and other unnecessary bureaucracy have only grown. Abortion is now illegal in 13 states, and patients and providers face a growing wave of criminalization, which raises the risks of exposure of information about abortion. FDA itself recognizes that Patient Agreement Forms undermine patients' interests in privacy and confidentiality, citing those concerns when concluding that Patient Agreement Forms were unnecessary for dispensing Korlym.[39]

Similarly, the prescriber certification requirement provides no additional safety benefit, and FDA has never explained why it remains necessary. Healthcare providers are already subject to numerous ethical and legal obligations to ensure that they practice only within their competency.[40]

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

[38] Compl. Ex. O (ACOG Citizen Petition) at 12.

[39] *See* Compl. Ex. M. (Korlym Review) at 9.

[40] *See, e.g.*, AMA Principles of Medical Ethics, Principle I, https://code-medical-ethics.ama-assn.org/principles (adopted June 1957, last revised June 2001) ("A physician shall be dedicated to providing competent medical care[.]");

Requiring providers to *say* that they are competent has no direct impact on patient care and simply poses barriers to entry, as medical experts informed FDA in 2016 and again in 2022. *See supra* at 11; *infra* at 30. And, providers dispensing the higher-dose form of mifepristone (Korlym) and providers who dispense other drugs that are far less safe than mifepristone are not subject to this requirement. Compl. ¶¶ 119–21.

Finally, the requirement that pharmacies be "specially certified" through the drug's manufacturer before they can dispense mifepristone is similarly unjustifiable. Like prescribers, pharmacies and pharmacists are subject to extensive regulation, and to discipline if they fail to adhere to established standards. *See*, *e.g.*, Va. Code Ann. §§ 54.1-3307, 54.1-3316; Mont. Code Ann. §§ 37-7-201, 37-7-323; K.S.A. §§ 65-1631, 65-1627. Instead, this requirement makes it more difficult for patients to access mifepristone.

c. The 2023 REMS harms patients.

As medical experts have informed FDA since at least 2016, evidence shows that the REMS worsens health outcomes by impeding access to abortion care. *See Michigan*, 576 U.S. at 753 (an agency must "pay[] attention to the advantages *and* the disadvantages of [its] decisions"). Multiple studies show the REMS acts as "a barrier to providing medication abortion," most notably by dissuading primary care providers from offering it.[41] Access to medication abortion is essential.

Va. Code Ann. § 54.1-2510 (Virginia Board of Health Professions "evaluate[s] all health care professions and occupations in the Commonwealth," determines the "degree of regulation to be imposed," and "promote[s] the development of standards to evaluate the competency of the professions and occupations represented on the Board"); Mont. Code Ann. § 37-3-202 (Montana Board of Medical Examiners maintains "reasonable and continuing supervision and surveillance over all licensees under this chapter to ensure that such licensees maintain standards of conduct and exercise the privileges granted hereunder in the greatest public interest"); K.S.A. §§ 65-2864–65 (Kansas Board of Healing Arts "shall enforce the provisions of all practice acts administered by the board" and accordingly shall "promulgate all necessary rules and regulations" and "make all necessary investigations").

[41] 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 (May 2022); *see also* Sara Neill, Alisa B. Goldberg & Elizabeth Janiak, *Medication Management of Early Pregnancy Loss:*

See supra at 16. Medication abortion has become an increasingly critical method on which patients and clinics rely in the face of an ongoing reproductive healthcare crisis; it makes up over half the abortion care provided in the country. Service-delivery advancements, like direct to patient telehealth, moderate the strain on the ever-shrinking number of clinics struggling to provide care for a dramatic increase in patients.[42]

For Plaintiffs and their patients, medication abortion is simpler, less expensive, and less resource-intensive, especially when provided by mail and prescribed by APCs. *See supra* at 16. Medication abortion is medically indicated for some patients. *See supra* at 16. And, for many of Plaintiffs' patients, medication abortion with mifepristone is preferable because it allows them to have more control over their experience, to guard the privacy of their decision, or to avoid instruments, which can be particularly important for survivors of sexual assault. *See supra* at 16. For those patients unable to access medication abortion, procedural abortion may be an option (depending on where they live and their resources), but it is an option that FDA itself acknowledges as slightly higher risk and more invasive.[43]

Given the dramatic reduction in abortion access, and particularly procedural abortion access caused by the overturning of *Roe*, restricting access to medication abortion means some patients will not be able to obtain an abortion at all. For them, the health risks are severe, given that carrying to term is far more dangerous than abortion by any method. A person who carries a pregnancy to term is at least fourteen times more likely to die than a person who uses mifepristone

The Impact of the U.S. Food and Drug Administration Risk Evaluation and Mitigation Strategy 139 Obstetrics & Gynecology 83S (May 2022).

[42] *See* Caitlin Myers et al., *Abortion Access Dashboard* (last updated Mar. 23, 2023), http://bit.ly/3KFOck7 (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

[43] *See* Compl. Ex. D (Citizen Petition Denial) at 5–6.

to end a pregnancy.[44] Forced pregnancy and childbearing also have long-term impacts on a person's educational and economic futures, and their ability to shape their lives. People who are denied a wanted abortion are more likely to experience economic insecurity and raise their existing children in poverty, and the financial impacts of being denied an abortion are as large as or larger than being evicted, losing health insurance, or being hospitalized.[45]

As ACOG explained in its 2022 citizen petition, the prescriber certification requirement disproportionately affects rural patients because REMS-certified providers "are almost always located in cities."[46] This requirement constrains the pool of clinicians that could be certified prescribers at Plaintiffs' and other clinics to those willing to take on the risks of becoming certified. *See* Compl. ¶ 100. "As with the certified provider requirement, the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural [patients], contrary to the REMS statute"[47]; as noted, under the statute, ETASU must "not be unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," 21 U.S.C. § 355-1(f)(2)(C).

The likelihood of being denied abortion care has grown exponentially since the U.S. Supreme Court overruled *Roe* nearly one year ago and abortion has become illegal in many states. In the states where abortion remains legal, and even protected, it is subject to restrictions not imposed on equally safe or more dangerous interventions. The persistence of a unique set of federal

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[44] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (Feb. 2012); Compl. Ex. D (Citizen Petition Denial) at 4 n.6.

[45] Diana G. Foster et. al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (Mar. 2018); Sarah Miller, Laura R. Wherry & Diana G. Foster, *The Economic Consequences of Being Denied an Abortion*, 15 Am. Econ. J.: Econ. Pol'y 394 (Feb. 2023).

[46] Compl. Ex. O (ACOG Citizen Petition) at 14.

[47] *Id.* at 16.

restrictions on mifepristone is part of the same set of efforts to put safe, effective options for pregnancy care out of reach.

Another district court in the Fourth Circuit has recognized that restrictions on accessing medication abortion harm patients. In 2020, during the height of the COVID-19 pandemic, ACOG sued to challenge FDA's in-person requirement for medication abortion that was then in effect (and would be resurrected if the Fifth Circuit's modified order had taken effect). The District of Maryland court ultimately entered an injunction blocking that requirement during the pandemic because it unduly burdened the then-existing federal right to abortion. But, even post-*Roe*, the court's analysis of the harms to patients caused by restrictions on medication abortion remains salient. The Court found that "delays in abortion care" can be burdensome "either because they increase the risk" associated with it, or because they can "cause the patient to miss the opportunity for a medication abortion such that they must seek a more invasive form of abortion." *Am. Coll. of Obstetricians & Gynecologists*, 472 F. Supp. 3d at 217. The impact of the pandemic—clinic closures, health risks, and other logistical barriers—is not unlike the current public health crisis caused by the overturning of *Roe*. The District of Maryland court concluded that restrictions on medication abortion can be particularly harmful when "medical offices that dispense mifepristone may be closed or operating with limited capacity, a disproportionate number of abortion patients are from demographic groups with heightened risk for serious illness from COVID-19, and such patients face particularized barriers posed by transportation, childcare, and the economic downturn during the pandemic . . . particularly where any delay in obtaining mifepristone that extends past the tenth week of pregnancy can force a woman to consider more complicated, invasive surgical abortions." *Id.* at 223. Further, the court found that a prohibition preventing the mailing of mifepristone did not serve a public health interest. *Id.* The Court should make a similar

determination here—that, considering the dramatic reduction in access to abortion around the country, and the legal uncertainty plaguing Plaintiffs' continued provision of medication abortion with mifepristone at least under the 2023 REMS, the harms to patients in Plaintiffs' states warrants a preliminary injunction to maintain the status quo.

Because FDA arbitrarily subjects mifepristone to more stringent restrictions than other, riskier medications—despite the mass opposition of every mainstream medical organization and despite FDA's own determination of mifepristone's thoroughly-proven safety—and because the REMS do not enhance patient safety but interfere with patients' access to an essential drug, leading to worse health outcomes, FDA's promulgation of the 2023 REMS is likely arbitrary and capricious.

B. Plaintiffs Are Excused from Filing a Citizen Petition with FDA

Ordinarily, plaintiffs challenging FDA actions under the APA are required to first file a citizen petition with FDA. *See* 21 C.F.R. §§ 10.25(a), 10.30, 10.45. In this case, however, Plaintiffs are excused from filing a citizen petition because the record demonstrates that any such filing would be futile. *See Wilson v. UnitedHealthcare Ins. Co.*, 27 F.4th 228, 241 (4th Cir. 2022). Historically, FDA refused similar relief to that sought here when it was requested in 2020 by 21 states,[48] and in 2022 by ACOG.[49] Earlier this year, when 17 states and the District of Columbia sought to roll back the 2023 REMS in the *Washington* Case, FDA opposed that relief, asserting in its brief that its decision to maintain the 2023 REMS restrictions on mifepristone was "reasonable."

[48] Letter from Xavier Becerra, Cal. Att'y Gen, et al., to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Servs. & Stephen Hahn, Comm'r, U.S. Food & Drug Admin. (Mar. 30, 2020), Compl. Ex. Q.

[49] Compl. Ex. O (ACOG Citizen Petition); U.S. Food & Drug Admin., FDA-2022-P-2425-0003, Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Maureen G. Phipps, Am. Coll. Obstetricians & Gynecologists, denying Citizen Petition, Docket. No. FDA-2022-P-2425 (Jan. 3, 2023) (hereinafter ACOG Citizen Petition Denial), Compl. Ex. P.

Defs.' Resp. Opp. Pl. States' Mot. Prelim. Inj. at 22, *Washington v. FDA*, No. 1:23-cv-03026-TOR (E.D. Wash. Mar. 17, 2023). There is no prospect that FDA would take a different view now if Plaintiffs were required to submit a citizen petition; there would only be harmful delay because the agency's own rule allows it 180 days to respond to citizen petitions, *see* 21 C.F.R. § 10.30(e)(2), and it often takes considerably longer to respond.

II. Plaintiffs Will Suffer Irreparable Harm Absent Injunctive Relief

For purposes of a preliminary injunction, the harm analysis focuses on irreparability, irrespective of the magnitude of the injury. *See, e.g.*, *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land, Owned by Sandra Townes Powell*, 915 F.3d 197, 216 (4th Cir. 2019) (recognizing irreparable harm when a movant makes a "clear showing" of "actual and imminent" harm that "cannot be fully rectified by the final judgment after trial"). Plaintiffs are irreparably harmed in at least three ways.

First, returning to an older regulatory scheme, as the Fifth Circuit's modified order would have required, would prevent Plaintiffs from providing direct to patient telehealth, which has had a tremendous impact on patients in rural areas or for whom in-clinic visits are difficult to access. For some patients, an in-person visit is simply impossible, and prohibiting access to direct to patient telehealth would greatly harm them. Smith Decl. ¶ 29. For others, the difficulty of arranging an in-person visit—requiring time off work or school, childcare, and adequate transportation—may delay their care, pushing them further into pregnancy when abortion care is more costly and potentially more complex. *Id.* Direct to patient telehealth mifepristone provides flexibility and discretion for patients whose privacy would be jeopardized by an in-person visit, including those in abusive relationships or who do not wish to disclose their abortion. Smith Decl. ¶ 28; Weems Decl. ¶ 32.

Second, resurrecting pre-2016 restrictions would confine certified mifepristone prescribers to physicians only. APCs can and do safely provide mifepristone: to hold otherwise limits access to mifepristone and undermines their licenses and expertise. Weems Decl. ¶¶ 27, 29; Smith Decl. ¶ 32; *see Richmond Med. Ctr. for Women v. Gilmore*, 11 F. Supp. 2d 795, 809 (E.D. Va. 1998) (finding irreparable harm where healthcare providers would be "constrained to alter their medical advice to, and their medical care of, their patients, contrary to their best professional medical judgments"). Reinstating this requirement would seriously threaten patient access to mifepristone, particularly in Montana: Plaintiff Helen Weems could no longer provide mifepristone at All Families Healthcare, and the next closest provider, Blue Mountain Clinic, is approximately a three-hour drive away. Weems Decl. ¶¶ 25, 28; Smith Decl. ¶ 33. Reinstating the physician-only certified prescriber requirement would also complicate Plaintiffs' staffing and operations, with no benefit to patient care. Hagstrom-Miller Decl. ¶¶ 37, 44. Delays in treatment—including those caused by a lack of "specially certified" providers under the reinstated requirements—may cause patients to miss their window for medication abortion altogether.

Third, the legal uncertainty surrounding mifepristone has unleashed chaos in Plaintiffs' states. Plaintiffs are unsure from one day to the next whether they will be able to maintain their protocols and procedures, or whether they will have to upend their practices to ensure that they are complying with various court orders. Weems Decl. ¶¶ 22–24; Tong Decl. ¶¶ 10, 31–32. Patients are unsure whether their appointments will be able to proceed as scheduled. Weems Decl. ¶ 22; Tong Decl. ¶¶ 24, 33. The constantly shifting law and policy landscape disrupts Plaintiffs' practices and places enormous strain on their clinicians, staff, and patients. Smith Decl. ¶ 27. Plaintiffs' energies should be focused on providing the highest-quality, evidence-based care to their patients—not parsing conflicting lawsuits to which they are not parties.

Because Plaintiffs will suffer irreparable harm in the absence of an injunction that cannot be remedied at the conclusion of litigation, temporary relief is warranted here. *See Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017).

III. The Equities and Public Interest Weigh Strongly in Plaintiffs' Favor

The final preliminary injunction factors merge and are properly considered together when the government is a party to the litigation. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, both the equities and the public interest strongly favor injunctive relief.

"There is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020). The ongoing legal chaos surrounding mifepristone threatens Plaintiffs' medical practices and their patients' access to timely and necessary medical care. Thus, "the public interest . . . favors a preliminary injunction" when agency action "will likely result in worse health outcomes." *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 87 (2d Cir. 2020) (cleaned up); *see also Mayor & City Council of Baltimore v. Azar*, 392 F. Supp. 3d 602, 619 (D. Md. 2019) (finding it "in the public interest to continue the existing structure and network of healthcare that [Plaintiff] currently provides while this Court addresses legal challenges" to agency action).

Equity also favors the relief sought. Providers in 17 states and the District of Columbia currently enjoy legal protection from the havoc that might ensue from any orders affecting the availability of mifepristone as a result of the *Alliance* Case. And Defendants will not be harmed by maintaining the status quo for providers in Virginia, Montana, and Kansas when they are already required to do the same for providers in the 17 states and the District of Columbia that are parties to the *Washington* Case. Accordingly, the balance of equities and the public interest both weigh strongly in Plaintiffs' favor.

IV. Maintaining the Status Quo on a Statewide Basis Is Necessary to Afford Plaintiffs Complete Relief

Plaintiffs seek a preliminary injunction preventing Defendants and any person in active concert or participation with them from altering the status quo as it relates to the availability of mifepristone under the 2023 REMS in Virginia, Montana, and Kansas, where Plaintiffs operate. "It is well established . . . that a federal district court has wide discretion to fashion appropriate injunctive relief in a particular case." *Richmond Tenants Org., Inc. v. Kemp*, 956 F.2d 1300, 1308 (4th Cir. 1992); *see also Trump v. Int'l Refugee Assistance Project*, 582 U.S. 571, 579 (2017) (per curiam) ("Crafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents."). The scope of relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

This temporary relief would put Plaintiffs and their patients in the same position as providers and patients in the 17 states and the District of Columbia that are party to the *Washington* Case. Granting this relief in this case does not impose any additional burden on Defendants, who are already obliged to maintain the status quo with respect to the state plaintiffs in the *Washington* Case. *See Washington*, 2023 WL 2825861, at *11; *Washington*, 2023 WL 2941567, at *2. The Fourth Circuit has "defined the status quo" for purposes of a preliminary injunction "to be the last uncontested status between the parties which preceded the controversy." *League of Women Voters of N.C.*, 769 F.3d at 236; *cf. Aggarao v. MOL Ship Mgmt. Co.*, 675 F.3d 355, 378 (4th Cir. 2012) ("To be sure, it is sometimes necessary to require a party who has recently disturbed the status quo to reverse its actions, but . . . [s]uch an injunction restores, rather than disturbs, the status quo ante." (internal quotation marks and citation omitted)). And granting this relief is appropriate here because Plaintiffs' patients—who must bear the repercussions of any abortion care that is delayed

or denied—come from all across the states in which Plaintiffs' medical practices operate. Accordingly, statewide relief is necessary to ensure complete relief to Plaintiffs and their patients. *See Mayor of Baltimore*, 973 F.3d at 294 (affirming statewide scope of injunction against HHS final rule as "a permissible exercise of the district court's broad discretion" to secure healthcare needs of patients across the state).

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court enter an order protecting access to mifepristone by issuing a preliminary injunction enjoining the Defendants from altering the status quo with respect to the 2023 REMS in the states of Virginia, Montana, and Kansas as it relates to the availability of mifepristone during the pendency of this litigation.

Dated: May 8, 2023

Respectfully submitted,

/s/ Gail M. Deady
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**Pro hac vice application forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of May, 2023, I filed the foregoing document with the Clerk of Court using the CM/ECF system, and I hereby certify that I will mail by United States Postal Service Certified Mail the document to the following non-CM/ECF participants:

United States Department of Health & Human Services
c/o General Counsel
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Xavier Becerra, Secretary
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United States Food and Drug Administration
Chief Counsel, Food and Drug Administration
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Robert M. Califf, Commissioner
Chief Counsel, Food and Drug Administration
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Attorney General Merrick Garland
Attorney General of the United States
U.S. Department of Justice
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I also hereby certify that on this 8th day of May, 2023, the foregoing document will be hand served to:

U.S. Attorney Christopher Kavanaugh
United States Attorney's Office

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF REBECCA TONG IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

1. I am a Co-Executive Director of Trust Women Foundation ("Trust Women"). Trust Women operates clinics offering reproductive health care, including abortion, contraceptive services, and gender-affirming care, with a focus on providing access for those in underserved communities. Trust Women opened its first clinic, South Wind Women's Center (doing business as "Trust Women Wichita"), in Wichita, Kansas on April 3, 2013. Trust Women opened a clinic in Oklahoma City, Oklahoma ("Trust Women Oklahoma City") in 2016.

2. As Co-Executive Director of Trust Women, I oversee operations at both Trust Women Wichita and Trust Women Oklahoma City. I am familiar with all aspects of our policies and practices and am frequently in contact with Trust Women's clinical staff and physicians. The facts I state here are based on my experience and information and knowledge I have obtained through my work for Trust Women.

3. I submit this declaration in support of Plaintiff's Motion for a Preliminary Injunction.

4. Trust Women Wichita provides reproductive health care, including both procedural and medication abortion, and contraceptive services.

5. Trust Women Wichita provides procedural abortions up to 21 weeks, 6 days of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP").

6. Trust Women Wichita provides medication abortions up to 11 weeks LMP. The regimen used at Trust Women involves two medications, mifepristone and misoprostol. The patient takes the mifepristone at the clinic. The patient then takes the misoprostol approximately 24 to 36 hours later outside of the clinic.

7. Trust Women Wichita has provided medication abortion since it opened in 2013, and the clinic's safety record has been excellent. We have never faced a serious complication from medication abortion.

8. We used to provide these same services safely and effectively in our clinic in Oklahoma City, but we had to shutter abortion services when multiple abortion bans took effect in Oklahoma at or about the time *Roe* was overturned. We have pivoted our services to provide other care our Oklahoma City community needs, including gender-affirming care, and medication assisted treatment.

9. Until 2018, Trust Women Wichita offered a telemedicine clinic for medication abortion, but we were forced to stop that practice due to a Kansas state law. That law was very recently enjoined, and we are interested in restarting our telemedicine clinic if we are able to. We are particularly interested in pursuing the option to mail mifepristone, which would greatly expand our ability to help patients. We would start as soon as we can if mifepristone remains available and possible to dispense by direct to patient telehealth.

I. Providing Abortions Post-*Roe*

10. I have worked at Trust Women since the Wichita clinic opened in 2013, and it has always been challenging to provide care in a hostile environment like Kansas or Oklahoma, where we are targets for harassment and violence. But, the last year has been the hardest I have ever experienced. Since even before the Supreme Court's decision in *Dobbs*, our clinics have been in a constant state of whiplash from unending legal uncertainty around providing care. On the other side of this chaos are our very real patients who suffer every time we have to change course due to the latest legal or regulatory change or court decision. Now we have uncertainty even about whether and how we can use mifepristone to provide medication abortion. In the last year, we have had to modify every single system in our clinics. As healthcare providers, we need to plan ahead—we need certainty around whether and how we can see patients tomorrow or the next day without fearing that we will have to reorder our entire practice every 24 hours or turn patients away. We cannot look more than a few steps ahead because we cannot anticipate what the legal environment will look like next week.

II. The Mifepristone Risk, Evaluation, and Mitigation Strategy ("REMS")

11. Mifepristone has long been subject to medically unnecessary requirements known as the REMS. The FDA has followed at least some of the science and changed these requirements over the years; but the REMS remains and continues to interfere with access. The requirements that providers and pharmacies be certified and patients and providers sign agreements do nothing to improve patient care. Rather, they significantly add to the operational and logistical burden of providing medication abortion. We have to use a special pharmacy other than the one we use for all other medications.

12. The REMS also contributes to the stigmatization of medication abortion. When patients read the medication guide, they feel they are taking something that is riskier than it is. Further, the information collected through this unnecessary bureaucracy puts patient and clinician privacy in jeopardy, which is particularly concerning now that abortion is criminalized with very limited exceptions in 13 states. Further, we are limited to hiring physicians that are willing to become certified prescribers and potentially expose themselves as abortion providers.

13. We have decades of evidence demonstrating that medication abortion with mifepristone is safe, effective, and, for many patients, preferable. It is bizarre to us that mifepristone is subject to a REMS when its risk profile is on par with Tylenol.

14. These requirements are severe and, in light of the chaos we have experienced in the last year, detailed below, they have become extremely difficult and sometime insurmountable for some patients. We are challenging them now so that we can devote more of our time to patient care and not senseless requirements that burden our ability to provide medication abortion, can compromise patient privacy and confidentiality, and have no medical benefit. Until this court can rule on this issue, we ask that the FDA be enjoined from deviating from our current status quo of providing medication abortion.

a. S.B. 8 in Texas, its Oklahoma Copycats, and the Overturning of *Roe*

15. On September 1, 2021, before *Roe* was overturned, abortion was banned in Texas beyond approximately 6 weeks LMP due to the enactment of Texas S.B. 8. S.B. 8 was blocked and then un-blocked several times, sending massive shocks through the system of provision of care, as Trust Women Wichita and Trust Women Oklahoma City and our patients struggled to navigate the upheaval caused by abortion services being available and then unavailable repeatedly in Texas.

Patients were frantic trying to be seen. The emotional toll that time took on patients cannot be overstated.

16. Then in Oklahoma, the state legislature started enacting no less than 4 abortion bans in succession with different prohibitions and penalties. First, in May 2022, a 6-week S.B. 8-style ban took effect, then a total S.B. 8-style ban with inconsistent exceptions, and then a 1910 criminal ban revived by Oklahoma's trigger ban. Because the S.B. 8-style laws had immediate effect, we had to schedule patients in Trust Women Oklahoma City understanding that the next day we might not be able to see them. We watched the legislature and the Governor's actions every day to the minute, in order to understand and try to guess when and how exactly these laws would be passed and signed. We had no idea when those laws would take effect. Ultimately, they did, and we had to immediately cease our abortion services in Oklahoma City.

17. After *Roe* was overturned in June 2022, Texas, Oklahoma, Missouri, and Arkansas began enforcing their trigger laws, banning abortion entirely in those states with criminal penalties.

18. I cannot express how devastating it is for patients when we have to call to tell them we cannot see them for an appointment they desperately want and need because a new legal change or court case has tied our hands. We have had patients threaten to harm themselves because they do not wish to be forced to birth and are terrified that they will not be able to receive care.

19. This wave of criminalization and civil liability has forced desperate patients to travel hundreds of miles to seek care. Trust Women Wichita, as one of the few remaining clinics somewhat close to Texas, Oklahoma, and other ban states, has seen a massive increase in patients seeking care due to abortion bans. In 2021, Trust Women Wichita saw around 1500 patients. In 2022, we saw around 3500 patients. For the first 4 months of 2023, we have seen 2*000 patients*

already—on pace for 6,000 for the year. Around two-thirds of our patients are coming from out of state.

20. Most of our patients are already parents. Often, they drive all night with their families in order to see us. Many of the patients we are now seeing have extremely complex pregnancies, with varying health conditions and previous c-sections. We now have people coming directly to us from hospitals in ban states because they cannot get care even in medical emergencies. In no other area of medicine are people treated this way.

21. In response, we have expanded to providing abortion services four days per week with more physicians. But, that expansion does not come close to meeting the need for patients seeking abortion care at Trust Women Wichita. The current call volume for appointments is so high that it could support filling appointments seven days a week, 24/7. Since S.B. 8 took effect, it is not uncommon for us to receive tens of thousands of calls a day.

b. The Chaos Comes for Medication Abortion

22. Now, we face a new rollercoaster around the use of mifepristone. On April 7, a district court in Texas issued an order saying that mifepristone could no longer be used anywhere in the country and gave the FDA only a week to seek an emergency appeal.

23. We were shocked by this because regardless of what someone might think about the morality of abortion, decades of research shows that mifepristone is one of the safest drugs you can take with an extremely low rate of serious complications—it is as safe or safer than taking Tylenol, and it is less risky than many other drugs we use in our practice such as medications for sedation. We have never had a serious complication associated with medication abortion in our entire history. To the contrary, mifepristone is a medical advancement that improves the experience

of abortion for many patients—it is simpler, less expensive, more private, and imposes less discomfort.

24. We immediately worked to develop medication abortion protocols for a hypothetical situation in which we would not be able to use mifepristone. In anticipation of the decision and after, we spent hours training staff on an alternative protocol. When the Texas decision came down, we reached out to hundreds of patients to re-do the consent process that is required in Kansas 24 hours in advance. We had to review the new protocol with patients. Around two dozen patients called us that week because they were confused about whether they could receive their abortion.

25. But that same day, a district court in Washington issued an order requiring the FDA to maintain the status quo for mifepristone but only in select states. Kansas was not included in that order.

26. We also use mifepristone for preparation for procedural abortions because we find that it prepares the cervix faster than misoprostol, which others use. We did not know how these orders would affect mifepristone when used for that purpose.

27. Then, on April 12, the Fifth Circuit put part of the Texas order on hold. The Fifth Circuit's order said that while mifepristone could still be used, the FDA's changes to the REMS from 2016 onward were no longer in effect. We understood this to mean that mifepristone was available but had to be prescribed as if we were rewinding 7 years of medical progress. The pre-2016 REMS effectively prevent a physician from writing a prescription for mifepristone that would allow a patient to pick the drug up at pharmacy. We were considering how to expand our telemedicine program, including using direct to patient telehealth, when mifepristone's approval was suddenly up in the air. Mailing mifepristone would greatly expand the amount of care we are

able to provide. We also weren't sure if we could use the generic Genbiopro mifepristone we have used for years and acquired Danco's mifeprex even though they are identical products.

28. We bought around $20,000 of Danco's mifeprex that we did not even know we would ultimately be able to use, and we had to get registered with Danco. Trust Women is a small nonprofit, and we do not have the resources to stock years of mifepristone, but we bought what we could.

29. We were grappling with how to adjust when, hours before it was set to take effect, the U.S. Supreme Court put the Texas order on hold.

30. Throughout this time, we faced challenges in staffing the clinic. We work with 18 doctors, and 16 of them fly in to Kansas to provide care. We had doctors on standby, but as changes occurred, we didn't know exactly how to plan our physicians' shifts.

31. We are not a part of any of these cases and have been left to sort out how—in all of this uncertainty—to continue to provide quality, evidence-based patient care. And so, for the third time in one year, we are going through a period where we have had to make rapid, senseless changes to our practice that have dramatically harmed patients.

32. Although the Supreme Court ultimately stayed that district court decision pending the appeals process in the Fifth Circuit and possibly a petition for certiorari, we remain extremely uncertain about our provision of mifepristone going forward, especially given that the Fifth Circuit is hearing argument in the case on May 17. Will we be able to use the mifepristone we have beyond a few weeks from now? If we can, under what conditions can we go ahead? What other decisions from the Texas court, other courts, or the FDA are going to interrupt our provision of mifepristone next?

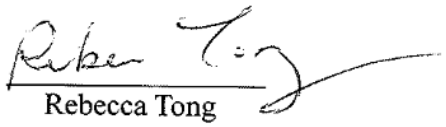
33. Abortion is an essential and time-sensitive service that pregnant people need to have available in order to live their lives with dignity and independence, and to preserve their health and lives. I clearly recall a mother who was desperate to bring her daughter in for care after S.B. 8. They traveled 13 hours to see us. She called us every day for a week, and every hour on the day of their appointment to make sure they could be seen after they made the journey. This confusion and terror is the result of all of this legal chaos. It is simply cruel to put pregnant people through this insanity, and it is all but impossible for us as providers to navigate.

34. Though abortion is extremely safe, the risks and complexity increase as pregnancy progresses. Delays also increase the stress and burdens of maintaining an unwanted pregnancy. This is particularly true for patients who have a medical condition that makes pregnancy a significant health risk or who are pregnant as a result of sexual assault or incest.

35. And, being unable to have a medication abortion specifically causes significant harm to patients. Some patients prefer medication abortion with mifepristone because it allows them to complete the abortion in private or allows them to feel more in control of the procedure. For others, medication abortion with mifepristone may provide them with the flexibility they need to fit the abortion into their schedules. Because experiencing a medication abortion is nearly identical to a miscarriage, patients can choose not to reveal their abortion to disapproving partners, family, or friends. This is a particular benefit for those who may be victims of domestic violence who are trying to conceal the abortion from their abusive partners. Likewise, medication abortion may be preferred by patients who are victims of sexual assault because it avoids any re-traumatization that could occur with a surgical abortion. Medication abortion may also be medically indicated for some patients for a variety of reasons. At Trust Women Wichita in 2021, almost half of our abortion patients chose a medication abortion with mifepristone.

36. If we are unable to get some certainty around our provision of medication abortion, we and our patients will continue to face disruptions and patients will thus be delayed in accessing care. We hope that the Court will preserve the status quo of our provision of mifepristone for the pendency of the litigation.

DATED: 5/5/2023



Rebecca Tong

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF NICOLE SMITH PHD, MPH, IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

NICOLE SMITH, PhD, MPH declares under penalty of perjury that the following is true and correct:

1. I am the Executive Director of Blue Mountain Clinic (the "Clinic"), a family practice and primary care services clinic in Missoula, Montana. Blue Mountain Clinic is one of the plaintiffs in this case.

2. For the past 46 years, Blue Mountain Clinic has provided patient-centered and evidence-based health care, education, and advocacy in Missoula County and beyond. Blue Mountain Women's Clinic first opened in 1977 as the first and only abortion clinic in the state of Montana. In 1991, the Clinic expanded its health services to include comprehensive family medical care to better serve its community.

3. I have been the Executive Director of Blue Mountain Clinic since August 2021. As Executive Director, I oversee all aspects of the Clinic's work, including the overall business operations of the Clinic, human resources and personnel management, fundraising, and budgeting,

as well as day-to-day clinic operations. I supervise our two medical directors who, in turn, oversee clinical operations. As a result, I am familiar with all aspects of the Clinic's work and patient care.

4. I am a fourth generation Montanan, and I have two decades of experience working on sexual and reproductive health in a variety of settings. Prior to joining Blue Mountain Clinic, I worked as a Research Scientist for the Center for Children, Families, and Workforce Development at the University of Montana College of Health. I have a PhD in Health Behavior from Indiana University's School of Public Health, a Master's degree in Public Health from Portland State University, and a Bachelor's degree in Psychology from Carroll College. I have published twenty peer-reviewed academic research articles, including one peer-reviewed commentary on the safety and efficacy of mifepristone.

Access to Abortion in Montana

5. Montana is a large and mostly rural state, with total size measuring over 147,000 square miles and is the fourth largest state in the country. With just over one million residents, Montana ranks 44th in population size. However, the state's population size grew by 11.5% between 2010 and 2021, highlighting the growing influx of new residents to the state. Montana is home to 13 federally recognized Tribes; seven sovereign Reservation communities are located in the state. Indigenous individuals comprise the state's largest minority racial group, representing 7% of Montana's population. Indian Health Services, a federal program, is subject to the restrictions of the Hyde Amendment and therefore abortion care is not available through IHS clinics located in Reservation communities. The state's largest population centers include Billings, Bozeman, Kalispell, Missoula, Helena, and Great Falls.

6. Abortion clinics are located in Billings, Missoula, Helena, Great Falls, and Whitefish, all except Billings are located on the western side of the state. The majority of residents

living in eastern Montana must travel several hundred miles and up to seven hours of driving time one-way, to reach a brick-and-mortar abortion provider. The eastern-western regions of Montana are separated by the Continental Divide of the Rocky Mountains. This means that for all seasons except a short three-to-four months of summer, drivers will frequently encounter hazardous road conditions that add logistical and travel barriers to accessing health care in western Montana's more urban city centers.

7. Montana is a critical site of access to abortion for people in the greater Northern Rockies and Plains regions. Abortion has never been as accessible in the region as it should be, but, since the U.S. Supreme Court overruled *Roe*, access has grown exponentially worse. Each of Montana's neighboring states—North Dakota, South Dakota, Wyoming, and Idaho—have passed draconian abortion bans, meaning that, today, Montana is bordered on all sides by states that have banned abortion, or where a court order has blocked an abortion ban. Despite escalating legislative attacks, discussed more below, Montana itself has retained a baseline for access to abortion, as a result of strong state constitutional protections for abortion.

Blue Mountain Clinic's Practice and Our Patients

8. Blue Mountain Clinic fully integrates family medicine, mental health counseling, reproductive and sexual health care, comprehensive gender-affirming care, and suboxone therapy into its medical practice. The Clinic has four full-time primary health care providers who are licensed to practice in Montana: two physicians and two physician assistants. We also have one licensed clinical social worker (LCSW) on staff who provides mental healthcare and counseling services.

9. The Clinic serves over 3,000 patients per year, accounting for over 7,000 visits. For many of them, Blue Mountain Clinic is their medical home—they turn to us whenever they need

health care.

10. About 25% of Blue Mountain Clinic's patients travel more than 50 miles (which takes approximately one hour or longer one-way, given weather and road conditions) to access services at the Clinic. Some travel even further, for example, from Deer Lodge—which is about 85 miles and over an hour and a half away. Others make use of the direct-to-patient telehealth program for abortion, and do not need to make this in-person trip.

11. Blue Mountain Clinic's family medicine practice offers care from pediatric care to elder care, and includes wellness exams, internal medicine, preventative care, and mental health. All four of the Clinic's primary health care providers serve patients as part of the Clinic's family medicine practice.

12. Blue Mountain Clinic's abortion care practice offers two options: medication abortion up to 11 weeks LMP and procedural abortion up to 21.6 weeks LMP. There are a few regimens for medication abortion, including mifepristone-misoprostol and misoprostol alone. For over two decades, Blue Mountain Clinic has used an evidence-based mifepristone-misoprostol regimen, and we have always had at least one provider who is a certified mifepristone prescriber.

13. In 2022, the Clinic launched its direct-to-patient telehealth program for medication abortion. This model enables patients to access abortion care without having to travel to the Clinic for an abortion. Patients consult with a provider remotely, and after counseling on the patient's options, including the risks and benefits of each, a review of patient medical history, confirmation of the patient's eligibility for medication abortion, and obtaining informed consent, the provider writes a prescription for medication abortion and abortion pills are mailed to the patient in Montana.

14. One of Blue Mountain Clinic's physicians provides both procedural and medication

abortion care, five days a week. Each physician assistant provides medication abortion in-person and via direct-to-patient telehealth, four days a week. Blue Mountain Clinic also has one locum (contract) physician who works in the Clinic on a contract basis, primarily to provide abortion care up to 21.6 weeks LMP or when no other clinician is available. Because the Clinic's physician assistants provide medication abortion, the Clinic prioritizes scheduling physicians to care for patients in need of procedural abortions.

15. In 2022, Blue Mountain Clinic provided about 400 abortions. Almost 40% of those abortions were for patients who are insured through Medicaid (which covers abortion care in Montana), and who are the most financially vulnerable in the state. Our patients seek abortion care for a variety of health, family, economic, and personal reasons. Many are parents who have decided that they cannot parent another child at that time, and some are young people who do not feel ready to carry a pregnancy to term because they want to pursue school or work opportunities. Others face serious health issues that make it dangerous to continue a pregnancy, some are in abusive relationships; and some patients we care for are pregnant as a result of rape or incest.

16. The availability of abortion care enables patients not to forego educational and economic opportunities due to unplanned childbirth, to provide care to existing family members, to avoid raising children with an absent, unwilling, or abusive partner, and to prevent health harms, pain, and suffering that can arise from carrying pregnancies to term and giving birth.

The 2023 REMS are Harmful and Unnecessary

17. Mifepristone is incredibly safe and effective, and our patients are highly satisfied with the medication abortion regimen they have been accessing for years. No other similarly safe drug is subject to a byzantine set of rules that do not advance patient care. Instead, the REMS simply contributes to the incorrect idea that mifepristone is unsafe and prevents it from being more

widely accessible.

18. Requiring our patients to sign the Patient Agreement and to have the Medication Guide adds unnecessary logistical mandates while providing care and it suggests to patient, and to the public, that mifepristone is unsafe when it is not. Despite the far greater risk that continuing a pregnancy and giving birth can entail, there is no requirement that our prenatal patients be given several pages of special instruction about the option of continuing a pregnancy—beyond what informed consent requires. For patients experiencing miscarriage, stating they are taking mifepristone "to end my pregnancy" can add confusion and pain to an already distressing experience.

19. Requiring prescribers of mifepristone and pharmacies that dispense mifepristone be specially certified means mifepristone is simply not as widely available as it should be. Blue Mountain Clinic is a family practice, that, unlike many other family practices, incorporates abortion care—and goes through the extra hurdles that sometimes requires. But, we—and our fellow family practice providers—should be able to simply write a prescription for mifepristone that our patients can pick up at their local pharmacy, as we do with all other medications with a similar safety and efficacy profile. Requiring both the clinician prescriber and the pharmacy to go through additional steps to be certified means, as a practical matter, mifepristone will be less available for our patients than medications that are just as critical to patient care and of comparable safety. We know from documented research that many family medicine, internal medicine, and OB/GYNs want to prescribe mifepristone for abortion care, but their hospital or clinic regulations prevent them from becoming certified prescribers because of the hyper-regulations of REMS

requirements for this medication.[1] Removing the REMS regulations would significantly expand the available pool of health care providers who could and who would prescribe mifepristone for abortion care and for miscarriage management.

20. The REMS requirements are severe and, in light of the chaos we have experienced in the last year, and how irrational these regulations are, the disruptions and the misinformation that has resulted, has become increasingly harmful. We are challenging them now so that we can devote more of our time to patient care and not to senseless paperwork that has the potential to compromise patient privacy and confidentiality and does not make administration of mifepristone any safer than it already is.

The REMS Contributes to the Chaos for Abortion Providers and Our Patients

21. Blue Mountain Clinic has provided abortion care for over 46 years. The chaos and uncertainty about the status of mifepristone—because it is used in abortion care, and, for that reason, it is subject to special, unnecessary rules— is part and parcel of the disruption that Blue Mountain Clinic has had to endure simply because it provides abortion care.

22. This year's state legislative session was one of the most heated on record. At one point, Blue Mountain Clinic was advocating against *13* egregious bills which seek to significantly restrict abortion access, and another five bills which discriminate against LGBTQ Montanans. The bills also perpetuate lies and inflammatory language meant to shame and stigmatize. None of them improve health outcomes or increase access to healthcare for families. Multiple proposed laws and policies included immediate or near-immediate effective dates, indicating that, should they become law, they could require Blue Mountain to immediately retool or fundamentally overhaul our

[1] 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 (July 2021), https://www.sciencedirect.com/science/article/pii/S0010782421001335.

practice.

23. Blue Mountain Clinic is now also contending with the threats to mifepristone. The clinic developed medication abortion protocols to implement should mifepristone be considered unusable as a result of any court order in the Texas *Alliance* case. Because we had only been certified prescribers with GenBioPro, the manufacturer of generic mifepristone, we ensured our clinicians were also certified prescribers with Danco, the manufacturer of Mifeprex, the brand name mifepristone, should that become the only version we could use—even though they are the same product.

24. And we have tracked the fast-paced, dizzying legal process, the outcome of which could, at a moment's notice, impact whether and how Blue Mountain prescribes mifepristone. First, on April 7, the Texas court issued a ruling claiming to take mifepristone off the market, while putting the order on hold for 7 days. Five days later, on April 12, the Fifth Circuit indicated it was further modifying mifepristone's status—although the drug would still be on the market, we were going back to a time when a pre-2016 version of the REMS governed, and the generic had not yet been approved. Two days later, the U.S. Supreme Court kept this on hold until April 19 and then extended that until April 21. On April 21, the U.S. Supreme Court issued a stay of the Texas court's preliminary injunction, pending appeal of that injunction at the Fifth Circuit and pending any request that the Supreme Court review what the Fifth Circuit decides.

25. I also understand that another lawsuit was filed in Washington State by 17 states and the District of Columbia, where a court enjoined the FDA enforcing the *Alliance* order in those states. Montana did not join with the other plaintiffs in that case, and Blue Mountain is not protected by that order. Instead, Montana's attorney general has asked to intervene in that case to restrict access to mifepristone, despite pre-viability abortion being legal in Montana.

26. During this period of instability, Blue Mountain marked on March 29 the 30-year anniversary of the devastating arson which destroyed the clinic in 1993. As we reflect on that somber anniversary, we are once again working to provide high-quality care in an environment meant to stoke anger and violence. And the disruptions in the delivery of health services—whether caused by direct harassment and violence, or obstruction and intimidation in the form of constantly changing laws and policies that impact the care we provide—harm our patients in similar ways. As Willa Craig, the Executive Director of the Clinic at the time of the 1993 firebombing, said then, it is not only our patients seeking abortion care who are impacted by anti-abortion harassment, but also "our prenatal patients, the families that we have served over the years in every way, by delivering their babies and immunizing their children, to the patients of our internist who provides care for our many elderly patients, and our therapist who spends much of her time in adoption counseling."

27. Our busy family practice works to be nimble and accommodating—to best serve our patients and our staff. One of our physicians, whose family medicine practice includes abortion care, is currently booked months out for family medicine appointments. Abortion is time-sensitive health care, and Blue Mountain Clinic works to schedule appointments for patients seeking abortion care as soon as we are able to. We are the only clinic in Montana that provides abortion care five days per week. The threat of ever-changing law and policy disrupts and strains our clinicians, administrative staff, and confuses our diverse patient population, to the point where patients may believe medication abortion is no longer a legal option for them. Each of us needs to be able to plan, to know what our schedule will look like the next day or the next week (to the best we are able), and so any energy spent on emergencies is about emergent issues our patients bring to us— emergencies should not be foisted upon us by courts or legislators.

Disrupting Access to Mifepristone By Mail

28. Although Blue Mountain Clinic's direct-to-patient telehealth abortion program for medication abortion is relatively new, it is critical for our patients who face the most challenges accessing in-person care, including those who would be traveling from more rural areas, Indigenous individuals who must travel from Reservation communities where there is no abortion access, people with disabilities, and people who struggle with gas money or those who do not have adequate transportation (like vehicles that can handle Montana's harsh winter weather). People who need to keep their abortion confidential because they live with an abusive partner, people who do not have control over their work schedule, or those who have to arrange for childcare, also benefit from the comparative ease of our direct-to-patient telehealth program.

29. For some, the requirement of an in-person visit is insurmountable and would cause patients to forgo abortion care. Others would try to manage the logistical arrangements—from time off of work or school, to childcare, and adequate transportation—but gathering the money for all of that can take time, pushing people further into pregnancy, and increasing the actual costs of obtaining an abortion later in pregnancy. Delay means a person continues to endure the symptoms and risks of pregnancy, and it can mean they are pushed too far to be eligible for a medication abortion or pushed beyond the point at which abortion is available in Montana.

30. As already noted, Montana is a huge and mostly rural state. Accessing medication abortion via direct-to-patient telehealth can be the difference between accessing abortion care or not. Reinstating a ban on dispensing mifepristone by mail would take mifepristone off the table as an option for these patients, who otherwise may be unable to make the in-person visit for a procedural abortion. As the FDA already acknowledges, there is simply no valid reason to turn the clock back and reimpose this barrier to a safe, effective medication that has been on the market for

23 years.

Restricting Certified Prescribers to Physicians

31. Blue Mountain Clinic has long relied on advanced practice clinicians to provide care, including abortion care. We currently have two physician assistants, both of whom provide medication abortions, and one of whom has done so for over 15 years. They are both exceptional, compassionate providers who our patients rely on for sensitive, essential care. State law has required that physician assistants practice under the supervision of a physician (for any care they provide, not only abortion care). Just last month, however, Montana passed a law (which also took effect immediately) that removed the physician supervision requirement, paving the way for further expansions in access to care for Montanans.

32. At the very same time, the REMS threatens to move mifepristone provision backward. Reinstating a requirement that permits advance practice clinicians, including PAs, to provide mifepristone, but requiring that a physician be the certified mifepristone prescriber—to order and prescribe the medication—makes no sense, undermines the licenses and contributions of advance practice clinicians, and overall, will limit access to this safe, essential medication.

33. Additionally, I understand that rolling back to the pre-2016 REMS threatens patients' access to mifepristone from All Families Healthcare, where the only clinician is a nurse practitioner. Blue Mountain Clinic is the next closest provider—though still approximately a three-hour drive one-way. When there was no abortion provider in the Kalispell area from around 2014 to 2018, before All Families Healthcare opened in 2018, Blue Mountain Clinic's clinicians were far busier with abortion patients. Reinstating the physician-only restriction for certified mifepristone providers would propel us backward and would increase travel barriers for Montanans for no valid reason whatsoever.

34. Decades of evidence and experience demonstrate that medication abortion with mifepristone is safe, effective, and the preferred option for many patients. As people in the health care field, we are trained to follow evidence and experience. There is no reason to continue maintaining the REMS at all. At a minimum, however, maintaining the 2023 REMS as the legal processes proceed would provide Blue Mountain Clinic, our providers, and patients, some certainty and stability.

DATED: 5 May 2023

Nicole Smith

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF HELEN WEEMS MSN, APRN-FNP, IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

HELEN WEEMS, MSN, APRN-FNP declares under penalty of perjury that the following is true and correct:

1. I am a nurse practitioner licensed to practice in Montana, and one of the plaintiffs in this case. I am the founder, owner, and sole clinician at All Families Healthcare ("All Families"), a sexual and reproductive health clinic in Whitefish, Montana, which opened in 2018.

2. I am also the only clinician providing abortion care in Northwest Montana. The next closest abortion provider is almost a 3-hour drive away, each way. Before All Families opened in 2018, the Northwest region had been without an abortion provider since 2014. And, prior to 2014, another advanced practice clinician—Susan Cahill, a physician assistant—was the only abortion provider in the region for many years.

3. I have a master's degree of science in nursing, family practice, from Vanderbilt University in Nashville, Tennessee. I am an advanced practice registered nurse, and I have been

board certified in family practice since 1999. I have full and independent practice authority in Montana—I do not practice in any official collaborative or supervisory relationship with a physician. I also have independent prescriptive authority from the Montana Board of Nursing. Additionally, I have a U.S. Drug Enforcement Authority ("DEA") license, which permits me to prescribe schedule II through V controlled substances.

4. For 22 years, I have provided health care services as a certified nurse practitioner. I have always provided patient-centered care based on trust and respect for my patients' decisions and use that same approach at All Families.

5. All Families serves nearly 600 patients per year, accounting for approximately 2,000 patient visits. We provide comprehensive sexual and reproductive health care services, including LGBTQ+ care and gender-affirming care; gynecological exams; same-day access to the full spectrum of contraceptive options, including insertion of IUDs and implants; diagnosis and treatment of sexually transmitted infections; miscarriage management; and abortion services.

6. At All Families, I provide medication abortion up to 11 weeks LMP and aspiration abortions up to 12 weeks and 6 days LMP. In 2022, I provided approximately 260 abortions. Medication abortion makes up well over half of the abortion care I provide—so far in 2023, medication abortion has been between 65% and 90% of the total abortion care I provide each month.

7. There are multiple regimens for medication abortion, including with mifepristone and misoprostol and with misoprostol alone. Since I became a certified mifepristone provider in 2018, I have used a mifepristone-misoprostol regimen for medication abortion. Patients obtain the medications from me at the clinic, or via mail after a telehealth visit (also called "direct-to-patient" telehealth). During a telehealth visit, I consult with a patient remotely about their available options,

review their prior medical history, and confirm the patient is eligible for medication abortion. I then write a prescription for mifepristone and misoprostol, which are dispensed via mail to the patient in Montana.

8. The mifepristone-misoprostol regimen for medication abortion is safe, effective, and evidence-based, and mifepristone is one of the safest medications available. While misoprostol-only is also a safe, effective, and evidence-based regimen used worldwide for medication abortion, mifepristone is a medical advancement that is preferable for many patients. The mifepristone-misoprostol regimen tends to have fewer uncomfortable side effects for patients. Evidence suggests that mifepristone is more effective than misoprostol alone, meaning there is a lower likelihood of ongoing pregnancy which would require follow up care—either additional medication or a procedure. Where both regimens are available, I prefer to use the mifepristone-misoprostol regimen. And my patients deserve the benefit of that medical progress.

9. My patients seek abortion services for a variety of reasons: some lack the financial means to raise a child; others are not ready to become a parent; many have physical and emotional health issues that would be exacerbated by continuing a pregnancy. In every circumstance, my patients deserve to be able to make the best decision for themselves, in consultation with the people they trust.

The 2023 REMS Has Imposed Unnecessary Restrictions on Patients and Providers

10. As a small, sole clinician practice in Whitefish, Montana, I am used to being nimble and innovative, to best serve my patients. As an abortion provider, however, each year, I am forced to confront increasing instability from hostile policies meant to undermine—not improve—the care I provide my patients.

11. The uncertain status of mifepristone is yet another one of those measures. The mere fact that it is subject to a REMS without any valid reason contributes to the idea that mifepristone

is unsafe and provides anti-abortion activists with unfortunate opportunities to further interfere with its accessibility.

12. The additional paperwork—the Patient Agreement and Medication Guide—suggests to patients that there is something to be concerned about with mifepristone, above and beyond other drugs that are equally safe.

13. For example, just before the Patient Agreement was updated in 2023, it included a statement that patients agreed to bring the Medication Guide to an emergency room in the rare event that they sought such care. But there is no reason for patients to take the Guide with them. And doing so can expose them to anti-abortion harassment and hostility in a health care setting where they deserve and should be able to expect compassion and care. Patients who take mifepristone for miscarriage are at the same risk because the Guide speaks about taking mifepristone for abortion.

14. The current Patient Agreement and Medication Guide can continue to be confusing for patients. For instance, both instruct that a patient take misoprostol 24 to 48 hours buccally after mifepristone. That does not account for the evidence-based protocol for vaginal administration of misoprostol, in which a patient takes misoprostol 6 to 72 hours following mifepristone. This protocol can be preferable for some patients who need or want more control over the timing of the medication abortion process—for example, for emotional reasons, or childcare or work constraints.

15. The special certification requirements for prescribers and pharmacists gate-keep access to mifepristone for no valid reason. Pharmacy certification means mifepristone is only available at select pharmacies that go through the hoops to become certified. It puts up an unnecessary roadblock for pharmacies that effectively prevents me from writing a prescription for

mifepristone a patient could pick up at local pharmacy as they do for many medications. And the prescriber certification and agreement requirements are unnecessary roadblocks for health professionals who can otherwise prescribe medications under their state licenses.

The Increasingly Hostile Legal and Policy Environment in Montana

16. When my clinic opened, I had to sue the State to block a criminal law that prevented me from providing abortion care because I am a nurse practitioner, rather than a physician. No similar law prevents me from providing the identical care to patients who need it to manage a miscarriage. The law I challenged prevented me from providing abortion care simply because it is abortion care. That law has been blocked since shortly after All Families opened in 2018. But, with each step in the judicial process, I wait for a court to decide whether I will be able to continue to provide abortion care I have been providing safely in Montana for 5 years.

17. In 2021, during the COVID-19 pandemic—which itself caused health care practices to quickly adjust to new circumstances—I and other Montana abortion providers waited on whether a court would block a set of abortion restrictions. One of those laws would have ended All Families' medication abortion by mail program, which had then become (and remains) critical to reach patients whose schedules make it challenging to make an in-person clinic visit or who live hours away, in remote rural areas of this vast state, or who opt to have an abortion in the privacy of their home.

18. Again this year, the State passed numerous restrictions on abortion, some with immediate or near-immediate effective dates. Individually and together, these policies could—on a moment's notice—decimate access to abortion care in Montana, which, today is bordered on all sides by states that have banned abortion, or where a court order has put a ban on hold. The instability into which mifepristone has been thrown—and therefore thrown my clinic and my patients—is no different.

The Chaos Created by the Texas *Alliance* Case

19. In advance of the Texas district court's ruling in the *Alliance* case, I developed medication abortion protocols without mifepristone. On Friday, April 7, the Texas ruling came down, apparently ordering mifepristone off the market. But the order would not take effect for 7 days. Then on Wednesday, April 12, the Fifth Circuit ruled, apparently ordering that, although mifepristone might still be on the market, we were going backward almost a decade, to the pre-2016 rules under which the generic form of the drug was no longer approved; I, as a nurse practitioner, could not be a certified mifepristone prescriber as I have been for 5 years; and All Families apparently would not be able to maintain its mifepristone by mail program with mifepristone. Additionally, for several years I had been a certified prescriber with GenBioPro (the generic manufacturer). After the Fifth Circuit ruled, I communicated with Danco (the manufacturer of the brand name drug) to ensure I remained a certified prescriber with Danco in case even though they are the same product, the generic became unavailable as the Fifth Circuit ruled—and assuming there was a way I could remain a certified prescriber as a nurse practitioner at all.

20. While still trying to sort through which set of rules abortion care might be governed by on Monday, the U.S. Supreme Court granted on Friday, April 14, another short pause—until 11:59 pm Eastern Time on Wednesday, April 19. That stay was then extended another two days, until Friday, April 21, at 11:59 pm Eastern. As I waited for notice from yet another court, I had to consider: When I saw patients on Tuesday, April 25, what set of restrictions would mifepristone be subject to? Would I be able to prescribe it? How much notice will my patients and I have? And what will the next weeks and months bring in this legal back and forth?

21. On Friday, April 21, the U.S. Supreme Court issued a stay that kept the status quo—the lower court orders would not take effect pending the Fifth Circuit's consideration of the appeal, and through the U.S. Supreme Court's review of that appeal, if that review occurs. For the next

few weeks, then, mifepristone would remain available, subject to 2023 restrictions. The legal back and forth, however, is not over. I still need to pay close attention to rapid legal developments in cases I am not involved in—unlike most other health care providers.

22. This is not how any other type of health care is practiced. It is not how any other small business is expected to operate. And it is not how any other patients are treated. Patients need to know whether they will be able to have their appointment the next day. I need to know whether I will see a patient the day they are scheduled. Especially as a small, solo practice, I need to know that when I buy medication, I will be able to use it. The instability and disruption my patients and I face simply because I provide and they seek abortion care is unrelenting, unjust, and unnecessary. It is also a deliberate effort to eliminate access to safe, compassionate abortion care.

23. I understand that a competing lawsuit brought in federal district court in Washington by 17 states and the District of Columbia has resulted in an order enjoining the FDA from enforcing the *Alliance* order in those states. Montana did not join that case initially, and I am not protected by that order. In fact, Montana's attorney general had asked to join the case as an intervenor to restrict the availability of mifepristone.

24. The threat of court orders turning back time to try to reinstate restrictions on mifepristone that were in place years ago remains. For example, the changes to the FDA's regulations that the Fifth Circuit ordered on April would be devastating to my practice.

Restricting Certified Mifepristone Prescribers to Physicians Only

25. Reinstating the physician-only certified prescriber requirement would mean I could no longer prescribe mifepristone as I have done for the last 5 years. As the only clinician at All Families, I am also the only certified mifepristone prescriber. Although the pre-2016 REMS permitted advance practice clinicians to provide mifepristone under the supervision of a physician

who is a certified prescriber, I do not work with a physician, and do not need a physician to prescribe mifepristone. As the only clinician at All Families and the only abortion provider in Northwest Montana, reverting to the old physician-only certified prescriber requirement could leave patients with no mifepristone provider.

26. Advanced practice clinicians have been critical to maintaining or restoring access to abortion in this region—including access to mifepristone—and this requirement would once again cut off that access.

27. Additionally, the requirement denies patients access to their *chosen* provider if that provider is me simply because I am a nurse practitioner. I have developed trusting relationships with my patients who come to me seeking intimate care. For 5 years I have provided that care with respect and compassion, free of judgment. This has made All Families a staple in Whitefish, beloved by the community. But preventing patients from accessing a safe, effective medication from me—for no other reason than an arbitrary distinction based on my credentials, not my experience or expertise—and in conflict with state licensure, makes no sense. It is unnecessary, disruptive for the patient, and strips them of a right to see a provider they trust.

28. Further, All Families' access to mifepristone will impact people from across Montana who seek medication abortion from me. Under the reinstated requirement, those patients, too, could seek this elsewhere—at one of the few clinics with physicians who provide abortion services in this state.

29. As the FDA itself concluded, restricting certified mifepristone prescribers to physicians only goes against overwhelming evidence and experience, including in Montana, which

demonstrate that advanced practice clinicians independently provide safe and effective abortion care on par with our physician counterparts. A consensus in the medical community agrees.[1]

30. Just as there is no reason to single out abortion care from the other care I provide, there is no reason to single out the mifepristone-misoprostol regimen simply because I am the clinician prescribing it. I can continue to prescribe potentially dangerous and addictive drugs, including, for example, Tylenol with codeine. Mifepristone is demonstrably safer than these medications, and, as the FDA itself knows, there is simply no valid reason to go backward and limit access to it.

Banning Mifepristone By Mail

31. More than half of all the abortion care I provide is medication abortion and more than half of the medication abortion care I provide is medication abortion by mail. That expansion in care opened up when a court order blocked the FDA from enforcing the in-person dispensing requirement in 2020. The FDA then temporarily suspended the requirement in 2021 and solidified that by updating the REMS in 2023 to eliminate this requirement.

32. The availability of mifepristone by mail has been critical to my patients. It provides flexibility and discretion, particularly for those who cannot take time from work, find childcare, or whose privacy would be jeopardized by making an in-person visit. It is also ideal for my many patients who live in the remote, rural regions of the state, which can be hours from All Families or the nearest clinic. Some live in the northeastern part of the state, about 9-10 hours away, and would otherwise have to travel through treacherous mountain passes and inclement weather to access

[1] *E.g.*, Nat'l Academies of Sciences, Engineering, and Medicine, Committee on Reproductive Health Services, *The Safety and Quality of Abortion Care in the United States* (2018); Tracy A. Weitz, et. al., *Safety of Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am J. Pub. Health 454-461 (2013).

abortion care. Patients may not have gas money or cars that can reliably and safely make it on these roads.

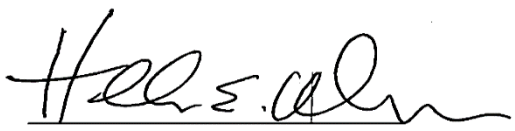
33. As the FDA's own decision to remove the ban on dispensing mifepristone via mail, reinstating the ban on mailing would propel patient care backward, with absolutely no benefit.

34. Before launching the medication abortion by mail program, patients would cancel or not show up to in-person appointments. During follow up calls, patients would say that something came up that made making the appointment impossible: they could not take off from work, a family member did not show up to take care of the kids, their car had broken down or could not handle the weather, they could not afford gas to travel to the clinic, or they could not discretely attend the appointment for fear of someone finding out. Since starting our telehealth and mail program, cancellations or no-shows are far more rare, and patients are able to access private, time-sensitive, safe and effective abortion care.

35. There is no basis to continue any of these restrictions in light of the established safety of mifepristone.

36. Providing high-quality abortion care in an increasingly hostile environment is challenging enough without having to contend with the fallout from the Texas *Alliance* case. At a minimum, having certainty that the status quo of regulation to which mifepristone was subject on April 7, 2023, applies, would allow All Families to continue to provide basic, safe, and effective care for our patients.

DATED: May 5, 2023



Helen Weems, APRN-FNP

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF AMY HAGSTROM MILLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

AMY HAGSTROM MILLER hereby declares under penalty of perjury that the following statements are true and correct.

1. I provide the following testimony based on my personal knowledge and review of Whole Woman's Health Alliance's, Whole Woman's Health's, and Whole Woman's Health of the Twin Cities, LLC's business records in support of Plaintiffs' Motion:

2. The clinics I operate are independent abortion providers, or abortion clinics that are not affiliated with any national organization (such as Planned Parenthood). Independent abortion providers provide approximately 60% of abortion care in the country.

3. I have been working in the abortion care field since 1989. I have done virtually every clinic job over the past three decades, from receptionist to sonographer to pathology technician to surgical assistant to counselor. I have spent thousands of hours talking with abortion patients over the course of my career. In my current role, I oversee all operations at the WWH and WHHA clinics as well as WWH's Virtual Program, from staff management, to clinic

security, to clinical services for patients. I am thoroughly familiar with all aspects of abortion clinic operations and patient care.

4. WWH was founded in 2003 and we have been providing medication abortion from the beginning. I, along with our clinicians, management, and staff, have lived through each iteration of the FDA's changes to the approval, labeling, and safety requirements of mifepristone. We have operated within the constraints of the Risk Evaluation and Mitigation Strategy ("REMS") which, far from improving our patients' experience with mifepristone, has made it more burdensome and difficult for patients to access. While each iteration of the REMS has posed challenges to our staff and our patients, the last several weeks have been the most challenging.

Whole Woman's Health of Charlottesville

5. I am the President and Chief Executive Officer ("CEO") of Whole Woman's Health Alliance ("WWHA").

6. WWHA is a nonprofit organization incorporated under Delaware law. Its mission is to provide abortion care in underserved communities, shift the stigma around abortion in our culture, and ensure that every pregnant person deserves the compassion, respect, and dignity of being able to safely and legally end a pregnancy.

7. WWHA currently operates abortion clinics in Charlottesville, Virginia, Bloomington, Minnesota, and South Bend, Indiana.

8. As President and CEO of WWHA, I oversee all aspects of the organization's work.

9. Whole Woman's Health of Charlottesville ("WWH of Charlottesville") provides abortion services up to 16 weeks, as dated from the first day of the patient's last menstrual period

("LMP"), including medication abortion up to 11 weeks LMP. We provide medication abortion up to 11 weeks consistent with evidence-based practice around the country.

10. Since WWH of Charlottesville started providing medication abortion in October 2017, it has been providing it using the FDA approved mifepristone/misoprostol regimen.

11. WWH of Charlottesville does not currently have any advanced practice clinicians providing abortion care but is actively recruiting for such providers.

12. The patients we treat at WWH of Charlottesville largely travel to our clinic from small towns or rural areas of Virginia without abortion providers or from out of state. Most patients travel from at least 1.5-2 hours away, and most require financial assistance to cover the cost of their abortion. WWH of Charlottesville serves large swaths of Appalachia, including patients from West Virginia, Kentucky, and Tennessee (where abortion is now banned) and Georgia (where a 6-week ban is in effect). WWH of Charlottesville provides abortion care to approximately 750 patients per year, and approximately 60% of those receive medication abortion.

Whole Woman's Health of Alexandria

13. I am also the President and CEO of Whole Woman's Health, LLC ("WWH").

14. WWH currently operates an abortion clinic in Alexandria, Virginia, d/b/a Whole Woman's Health of Alexandria ("WWH of Alexandria). WWH also operates abortion clinics in Baltimore, Maryland and Albuquerque, New Mexico.

15. As President and CEO of WWH, I am responsible for the management of these clinics and therefore am familiar with our finances and operations, including the services we provide and the communities we serve.

16. WWH of Alexandria provides abortion services up to 16 weeks LMP, including medication abortion up to 11 weeks LMP.

17. WWH of Alexandria originally opened in 2019 under the name Whole Woman's Health and Family Center and began using the d/b/a name Whole Woman's Health of Alexandria in 2022. Since opening, it has provided medication abortion using the FDA approved mifepristone/misoprostol regimen.

18. WWH of Alexandria currently employs a nurse practitioner who provides medication abortion to patients in-clinic, and has employed other advanced practice clinicians in the past. Since the clinic opened, nurse practitioners have provided around 1,500 medication abortions, which is more than 40% of the total medication abortions.

19. WWH of Alexandria serves a remarkably diverse population of patients, most of whom require financial assistance, and 6-7 languages are spoken by both our patients and our staff. Because WWH of Alexandria is close to a large airport, many of our patients travel to us by plane from states where abortion in banned. Patients travel from West Virginia, Kentucky, Tennessee, and Georgia, and other states in the deep south, including many patients from Texas. WWH of Alexandria provides abortion care to approximately 2,300 patients per year, and approximately 64% of those receive medication abortion.

Whole Woman's Health's Virtual Abortion Care

20. I am also the President and CEO of Whole Woman's Health of the Twin Cities, LLC, which has operated a virtual healthcare program since August of 2021 that provides telehealth services for medication abortion in Virginia, Maryland, Minnesota, New Mexico, and Illinois ("WWH's Virtual Program").

21. WWH's Virtual Program provides telehealth medication abortion services up to 11 weeks LMP using the FDA approved mifepristone/misoprostol regimen.

22. WWH's Virtual Program provides medication abortion to approximately 2,400 patients per year, and the majority of those patients seek telehealth in Virginia. Around half of our virtual patients live in the states where we provide telehealth, while the other half travel to those states from other places. For our Virginia patients specifically, around half are Virginians who choose telehealth over coming to a clinic in person. Many patients require funding to pay for their telehealth abortion, both for the visit and any associated travel to the states where telehealth is available.

The REMS Has Led to Chaos in the Healthcare System

23. As abortion providers who, until *Roe v. Wade* was overturned in June 2022 operated abortion clinics in Texas, we are no stranger to the instability created by anti-abortion laws and policies. The chaos regarding the legal status of mifepristone over the last several weeks is reminiscent of our prior experiences in Texas and elsewhere.

24. Before being forced to close our Texas clinics in 2022, WWH and WWHA operated multiple abortion clinics in Texas. For years, regulatory interference in Texas caused us to endure constant service disruptions, ranging from changing our medical practices and protocols, to mandatory construction remodeling, to temporary or permanent closures due to rapid fire judicial orders. The result was incredibly destabilizing for our staff and patients. As those outside the field fail to grasp, healthcare practices cannot change overnight.

25. For example, in 2013, Texas passed House Bill 2, a law that required all abortion facilities to be licensed ambulatory surgical facilities and all abortion providers to have local hospital admitting privileges. Because WWH lacked sufficient physicians with admitting

privileges in Beaumont and Austin, we had to shut those clinics down. Additionally, our clinic in McAllen was shut down for eleven months and was only reopened because of an injunction awarded by a district court. Ironically, one of our physicians in Austin was able to obtain admitting privileges in Fort Worth, and so he commuted by plane in order to keep our clinic in Fort Worth open. While H.B. 2 was ultimately struck down in 2016 as unconstitutional by the Supreme Court, WWH was severely strained by the litigation.

26. In early 2020, we had a similar experience when the Texas Governor issued a COVID-19 executive order that forced all of the abortion providers in the state to stop providing abortions for around three weeks. While there were brief periods of time during those three weeks when court orders technically permitted us to reopen, practically speaking, it was impossible to call patients back quickly enough before another court order shut down abortion access once again.

27. In 2021, we again faced on-again off-again chaos when S.B. 8, the 6-week abortion ban enforced via a vigilante bounty-hunting scheme, took effect. A district court entered a preliminary injunction that was only in effect for several days before another court order reversed it again, leaving us with whiplash. While our Texas clinics continued to provide abortions under 6 weeks until *Roe* was overturned, we never recovered.

28. Now, our remaining clinics in Virginia and other states where abortion remains legal are facing extreme destabilization to patient care once again. First, on April 7, a district court in Texas issued an order saying that mifepristone could no longer be used anywhere in the country and gave the FDA only a week to seek emergency appeals. We immediately worked to develop protocols for non-mifepristone medication abortion protocols. But that same day, a district court in Washington issued an order requiring the FDA to maintain the status quo for

mifepristone but only in select states. While most of the states where WWH operates were included in that order, Virginia was not. We were left to figure out how, if at all, our use of mifepristone for patients in Virginia would need to differ from the rest of the country.

29. Then on April 12, the Fifth Circuit put part of the Texas order on hold. The Fifth Circuit's order only added to the confusion, as it said that while mifepristone could still be used, the FDA's changes to the REMS from 2016 onward were no longer in effect. Presumably this meant the court intended us to go back in time and use non-evidence based, outdated protocols for medication abortion. But did this apply to our clinics nationwide, or only in Virginia? We were still scrambling to make sense of this order when, hours before it was set to take effect, the U.S. Supreme Court put it on hold, but only for a couple days. That order was extended until April 21, 2023.

30. For our leadership and staff, the last few weeks have been extremely disruptive. We have devoted significant time to developing multiple new protocols that we do not know if we will ever need to use. We have re-written clinic procedures and patient consent forms. We have tried to prepare staffing for increased demand for procedural abortions and increased need for after-hours call. We have been doing our own medical research, reading studies to help inform new policies and procedures. When the Fifth Circuit's order came out, we also had to start looking for paperwork we haven't used in a decade and that may no longer exist. We have clinicians who have only ever worked in our virtual program and clinics that no longer have the equipment to comply with the 2016 REMS. In one week, we had four separate all staff meetings. All of this takes time, energy, and resources. This is time that is taken away from patient care.

31. Our patients are suffering too. We are seeing an increased call volume from confused and even panicked patients: many patients think that medication abortion is already

banned, and others are understandably confused about whether or not their appointments have been canceled. Pregnant people are scared that their rights are already gone, again.

32. We are also seeing an increased demand for procedural abortions because patients think that medication abortion is already banned. This is particularly challenging for clinics to manage because post-*Dobbs*, with abortion entirely banned in 13 states, there are many fewer clinics able to absorb the demand for procedural abortions. Telehealth has been instrumental in allowing clinics to meet the demand for abortions, and estimates indicate that after *Dobbs*, abortions provided via telehealth increase 137%.[1]

33. Throughout this dizzying time, our clinicians and staff—none of whom are party to any of the existing litigation—have been left to make sense of conflicting court orders, explain them to patients, and find some way to continue on with quality, evidence-based patient care. Neither we nor our patients have had any say in the matter. As a longstanding abortion provider, I know that regulatory interference with patient care creates chaos, and that chaos is by design.

34. The disruptions and constant instability have been extremely damaging to the emotional wellbeing of the abortion healthcare taskforce. As abortion bans took effect nationwide, our staff in Virginia and elsewhere watched their colleagues in Texas lose their jobs after decades of dedication to providing abortion care. Now they wonder if they will be next.

35. At base, the medically unnecessary REMS restrictions, with their burdens on patients and clinicians, and the unfounded safety concerns they have generated, have significantly contributed to the chaos surrounding medication abortion provision.

[1] *#WeCourt Report*, Society of Family Planning (April 11, 2023), https://www.societyfp.org/wp-content/uploads/2023/03/WeCountReport_April2023Release.pdf.

Restricting Certified Mifepristone Prescribers to Physicians Only

36. Whole Woman's Health clinics currently employ and seek to employ advanced practice clinicians ("APCs") like nurse practitioners to provide medical services within their scope of practice, including administering or dispensing medication abortion. WWH of Alexandria, for example, only has physicians providing abortion Thursday through Saturday, so employing APCs allows the clinic to offer abortions for the rest of the week and frees up clinic space and resources for later abortion cases over the weekend. Yet under the physician-only certified prescriber requirement in the REMS for mifepristone, APCs can only provide mifepristone if done so under a certified prescriber and supervisory relationship. The FDA eliminated this requirement of the REMS in 2016 precisely because it was overly onerous and medically unnecessary.

37. Reinstating the physician-only certified prescriber requirement would complicate WWH's operations and recruiting of APCs with no benefit to patient care.

Banning Mifepristone by Mail

38. Telehealth has been a significant innovation in the provision of medical care, particularly to underserved and rural communities. The COVID-19 pandemic in particular led to significant improvement in patient access to and comfort with using telehealth services for any number of medical conditions. The optimal use of telehealth in the provision of abortion care, however, depends on the ability to dispense mifepristone remotely. Because the REMS still prohibit clinicians from writing a prescription for mifepristone, the only remote option for distribution of mifepristone is by mail.

39. If clinicians are required to dispense mifepristone in person, their patients are forced to travel to the clinic to pick up the medication, even if doing so requires significant travel and other logistical challenges.

40. After temporarily suspending the in-person requirement during the COVID-19 pandemic, the FDA updated the REMS in January of 2023 to permanently eliminate the requirement.

41. For WWH and our patients, this change in the REMS was huge. It allowed us to build out our telehealth practice and begin working with a mail order pharmacy to dispense mifepristone.

42. In turn, WWH's Virtual Program has been critical in allowing WWH to meet the demand for abortions from patients traveling from states where abortion is now banned. The program allows us to free up clinic space and appointment times for patients who either prefer procedural abortion or who need a procedural abortion, particularly patients traveling from out of state. At our clinics nationwide, we are seeing many more patients pushed later into pregnancy by abortion bans in their states, so we have been forced to find ways to serve more patients in need of second trimester abortions. Telehealth has been instrumental in that effort.

43. For example, expanding our virtual program to New Mexico allowed us to continue seeing patients traveling from Texas, even after our Texas clinics were forced to close. Even though we now have a clinic site in New Mexico, almost all of our patients seeking telehealth in New Mexico travel from out of state. The virtual program allows patients to reduce their travel time and expense and helps ease clinic congestion. This is particularly important

because the New Mexico clinics, who have been inundated with patients traveling from out of state since *Roe v. Wade* was overturned, often have a 3-week wait for appointments.[2]

Harm of the 2023 REMS

44. While the FDA's decisions to follow at least some of the science and remove many onerous and medically unnecessary restrictions on mifepristone over the years has helped our patient access care, barriers still remain. The requirements that providers and pharmacies be certified and patients and providers sign agreements do nothing to improve patient care. Rather, they significantly add to the operational and logistical burden of administering and dispensing medication abortion, reduce the pool of clinicians we can hire to provide medication abortion, and incorrectly leave some with the impression that mifepristone is less safe than it is. Critically, these requirements effectively prevent a physician from writing a prescription for mifepristone that would allow a patient to pick the drug up at their local pharmacy.

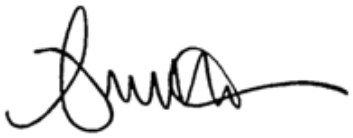
45. We have decades of evidence demonstrating that medication abortion with mifepristone is safe, effective, and preferable for many patients. In our experience, patients prefer medication abortion for a variety of reasons, including: it is less medicalized; it is more private and allows patients, particularly those in abusive relationships, to play off their abortion as a miscarriage to protect their own safety; it can be done on the patient's schedule; it allows the patient to have more control; it is more appropriate for some survivors of sexual assault; and it is medically indicated for some common health conditions like fibroids or obesity and certain kinds of cervical anatomy.

[2] *See* Elise Kaplan, *'They're Fearful': What New Mexico Abortion Providers are Seeing as Their Patient Numbers Soar*, Albuquerque Journal (Mar. 25, 2023), https://www.abqjournal.com/2585163/theyre-fearful-what-new-mexico-abortion-providers-are-seeing-as-their-numbers-of-patients-soar.html.

46. I think it is high time that the FDA eliminated the REMS altogether. It is the evidence-based and patient-centered thing to do.

47. At a minimum, it is critical to the care of our patients, the sustainability of our medical clinics, and the retention of our clinicians and staff that the 2023 REMS be maintained while this and other litigation proceeds.

Dated: May 8, 2023



Amy Hagstrom Miller