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

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. In the wake of the overruling of *Roe v. Wade*, Plaintiffs, who are independent abortion providers in Virginia, Montana, and Kansas, have made herculean efforts to provide high-quality, compassionate, patient-centered abortion care. They have done so not only for residents of their states, but also for the thousands of patients forced to travel hundreds of miles for basic healthcare from the 13 states and counting where abortion is now banned, and the many others where it remains severely restricted. Pregnant people who struggle to make ends meet, live in rural areas, and have limited access to healthcare face more barriers than ever to accessing abortion.

These barriers are also particularly severe for people of color and people with disabilities who experience significant disparities in healthcare access and maternal health outcomes.

2. In order to meet the needs of their patients, Plaintiffs rely on the ability to prescribe medication abortion, which is safe and effective, less expensive and less resource-intensive than procedural abortion, and preferred by many patients. Plaintiffs all use a two-drug regimen for medication abortion, where patients take the first drug, mifepristone, followed by a second drug, misoprostol, around 24-72 hours later. Medication abortion, and specifically, provision of mifepristone by advanced practice clinicians (including nurse practitioners and physician assistants) and the availability of medication abortion by mail ("direct to patient telehealth") has been critical to their efforts to meet people's need for abortion care.

3. Not content with—as they claimed—"return[ing] the issue of abortion to the people's elected representatives," *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022), anti-abortion activists have turned their attention to restricting abortion nationwide. Their latest attack is on medication abortion, seeking to curtail its availability anywhere and by any means necessary, including in states where abortion remains legal and even protected.

4. The two-drug medication abortion regimen has been used safely and effectively for the past 23 years by over five million Americans. Despite this strong track record of safety and the well-documented benefits of medication abortion for many patients—including survivors of sexual assault, pregnant people with certain common chronic conditions, and those who prefer to manage their abortion care in a private location—mifepristone has faced unique and discriminatory scrutiny, which has generated significant stigma. From the very beginning, mifepristone has been treated differently from comparable drugs.

5. It is time that defendants the United States Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS") follow the science, respect pregnant people's autonomy, and discard the unique set of restrictions known as a Risk Evaluation and Mitigation Strategy ("REMS") it has applied to mifepristone in various guises since its approval. FDA's decision to continue these burdensome restrictions in January 2023 on a drug that has been on the market for more than two decades with only "exceedingly rare" adverse events has no basis in science. It only makes mifepristone harder for clinicians to prescribe, harder for pharmacies to dispense, and harder for patients to access. And, by making mifepristone *seem* uniquely dangerous, FDA's continuing restriction of mifepristone stigmatizes medication abortion and contributes to the chaos anti-abortion activists now sow. Plaintiffs are continuously facing the weaponization of the REMS by anti-abortion activists around the country.

6. Ensuring that access to mifepristone is based on science and the needs of patients has only increased in urgency over the last few weeks. Federal district courts in Texas and Washington have issued competing orders regarding mifepristone's continued accessibility. The Texas order purports to "stay" the effective date of FDA's 2000 approval of mifepristone, which could render it unavailable anywhere. *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-223-Z, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023) (the "*Alliance* Case"). A subsequent order from the Fifth Circuit modified the Texas order, purporting to turn back time and reinstate one version of the REMS that was in place prior to 2016—including restricting certified prescribers of mifepristone to physicians only (not advanced practice clinicians) and banning direct to patient telehealth. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *1, *17, *21 (5th Cir. Apr. 12, 2023) (per curiam). Meanwhile, the Washington order enjoins FDA from "altering the status quo and rights" as to the availability of mifepristone under the REMS in place

as of January 2023 in 17 states and the District of Columbia, *Washington v. FDA*, No. 1:23-CV-3026-TOR, 2023 WL 2825861, at *11 (E.D. Wash. Apr. 7, 2023), "irrespective of" the Texas and Fifth Circuit decisions, *Washington v. FDA*, No. 1:23-CV-3026-TOR, 2023 WL 2941567, at *2 (E.D. Wash. Apr. 13, 2023). Anti-abortion activists are continuing with other efforts to threaten mifepristone, including a citizen petition to FDA by Students for Life seeking to have mifepristone's approval revoked because it somehow endangers the environment.[1]

7. Although the Supreme Court has 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), threats to the availability of mifepristone continue to loom large—prompting a growing number of states to stockpile large amounts of mifepristone even after the Supreme Court's stay. As Monica Simpson, Executive Director of SisterSong Women of Color Reproductive Justice Collective and an abortion access advocate in Georgia, attested, although access remains for now: "the week-by-week uncertainty of not knowing the fate of this access" remains.[2]

8. Plaintiffs—independent abortion providers with limited resources in hostile states—are caught in the middle of this maelstrom. They provide care in states that are party to neither case and are thus in a particularly precarious and uncertain position. Plaintiffs cannot retool their practices overnight with no notice—healthcare has no on/off switch. They and their patients require clarity around their continued provision of mifepristone.

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[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.

[2] Ava Sasani, *The Decision Brought Vows to Keep Fighting from Both Sides of the Abortion Debate*, N.Y. Times (Apr. 21, 2023), https://www.nytimes.com/2023/04/21/us/abortion-pill-supreme-court-reactions.html.

9. No other facet of healthcare is treated in this way, much less any other essential medication with such an established record of safety and efficacy. It is neither rational nor sustainable, especially in light of the unique challenges Plaintiffs now face in the post-*Roe* world.

10. Throughout this chaos, there is one constant: mifepristone remains a highly safe and effective medication and it remains essential for patients. FDA has recognized these basic facts time and again, and yet continues to subject the drug to medically baseless restrictions, prompting repeated attempts to target mifepristone for further restriction or outright removal from the market. Without relief, Plaintiffs remain vulnerable to the continued attacks on medication abortion from anti-abortion activists and state and federal regulators across the country who will continue to weaponize FDA's REMS while they stand.

11. Plaintiffs request that the Court order FDA to remove the REMS restrictions that have, for too long, impeded access to medication abortion, and are the source of the current chaos for people seeking essential abortion care nationwide. In the alternative, Plaintiffs seek an order enjoining Defendants from altering the availability of mifepristone under the January 2023 REMS, to ensure some modicum of certainty and continued patient access to a safe, effective medication that has been repeatedly targeted simply because of its association with abortion.

JURISDICTION AND VENUE

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

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

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

15. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a judicial district in which Plaintiff Whole Woman's Health Alliance resides and Defendants' policies adversely affect the health and wellbeing of residents in this district.

PARTIES

I. Plaintiffs

Whole Woman's Health Alliance

16. Plaintiff Whole Woman's Health Alliance ("WWHA") is a nonprofit organization committed to providing holistic reproductive care for its patients. It operates Whole Woman's Health of Charlottesville ("WWH of Charlottesville"), a healthcare facility located in Charlottesville, Virginia that provides abortion services up to 16 weeks as dated from the patient's last menstrual period ("LMP"),[3] including medication abortion up to 11 weeks LMP, and miscarriage management. WWH of Charlottesville started providing medication abortion in October 2017 and has been providing medication abortion using the FDA-approved, evidence-based mifepristone/misoprostol regimen ever since.

17. While WWH of Charlottesville currently has physicians providing all of its abortion care, it is actively recruiting advanced practice clinicians to join its staff to provide abortion care.

18. WWHA sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

[3] Consistent with standard medical practice, gestational ages as used in this complaint are dated from the first day of the patient's last menstrual period ("LMP"), which is typically approximately two weeks before the estimated date of fertilization of a pregnancy.

Whole Woman's Health

19. Plaintiff Whole Woman's Health ("WWH") operates a licensed healthcare facility in Alexandria, Virginia ("WWH of Alexandria") that provides abortion services up to 16 weeks LMP, including medication abortion up to 11 weeks LMP, and miscarriage management. 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.

20. WWH of Alexandria currently has a nurse practitioner on staff who provides medication abortion to patients in-clinic.

21. WWH sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Whole Woman's Health of the Twin Cities, LLC

22. Plaintiff Whole Woman's Health of the Twin Cities, LLC ("WWH of the Twin Cities") 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 of the Twin Cities provides telehealth medication abortion services up to 11 weeks LMP using the FDA-approved mifepristone/misoprostol regimen to approximately 2,400 patients per year, the majority of whom are in Virginia.

23. As part of its telehealth abortion services, WWH of the Twin Cities provides medication abortion to patients in Virginia via direct to patient telehealth. For this service, a provider meets with a patient via a telehealth visit, confirms that the patient is eligible for medication abortion, and obtains informed consent. The medications are then mailed to the patient.

24. While WWH of the Twin Cities currently has physicians providing all of its abortion care, it would like to hire advanced practice clinicians to work in its telehealth program.

25. WWH of the Twin Cities sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Blue Mountain Clinic

26. Plaintiff Blue Mountain Clinic ("Blue Mountain") is a family practice in Missoula, Montana. It first opened in 1977 as the first and only abortion clinic in the state of Montana. In 1991, Blue Mountain expanded its health services to include comprehensive family medical care to better serve its community. Blue Mountain serves over 3,000 patients annually. It provides care across the lifespan, from pediatric care to elder care, including wellness exams, contraception, abortion care, and gynecological care. Blue Mountain provides medication abortion (in person and via telehealth) up to 11 weeks LMP and procedural abortions up to 21.6 weeks LMP, along with miscarriage management.

27. Blue Mountain's primary physician and its two physician assistants provide medication abortion using the FDA-approved, evidence-based mifepristone/misoprostol regimen. Blue Mountain also provides direct to patient telehealth, in which a provider meets with a patient via a telehealth visit, confirms that the patient is eligible for medication abortion, and obtains informed consent. The medications are then mailed to the patient at a Montana address.

28. Blue Mountain sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Helen Weems and All Families Healthcare

29. Plaintiff Helen Weems is a certified nurse practitioner licensed to practice in Montana with over 20 years of clinical experience. She owns All Families Healthcare and is its

sole clinician and sole certified mifepristone prescriber. She is also the sole provider of abortion care in Montana's Flathead Valley.

30. Ms. Weems sues on her own behalf and on behalf of her patients.

31. Plaintiff All Families Healthcare is a sexual and reproductive health clinic in Whitefish, Montana, that provides LGBTQ+ care and gender-affirming care for transgender people, gynecological exams, diagnosis and treatment of sexually transmitted infections, contraception, and abortion care. All Families has been serving the Flathead Valley and patients across the entire state of Montana and beyond since it opened in 2018 and serves approximately 600 patients each year. All Families provides medication abortion (in person and via telehealth) up to 11 weeks LMP and procedural abortion up to 12.6 weeks LMP, along with miscarriage management. All Families provides medication abortion by direct to patient telehealth.

32. All Families sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Trust Women

33. Plaintiff Trust Women operates clinics in Wichita, Kansas, and Oklahoma City, Oklahoma. Its mission is to provide essential and compassionate care to underserved populations. In Wichita, Kansas, 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.

34. Trust Women Wichita provides medication abortion up to 11 weeks LMP using the mifepristone/misoprostol regimen, as well as procedural abortion up to 21.6 weeks LMP and miscarriage management.

35. Until 2018, Trust Women Wichita offered a telemedicine clinic for medication abortion, but was forced to stop that practice due to a Kansas state law. That law is now enjoined, and Trust Women Wichita is eager to restart its telemedicine clinic, including implementing direct to patient telehealth provision of mifepristone. But Trust Women Wichita has paused these plans given the cloud of uncertainty over mifepristone.

36. Trust Women sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

II. Defendants

FDA

37. Defendant FDA is an agency of the federal government within HHS. FDA is responsible for administering the provisions of the federal Food, Drug, and Cosmetic Act ("FDCA") that are relevant to this Complaint.

38. Defendant Robert M. Califf, M.D., is the Commissioner of FDA and is sued in his official capacity. He is responsible for administering FDA and its duties under the FDCA.

HHS

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

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

ALLEGATIONS

I. FDA Has Repeatedly and Correctly Concluded that Mifepristone is Safe and Effective

41. In September 2000, FDA first approved mifepristone under the brand name Mifeprex,[4] developed by Danco Laboratories, to be used with the already approved drug misoprostol in the two-drug regimen: (1) mifepristone, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol, which causes uterine contractions that expel the pregnancy from the uterus. Shortly after taking mifepristone and then misoprostol, a patient will experience bleeding akin to a heavy period or a miscarriage.[5]

42. To date, mifepristone has been used by over five million Americans.

43. FDA's initial approval of mifepristone was the result of a thorough, nearly five-year scientific review that determined mifepristone was safe for widespread use in the United States.

44. Mifepristone had already been approved in multiple countries across the world before being approved for use in the United States, and FDA reviewed extensive evidence from those countries.[6] Specifically, FDA reviewed: (1) three clinical trials that together involved 4,000 women—two French trials that were complete at the time of the application, and one then-ongoing United States trial for which summary data on serious adverse events was available;[7] (2) results

[4] U.S. Food & Drug Admin., NDA 20-687 Mifeprex Approval Memo, Sept. 28, 2000, attached hereto as Ex. A.

[5] *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), attached hereto as Ex. B.

[6] U.S. Food & Drug Admin., Medical Officer's Review of NDA 20-687, at 2 (Nov. 1999), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf, attached hereto as Ex. C; *see also* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022).

[7] Ex. B (FDA Approval and Oversight of Mifeprex) at 15.

from other European data, including a database of approximately 415,000 women who received the mifepristone/misoprostol regimen;[8] and (3) data on the drug's manufacturing and chemistry.[9]

45. Based on its extensive review, in 2000, FDA concluded that there is "substantial evidence that Mifeprex is safe and effective for its approved indication in accordance with [the FDCA]"[10] and that mifepristone was safe for use in the United States.

46. In 2016, 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.

47. FDA updated the label for Mifeprex in 2016 to reflect the mounting research supporting the safety and efficacy of mifepristone.

48. Overall, in the 2016 review, FDA concluded: "[Mifeprex] has been increasingly used as its efficacy and safety have become well-established by both research and experience," "serious complications have proven to be extremely rare," "no new safety concerns have arisen in recent years," and "known serious risks occur rarely."[11]

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[8] 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 8 (Mar. 29, 2016) (hereinafter Citizen Petition Denial) attached hereto as Ex. D.

[9] Ex. B (FDA Approval and Oversight of Mifeprex) at 15.

[10] Ex. D (Citizen Petition Denial) at 8.

[11] 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), attached hereto as 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"), attached hereto as Ex. F.

49. FDA has 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."[12]

50. Still further, FDA has stated that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low" for Mifeprex.[13]

51. In reaching those conclusions, FDA relied on no fewer than 11 independent clinical studies, collectively representing "well over 30,000 patients," and conclusively showing "serious adverse events" at rates "generally far below 1.0%."[14]

52. The 2016 review cited a host of studies showing that the rate of major adverse events was roughly 0.3%, with multiple studies reporting even lower rates of infection (such as 0%, 0.014%, and 0.015%).[15] *Hundreds* of additional high-quality studies conducted since mifepristone's 2000 approval show the same. Mifepristone has been used in over 600 published clinical trials and discussed in nearly 800 medical reviews.[16]

53. FDA determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result

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[12] 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), attached hereto as Ex. G.

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

[14] *Id.* at 50, 56.

[15] *Id.* at 54, 56.

[16] Based on a review of publications on PubMed. *See generally* PubMed, Nat'l Library of Med., https://pubmed.ncbi.nlm.nih.gov/?term=mifepristone (last visited Apr. 27, 2023).

in patients being in an "appropriate and safe location" when cramping and bleeding caused by the drug would begin.[17]

54. FDA's 2016 review further 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%—and none of these can be causally attributed to mifepristone.[18] In either case, that is far less than the risk of death from the use of Viagra[19] or over-the-counter medications such as acetaminophen.[20]

55. 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.[21]

56. In updating the Mifeprex label in 2016, FDA stated: "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth" and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[22]

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[17] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Summary Review 15 (Mar. 29, 2016) (hereinafter 2016 Summary Review), attached hereto as Ex. H.

[18] 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), attached hereto as Ex. I (concluding that there are 28 reported deaths total, which are included in the adverse events summary "regardless of causal attribution to mifepristone," and these cases include instances of homicide, drug overdose, ruptured ectopic pregnancy, and sepsis.)

[19] 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).

[20] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) (hereinafter National Academies Report), http://nap.edu/24950; Suneil Agrawai & Babek Khazaeni, *Acetaminophen Toxicity*, Nat'l Library of Med. (Feb. 12, 2023), https://www.ncbi.nlm.nih.gov/books/NBK441917.

[21] Ex. D (Citizen Petition Denial) at 25 n.69.

[22] Ex. F (Mifeprex Labeling) at 2, 16.

57. FDA found that mifepristone was just as safe when administered by an advanced practice clinician as it was when administered by a physician, noting that "5 studies clearly demonstrate[] that efficacy is the same with non-physician providers compared to physicians."[23]

58. FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments.

59. Relying on the updated safety data and efficacy it had collected for mifepristone, FDA made several changes to the REMS, including allowing a broader set of healthcare providers, rather than only physicians, to become certified prescribers of mifepristone, and several changes to the labeling, including increasing the indicated gestational limit from 49 to 70 days and reducing the indicated number of in-person clinic visits to one.[24]

60. In 2019, FDA approved an abbreviated new drug application for a generic version of mifepristone from GenBioPro, relying on the extensive safety and efficacy determinations made in connection with Danco's Mifeprex.

61. 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.).

62. 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-

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

[24] 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).

person dispensing requirement had been enjoined, the availability of direct to patient telehealth showed no increases in serious patient safety concerns.[25]

63. On January 3, 2023, FDA removed the in-person dispensing requirement permanently due to the proven safety record of dispensing mifepristone through direct to patient telehealth.[26]

64. Finally, when the safety of mifepristone was called into question by anti-abortion activists in a lawsuit filed in November 2022, FDA defended its approval of mifepristone by repeatedly emphasizing its proven safety record 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).

65. FDA's analysis of mifepristone's safety has been echoed by other leading medical organizations. In 2018, the National Academies of Sciences, Engineering, and Medicine ("National Academies"), a universally respected non-partisan advisory institution, reviewed all available scientific evidence 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"[27] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[28] This massive body of

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[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), attached hereto as 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] National Academies Report, *supra* n.20, at 45, 79.

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

evidence has shown that mifepristone is safer than many other common drugs, including Viagra and penicillin, and over-the-counter drugs like Advil and Tylenol. This evidence has specifically shown that mifepristone is safe and effective when provided without an in-person visit, by advanced practice clinicians, and through 11 weeks of pregnancy.

II. Mifepristone is Essential Medication for People's Health and Wellbeing

66. People end their pregnancies with medication or by procedure. Many people seek medication abortion with mifepristone because it can be easier to access, particularly for patients in communities facing the most obstacles to care, including Black, Indigenous, and other people of color, those with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and those living at the intersection of those identities.

67. Medication abortion actively reduces what may be insurmountable barriers people face in accessing abortion care. People commonly take mifepristone at home following a consultation with a healthcare provider because they can have an abortion in privacy, at a place of their choosing, and with the support of their immediate network.[29] And it allows people to forgo the physical contact and vaginal insertions of a procedural abortion, which may be particularly important for survivors of sexual violence and people experiencing gender dysphoria.

68. Having an abortion at home also can benefit both patients and providers. Telehealth, including direct to patient telehealth, can eliminate the exposure risks inherent in in-person clinic visits, particularly in light of the persistent and escalating violence and harassment at clinics known

[29] *See* Charlotte Kanstrup et al., *Women's Reasons for Choosing Abortion Method: A Systematic Literature Review*, 46 Scandinavian J. Pub. Health 835 (2018); Pak Chung Ho, *Women's Perceptions on Medical Abortion*, 74 Contraception 11 (2006).

to provide abortion.[30] It can also reduce wait times[31] and remove barriers to healthcare due to travel costs.[32] For people with disabilities and others for whom travel is difficult, the use of local and mail-order pharmacies significantly increases the accessibility of medication abortion.[33]

69. These concerns are neither abstract nor insignificant for someone who is pregnant. Each day a person remains pregnant means they continue to experience the symptoms, risks, and potential complications of pregnancy. Pregnancy—even when uncomplicated—stresses the body, causes physiological and anatomical changes, and affects every organ system.

70. Pregnancy can also worsen underlying health conditions, many of which are common, such as diabetes and hypertension. Other conditions can develop simply because a person is pregnant, including gestational diabetes, gestational hypertension (including preeclampsia), and hyperemesis gravidarum—a condition that causes severe nausea and vomiting. For people who continue their pregnancies and give birth, health conditions such as hypertension and diabetes can contribute to preterm birth.

71. People who continue their pregnancies and give birth face significant risk in the United States—in large part as a result of systemic discrimination and inequitable access to healthcare. Every pregnancy-related complication is more common among people having live

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[30] *See* Press Release, Nat'l Abortion Fed'n, *National Abortion Federation Releases 2021 Violence & Disruption Report* (June 24, 2022), https://prochoice.org/national-abortion-federation-releases-2021-violence-disruption-report (reporting steady increase in harassment and violence at abortion clinics over 45-year period); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers* (Oct. 18, 2022), https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers.

[31] Liam Caffery, Mutaz Farjian & Anthony C. Smith, *Telehealth Interventions for Reducing Waiting Lists and Waiting Times for Specialist Outpatient Services: A Scoping Review*, 22 J. Telemed. & Telecare 504 (2016).

[32] Abid Haleem et al., *Telemedicine for Healthcare: Capabilities, Features, Barriers, and Applications*, 2 Sensors Int'l 100117 (2021).

[33] *See, e.g.*, Allison M. Whelan & Michele Goodwin, *Abortion Rights and Disability Equality: A New Constitutional Battleground*, 79 Wash. & Lee L. Rev. 965, 989–90, 996–97 (2022).

births than among those having abortions. Vaginal delivery can result in trauma to the pelvic floor and other significant injury. And, for the approximately one-third of pregnancies ending in a caesarean section (C-section), patients will undergo a major abdominal surgery that carries risks of infection, hemorrhage, and damage to internal organs. Pregnancy also has potentially long-term physical, emotional, and mental effects on a person who goes through childbirth, sometimes persisting well after birth.

72. 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. The financial impacts of being denied an abortion are as large as or larger than being evicted, losing health insurance, or being hospitalized.[34]

73. The likelihood of being denied abortion care has grown exponentially since the U.S. Supreme Court overruled *Roe* nearly one year ago. Thirteen states have banned abortion, and several others have severely restricted access to this basic, yet critical, care. 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 restrictions on mifepristone is part of the same set of efforts to put safe, effective options for pregnancy care out of reach.

74. 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 providing medication

[34] 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).

abortion via direct to patient telehealth, moderate the strain on the ever-shrinking number of clinics struggling to provide care for a dramatic increase in patients.[35] Dozens of clinics have closed or stopped offering abortion care since the U.S. Supreme Court overruled *Roe*.[36] Currently, roughly 10 percent of U.S. counties have an abortion provider that offers either procedural or medication abortion (or both); in roughly 2 percent of U.S. counties, the only option is medication abortion.[37]

75. For people who remain pregnant—or need care at some point during a pregnancy—there are also dwindling options. Counties in more than one-third of the country are maternity care deserts, without obstetric providers, birth centers, or labor and delivery hospitals.[38] Federal law requires Medicaid, which covers 4 births in 10 each year—and even more for people of color and people in rural areas—to provide pregnancy-related coverage through only 60 days postpartum, disenrolling people just 2 months after birth, when consistent coverage remains critical. States may provide additional coverage, but must take additional steps to implement that extension.

76. The United States has one of the highest maternal mortality rates among wealthy democracies. According to recent Centers for Disease Control and Prevention reports, the maternal mortality rate has risen since 2018.[39] This human rights crisis in U.S. maternal health

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[35] *See* Caitlin Myers et al., *Abortion Access Dashboard* (last updated Mar. 23, 2023), https://experience.arcgis.com/experience/6e360741bfd84db79d5db774a1147815/page/Page/?views=March-2023 (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

[36] Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care.

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

[38] Christina Brigance et al., March of Dimes, *Nowhere to Go: Maternity Deserts Across the U.S.* 5 (2022), https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf.

[39] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Centers for Disease Control and Prevention National Center for Health Statistics (Mar. 2023), https://www.cdc.gov/nchs/data/hestat/maternal-

disproportionately impacts Black, Indigenous, and low-income communities, who consistently face the greatest risks during pregnancy, childbirth, and postpartum due to racism, discrimination, and inadequate access to quality health services. As a result, Black women are three to four times more likely to die of a pregnancy-related death in the United States, and Indigenous women are 2.3 times more likely than white women.[40] As the National Academies summarizes, as a result of systemic racism, including inequitable treatment and distribution of resources, "women of color enter into their reproductive lives, and ultimately their pregnancies, at risk for adverse pregnancy outcomes."[41] Pregnancy "represents a dangerous time for disabled and nondisabled persons alike in the United States" given the country's high maternal mortality rate, and while "[m]ost persons with disabilities can safely carry pregnancies to term . . . some may face a higher risk of complications, rendering pregnancy dangerous or even life-threatening."[42]

77. Bringing a child into the world, raising children, and building families and communities are, for many, among the most joyful and meaningful experiences in life. At the same time, these life-changing events bring challenges and risks, as evidence well documents. The ability to make decisions about whether to continue or end a pregnancy, and by what method, is critical to a person's dignity and autonomy. Continued enforcement of the REMS perpetuates

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mortality/2021/maternal-mortality-rates-2021.pdf (citing maternal mortality rate of 20.1 in 2019, 23.8 in 2020, and 32.9 in 2021); Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2019*, Centers for Disease Control and Prevention National Center for Health Statistics (Apr. 2021), https://www.cdc.gov/nchs/data/hestat/maternal-mortality-2021/E-Stat-Maternal-Mortality-Rates-H.pdf (describing maternal mortality rate of 20.1 in 2019 as "significantly higher than the rate for 2018," which was 17.4).

[40] Emily E. Petersen, et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007-2016*, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (Sept. 6, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w#T1_down.

[41] *See* Nat'l Acads. of Sci., Eng. & Med., *Birth Settings in America: Outcomes, Quality, Access, and Choice* 122 (2020), https://nap.nationalacademies.org/download/25636#.

[42] Whelan & Goodwin, *supra* n.33, at 997.

harmful and unnecessary barriers that make it more difficult to access essential healthcare and interferes with this decision-making.

III. Despite Acknowledging its Safety, FDA Has Continued to Saddle Mifepristone with the REMS, A Uniquely Burdensome Regulatory Scheme

78. From the very beginning, FDA has overregulated mifepristone in ways that are unjustified and discriminatory. But even as decades of data has accumulated showing mifepristone to be one of the safest medications available in the United States, FDA has continued to subject mifepristone to uniquely burdensome restrictions with increasingly little reason for doing so. These restrictions are already irrational, but in light of the recent chaos surrounding mifepristone, they have also become intolerable and incompatible with Plaintiffs' ability to meet the needs of their patients.

79. Under the FDCA, a new drug must undergo a rigorous examination to determine its safety and efficacy. *See generally* 21 U.S.C. § 355. For all prescription drugs, FDA ensures that certain safeguards are in place before it approves a medication. As part of this process, FDA may impose specific warnings, indications, and instructions.

80. A "Risk Evaluation and Mitigation Strategy" ("REMS") is an unusual overlay of requirements, far outside of the norm, that FDA can choose to impose 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).

81. The most burdensome type of REMS is "Elements to Assure Safe Use" ("ETASU"), which FDA imposes only if medically necessary due to a drug's "inherent toxicity or potential harmfulness." 21 U.S.C. § 355-1(f)(1). By statute, ETASU is only appropriate for drugs with serious side effects such as death, incapacity, or birth defects, and only where the risk of side effects is sufficiently severe that the drug requires ETASU for safe use. 21 U.S.C. §§ 355-1(b)(4), (f)(1)(A).

82. REMS, and in particular REMS with ETASU, are extremely unusual: only 60 REMS programs are in place, 56 of which include ETASU, among the more than 20,000 prescription drug products approved by FDA and marketed in the U.S. Other than mifepristone, the drugs with ETASU are dangerous drugs like fentanyl and other opioids.

83. Over the years, FDA has imposed numerous requirements on mifepristone through the REMS and ETASU, including:

- An in-person dispensing requirement (or ban on direct to patient telehealth) (21 U.S.C. § 355-1(f)(3)(C)) that provided mifepristone be dispensed only in a clinic, medical office, or hospital by or under the supervision of a "certified provider," who until 2016 could only be a physician. As a result, people could not access mifepristone by prescription from a brick-and-mortar or mail-order pharmacy. This requirement was temporarily suspended in 2021 and permanently removed in 2023, enabling patients to access medication abortion by mail and opening the door for brick-and-mortar pharmacies to dispense mifepristone. Although it removed the in-person dispensing requirement, FDA imposed a mandate that pharmacies, like prescribers, be "certified."
- A Prescriber Certification requirement (21 U.S.C. § 355-1(f)(3)(A)), which mandated that clinicians who prescribe mifepristone attest to their clinical abilities in a signed form kept on file by the manufacturer, and agree to comply with reporting and other REMS requirements.
    - Before 2016, only physicians could be certified mifepristone prescribers, although advanced practice clinicians (nurse practitioners, nurse midwives, and physician assistants) could provide mifepristone under the supervision of a physician.

- The certified prescriber requirement remains under the January 2023 REMS, but, in 2016, FDA expanded who could be a certified prescriber to include other clinicians, such as advanced practice clinicians.

- A Patient Agreement requirement (21 U.S.C. § 355-1(f)(3)(D)), mandating the prescriber and patient to 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. The same information contained in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling provided to patients with mifepristone. This requirement remains part of the 2023 REMS.

84. None of these requirements were justified at any time in light of FDA's repeated determination about the safety and efficacy of mifepristone.

IV. Over the Pleas of the Medical Community that Each Iteration of the REMS is Medically Baseless and Harms Patients and Providers, FDA has Maintained a REMS on Mifepristone for No Valid Reason

85. FDA reevaluated the provisions of the mifepristone REMS in 2016, and again in 2019, 2021, and 2023, but it has continually decided to reimpose the REMS despite longstanding objections from the medical community and its own review of the data showing mifepristone's safety and efficacy.

86. During FDA's 2016 review of the REMS, dozens of medical experts and their organizations asked FDA to eliminate the REMS because of the harms it imposed on patients and providers without any medical benefit. Among those groups were the preeminent medical professional organizations in the United States, including the American College of Obstetricians and Gynecologists (ACOG), the American Public Health Association (APHA), and the Society of Family Planning (SFP).

87. As one letter, signed by 30 organizational experts in reproductive rights and health, advanced: "[a]lthough the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU)."[43]

88. The letter further urged FDA to "[c]onsider the current legal and social climate," explaining that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[44] The letter concludes:

> Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that the drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS . . . .[45]

89. In addition to requesting that FDA remove the REMS entirely, the letter made specific requests about several particularly baseless aspects of the REMS.

90. Specifically, the letter requested that FDA remove the restriction preventing advanced practice clinicians from becoming certified prescribers of Mifeprex. It stated that this

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[43] 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. 2 (Feb. 4, 2016) (hereinafter SFP Letter to FDA), attached hereto as Ex. K.

[44] *Id.* at 5.

[45] *Id.* at 6.

limitation was "medically unnecessary and severely limits patients' access to medication abortion care."[46]

91. FDA modified the certified prescriber requirement, eliminating language that a certified prescriber had to be a physician, and instead providing that a healthcare provider may prescribe mifepristone so long as doing so is consistent with their state licensure.[47]

92. The letter also requested the removal of the requirement that mifepristone only be dispensed in clinics, medical offices, or hospitals—effectively banning it from being dispensed by direct to patient telehealth. In addition to the fact that it was "not medically warranted," the letter stated, the "requirement significantly curtails mifepristone's potential to expand patient access to abortion care," which is "especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs."[48]

93. FDA decided to retain the in-person dispensing requirement in 2016, citing no medical risks associated with direct to patient telehealth, and stating in a conclusory fashion that this requirement ensures mifepristone is dispensed by or under the supervision of a certified prescriber.[49]

94. In 2021, FDA temporarily suspended the in-person dispensing requirement during the COVID-19 public health emergency, citing a review of studies demonstrating no increase in

[46] *Id.* at 4.

[47] *See* Ex. E (FDA 2016 Medical Review) at 79–80.

[48] Ex. K (SFP Letter to FDA) at 2.

[49] Ex. E (FDA 2016 Medical Review) at 89.

serious safety concerns with this change.[50] FDA also noted that requiring patients to make in-person visits to a clinic solely to access mifepristone could "present additional COVID-related risks to patients and healthcare personnel."[51]

95. And, based on a 2021 review, FDA permanently removed the in-person dispensing requirement in January 2023, concluding that available data and information supported this modification to the REMS "to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks."[52] FDA, however, imposed a requirement that, like prescribers, pharmacies that dispense mifepristone be specially certified.[53]

96. In 2016, the experts further asked FDA to: (1) "[e]liminate the Prescriber Agreement certification requirement" and (2) "[r]emove the confusing and unnecessary Patient Agreement."[54] Neither requirement was necessary for the safe distribution of mifepristone—especially considering the "many laws, policies, and ordinary standards of practice" to which health professionals are subject.[55] The requirements also did not apply to drugs that carry more risk than mifepristone.[56] The experts argued that the Patient Agreement "should be eliminated entirely" as it was "medically unnecessary and interferes with the clinician-patient relationship."[57]

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[50] Ex. J (Woodcock Letter) at 1–2.

[51] *Id.* at 2.

[52] U.S. Food & Drug Admin., Information About Mifepristone for Medical Termination of Pregnancy Through 10 Weeks Gestation (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[53] *Id*. ("To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form.")

[54] Ex. K (SFP Letter to FDA) at 3–4.

[55] *Id.* at 3.

[56] *Id*.

[57] *Id.* at 4.

97. The FDA expert review team 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."[58]

98. They were, however, overruled by the FDA Commissioner for no apparent reason.[59]

a. Reimposing the Pre-2016 REMS Would Gravely Harm Plaintiffs' Practices and Patients

99. The harms of *reimposing* those parts of the REMS eliminated in 2016 (parts that would be reinstated if the Fifth Circuit's decision in the *Alliance* Case takes effect in the Plaintiffs' states) are even greater than when FDA reviewed and removed these requirements initially—and exponentially so in the wake of the Supreme Court's overruling of *Roe* and half the country moving to ban or severely restrict abortion. And the mountain of evidence and experience demonstrating safety, efficacy, and patient satisfaction in the absence of these requirements has only grown.

100. *First*, reinstating the physician-only requirement for certified prescribers retracts the pool of qualified mifepristone providers. And it does so after years of incremental progress to build a network of advanced practice clinicians (including nurse practitioners, nurse midwives, and physician assistants) with the training and experience to provide this critical care. Indeed, since 2016, the number of states that permit clinicians other than physicians to provide abortion care has grown from 12 to 18.

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

[59] 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"), attached hereto as Ex. L.

101. Plaintiffs WWH, Blue Mountain, and All Families all employ advanced practice clinicians who provide abortion care. Trust Women would want to use advanced practice clinicians to mail mifepristone if they are ultimately able to start their telehealth program.

102. In the case of All Families, *the sole clinician prescribing and providing abortion is an advanced practice clinician*. Reinstating the REMS' physician-only requirement for certified prescribers will thus eliminate the sole mifepristone provider from the northwest region of Montana.

103. *Second*, reinstating the REMS requirement that mifepristone be dispensed only in a clinic, medical office, or hospital—and not via mail-order pharmacy—will eliminate abortion access for the large number of patients who have come to rely on direct to patient telehealth services, and destroy Plaintiffs' virtual care models for mifepristone. Plaintiffs WWH, Blue Mountain, and All Families have all devoted substantial time and effort to developing telehealth abortion services. Their patients, many of whom are in rural or underserved communities, depend on telehealth services to access abortion care, particularly post-*Roe*. Trust Women Wichita, which has experienced a huge surge in patients seeking care following the criminalization of abortion in neighboring states, is interested in starting a direct to patient telehealth program if able, and intended to develop a telemedicine program involving direct to patient provision of medication abortion when the present uncertainty around mifepristone began.

104. At a minimum, Plaintiffs must be able to rely on the 2023 REMS to be able to continue providing their patients with high-quality, evidence-based abortion care.

b. The 2023 REMS Also Gravely Harms Plaintiffs' Practices and Patients

105. Yet, even the 2023 REMS erects unnecessary barriers to mifepristone. Experts have repeatedly told FDA to abandon three primary hurdles to accessing mifepristone that continue to plague Plaintiffs and their patients. Each restricts mifepristone without any valid medical basis.

106. *First*, the 2023 REMS retains the Patient Agreement Requirement even though FDA experts unanimously recommended its abandonment in 2016. It requires a patient to certify: "I have decided to take mifepristone and misoprostol to end my pregnancy." It must be signed by both the patient and provider, a copy must be placed into the patient's medical record, and a copy must be given to the patient along with the Medication Guide.

107. This Patient Agreement Form risks the privacy of patients and providers by specifically identifying the patient as taking the medication for the purpose of ending their pregnancy—as opposed to, for instance, miscarriage management, for which the medication is also frequently prescribed.[60]

108. If someone obtains access to the patient's medical record—which is all the more possible with states criminalizing abortion and imposing civil liability for people assisting others in accessing abortion—they will have evidence that the patient received the medication for abortion. This is a particular concern for patients who travel from a state where abortion is banned to a state where it is legal.

109. Further, patients receiving mifepristone for miscarriage management must also sign the Patient Agreement Form, requiring them to make a false and potentially traumatizing attestation that they are "decid[ing]" to "end [their] pregnancy" when they are experiencing a pregnancy loss.

110. The form also identifies the provider to people who have access to the patient record, potentially including, for example, a patient's spouse, partner, or parent. This exposes providers and patients to threats of reprisal, especially in today's climate of hostility to abortion.

[60] *See, e.g.*, ACOG Practice Bulletin No. 200, Early Pregnancy Loss, e197, e203 (Nov. 2018, reaff'd 2021), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss; *see also* Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161 (2018).

111. There is no countervailing benefit in the face of these harms, as the information contained on the form is useless; it is duplicative of the information already provided to patients in the five-page Medication Guide that accompanies mifepristone. The comprehensive Medication Guide answers questions about symptoms, side effects, and eligibility, as does the provider when they counsel patients on the risks and benefits of treatment.

112. *Second*, the 2023 REMS retains the Certified Prescriber Requirement: mifepristone can only be prescribed by a healthcare provider who has undergone a "special[] certif[ication]" process. This "special certification" must be submitted to each certified pharmacy used by the provider and to the distributor if a provider intends to dispense in their office.

113. As plaintiffs in the Washington case attested, for many healthcare providers, "becoming specially certified is unduly burdensome and raises safety concerns." Compl. ¶ 97, *Washington v. FDA*, No. 1:23-CV-3026, 2023 WL 2223480 (E.D. Wash. Feb. 23, 2023). Some providers "are deterred by the unusual step of having to become certified to prescribe the medication; others, misled by mifepristone's REMS designation, misperceive it is a dangerous medication or out of the prescriber's scope of practice; and still others are not comfortable having their names compiled in a list of medication abortion prescribers for fear that they or their families may be targeted by anti-abortion activists." *Id.* This fear is particularly acute for clinicians who hold licenses in multiple states. *Id.*

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

115. There is no reason that providers at Plaintiffs' clinics, who are not party to the Washington case, should have to be subject to these same risks from being certified prescribers.

Nor should they be subject to the instability about their status as certified prescribers—caused most recently by the current chaos and dueling court orders. The medically baseless certified prescriber requirement contributes to the stigma around abortion care and abortion providers that Plaintiffs experience, and it restricts the number of available clinicians who might be able to be certified prescribers at Plaintiffs' clinics to those who are willing to go through additional hurdles. Plaintiffs' patients should be able to access mifepristone from their trusted provider—whether it be the Plaintiff providers, or a primary care clinician in another practice.

116. *Finally*, the 2023 REMS imposes a Pharmacy Certification Requirement, which like for prescribers, mandates pharmacies be "specially certified" by the manufacturer. To certify, pharmacies must verify the status of "certified" providers and follow unnecessary and burdensome recordkeeping and training requirements not associated with any comparable medication. By limiting mifepristone dispensing to "certified" pharmacies, the REMS requires providers like Plaintiffs to track certified pharmacies, instead of allowing patients to decide from which pharmacy to pick up the medication, as they could do with numerous other prescription medications. Pharmacies, too, will have to track and confirm which prescribers are "certified" to ensure that, each time they seek to dispense mifepristone, they only dispense it to a patient whose prescription came from a certified prescriber.

117. As a practical matter, erecting this logistical "certification" barrier limits the number of pharmacies that dispense mifepristone, and thus limits access to mifepristone for Plaintiffs and their patients—just as the requirement that prescribers be certified has limited access to mifepristone. Although the 2023 REMS opens the door to allow brick-and-mortar pharmacies to dispense mifepristone, the mandate that they be certified may just as quickly shut that door.

118. Simply put, the 2023 REMS retains unnecessary and harmful dispensing and prescribing requirements that threaten patient and provider privacy and continue to put mifepristone out of reach despite its exemplary safety record. As one recent study of clinicians and administrators put it, although mifepristone is safe and effective, the REMS are the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice."[61]

119. FDA has tacitly acknowledged that mifepristone is subject to discriminatory restrictions. In 2012, FDA approved *without a REMS* a higher-dose mifepristone product—Korlym—as treatment for Cushing's syndrome. Patients prescribed Korlym take one to four 300 mg pills *daily*—which is 1.5 to 6 times the recommended dose of mifepristone used for abortion care, which typically involves only one 200 mg pill.[62] FDA concluded that "[a]ny restrictions will impede access with little to no benefit to Cushing's syndrome population" and that risks "can be adequately addressed through labeling," as with other drugs.[63] Indeed, FDA identified two drugs—misoprostol and methotrexate—associated with pregnancy termination which are regulated only through labeling, not a REMS.[64]

120. And, as the American Academy of Family Physicians has summarized, numerous "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and

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[61] 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).

[62] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Full Prescribing Information for Korlym (mifepristone), at 3 (Feb. 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lbl.pdf.

[63] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Korlym (mifepristone) Risk Assessment and Risk Mitigation Review(s) 9, 11 (Jan. 27, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf (hereinafter Korlym Review), attached hereto as Ex. M.

[64] *Id*. at 8.

sildenafil, do not have REMS restrictions."[65] Penicillin has a mortality rate three times greater than mifepristone.[66] Viagra has a mortality rate more than six times greater than mifepristone.[67] Tylenol overdose is one of the *most common* causes of liver transplantation in the U.S.—it leads to 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[68] No REMS applies to any of these drugs.

121. Not even opioids—some of the most dangerous drugs on the market—are subject to similar restrictions. REMS applicable to opiates require opioid manufacturers to offer optional training—a far cry from the mandatory, burdensome requirements imposed on mifepristone. Indeed, according to FDA, "[t]here is no mandatory federal requirement that prescribers or other [healthcare providers] take the training and no precondition to prescribing or dispensing opioid analgesics to patients."[69]

122. On June 21, 2022, ACOG and the American Medical Association (AMA) again urged FDA to eliminate the in-person dispensing and certification requirements, as "[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[70]

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[65] Am. Acad. Fam. Physicians Congress of Delegates, Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization of Mifepristone 2 (May 24, 2018), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[66] Greer Donley, *Medication Abortion Exceptionalism*, 107 Cornell L. Rev. 627, 651–52 (2022).

[67] *Id.*

[68] Agrawai & Khazaeni, *supra* n.20.

[69] U.S. Food & Drug Admin., Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) (Apr. 3, 2023), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

[70] Letter from Maureen G. Phipps, Am. Coll. Of Obstetricians & Gynecologists, and James L. Madara, CEO & Exec. Vice President, Am. Med. Ass'n, to Robert Califf, Comm'r, U.S. Food & Drug Admin. 2 (Jun. 21, 2022), attached hereto as Ex. N.

123. The same year, ACOG, AMA, and many other groups filed a citizen petition to FDA seeking to remove the REMS and add miscarriage management to mifepristone's indications.

124. The petition highlighted the same three troublesome remaining aspects of the REMS: the Patient Agreement Requirement, the Prescriber Certification Requirement, and the Pharmacy Certification Requirement.

125. As to the Patient Agreement Requirement, it should "be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by [the FDA review team] determined in 2016."[71]

126. As to the Prescriber Certification Requirement, it "serves no benefit to patient safety" and is "redundant and unnecessary."[72] Additionally, the petition noted the privacy and safety concerns inherent in a certification system.[73] The petition also highlighted that because of the certification requirement, "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities," making access particularly difficult for people living in rural areas.[74]

127. And, the petition urged FDA not to include a certification requirement for pharmacies because "research . . . suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access."[75] Moreover, "[a]s

[71] 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 12 (Oct. 4, 2022) (hereinafter ACOG Citizen Petition), attached hereto as Ex. O.

[72] *Id.* at 13.

[73] *Id.* at 13–14.

[74] *Id.* at 14.

[75] *Id.* at 15.

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."[76]

128. FDA rejected the medical groups' citizen petition.[77] This is not surprising, as FDA has repeatedly brushed aside concerns raised by leading medical organizations and its own data that show that the REMS harms patients and providers and is medically baseless. The agency kept renewing the REMS—in 2016, 2019, 2021, and yet again in 2023. FDA retained these restrictions notwithstanding its periodic reviews of the post-marketing data, which have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy.

V. The REMS Has Always Been Contrary to the FDCA

129. FDA's imposition of the REMS, including the 2023 REMS, is contrary to its statutory authority under the FDCA. As described above, a "Risk Evaluation and Mitigation Strategy" (REMS) is an unusual overlay of requirements outside of the norm that FDA can choose to impose 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). And, FDA may impose an ETASU on a medication only if it is "associated with a serious adverse drug experience," which is defined as a medication that "results in" death or "immediate risk of death," "inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or that "may jeopardize

[76] *Id.* at 16.

[77] 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), attached hereto as Ex. P.

the patient and may require a medical or surgical intervention to prevent [such] an outcome." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4).

130. Mifepristone has never come close to meeting these criteria. Indeed, FDA itself has repeatedly concluded that serious adverse events following mifepristone use are "exceedingly rare."[78]

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

VI. FDA's Decision to Retain the REMS Contributes to the Current Chaos and Ongoing Questioning of Mifepristone's Safety

132. Ensuring protected access to mifepristone—in line with all medical evidence—is more important now than ever, with abortion rapidly becoming criminalized across large swaths of the nation, and with anti-abortion zealots seeking to destroy the ability of any person *in any state* to use mifepristone.

133. The *only* actors who have *ever* attempted to suggest that mifepristone is unsafe are anti-abortion ideologues who ignore the conclusions of the AMA, ACOG, and every other mainstream medical and public health organization to have addressed the issue. Instead, they invoke junk science and purported experts whose opinions have been thoroughly discredited.[79]

134. Biased studies seeking to show that abortion by any method—whether medication or procedural—carries negative physical and mental health consequences have repeatedly been

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

[79] *See, e.g.*, Ex. D (Citizen Petition Denial) at 6.

deemed by the scientific community to be counter to the evidence. The National Academies concluded that "much of the published literature on" the topics of "abortion's long-term effects" on health and wellbeing "fails to meet scientific standards for rigorous, unbiased research."[80] When the National Academies considered only the "high-quality research" that met scientific standards, that research showed that "having an abortion does not increase a woman's risk of secondary infertility, pregnancy-related hypertensive disorders, abnormal placentation . . . preterm birth, breast cancer, or mental health disorders."[81]

135. Anti-abortion idealogues have now resorted to challenging the decades-old 2000 approval of mifepristone in the *Alliance* Case. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *3.[82]

136. Two courts agreed with the plaintiffs in the *Alliance* Case and issued stays to some degree of FDA's actions on mifepristone, relying on the flawed science that the plaintiffs put forth. On April 7, 2023, a district court in Texas ordered an unprecedented stay of FDA's longstanding approval of mifepristone. *See All. for Hippocratic Med.*, 2023 WL 2825871, at *32. 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, the court—citing

[80] National Academies Report, *supra* n.20, at 152.

[81] *Id.* at 153.

[82] *See also* 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 numerous courts that have rejected plaintiffs' experts 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.").

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.

137. At the same time on April 7—almost to the minute—a district court in Washington issued an injunction in 17 states and the District of Columbia preventing FDA from deviating from the status quo—the 2023 REMS. The Washington court 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." *Washington*, 2023 WL 2825861, at *8. Further, the district court found that FDA's repeated determination that "[s]erious adverse events . . . are rare" and that mifepristone "is safe and effective through 70 days gestation," along with its mystifyingly inconsistent approval of mifepristone for Cushing's syndrome without a REMS, suggest that FDA has ignored an important aspect of the issue before it when it issued REMS requirements repeatedly without scientific basis. *Id.*

138. Then, on April 12, the United States Court of Appeals for the Fifth Circuit compounded the confusion wrought by the Texas district court order, staying the decision only in limited part. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *1. The panel 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 other holdings—essentially enjoining the 2016 and 2023 REMS. *Id.* at *21.

139. Providers in states covered by the Washington injunction may proceed with abortion care as usual under the Fifth Circuit order, but the Plaintiffs here, and their states, are left out, as are their patients.

140. The U.S. Supreme Court entered a stay of the Texas district court decision through the appeals process of the preliminary injunction order entered by the district court, and possibly longer if the Court decides to take the case up at the preliminary injunction stage. However, the Fifth Circuit will hear argument in the case as soon as May 17, and uncertainty continues to abound.[83]

141. For these reasons, states are continuing to stockpile mifepristone (and even misoprostol) because of the day-to-day, week-to-week uncertainty about whether and how providers can use mifepristone.[84]

142. Plaintiffs, however, do not have the resources to stockpile years of mifepristone, nor are they able to accommodate massive shifts to their practice every 24 hours. They require certainty about their provision of mifepristone to maintain their medical practices and provide high-quality, evidence-based care to their patients.

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[83] *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 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").

[84] *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).

VII. Plaintiffs Do Not Need to File a Citizen Petition.

143. Plaintiffs are excused from any need to file a citizen petition under FDA regulations. *See* 21 C.F.R. §§ 10.30, 10.45. Such a filing would be futile because FDA has refused similar relief to that sought here when requested in 2020 by 21 states[85] and in 2022 by ACOG.[86] Moreover, when 17 states and the District of Columbia filed the Washington lawsuit in 2023, which seeks identical relief, the FDA opposed it, asserting in its brief that its decision to maintain the REMS restrictions on mifepristone was "reasonable." Defs.' Resp. Opp. Pl. States' Mot. Prelim. Inj. at 22, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Mar. 17, 2023). There is no prospect that FDA would take a different view if Plaintiffs were required to submit a citizen petition now; 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.

CLAIMS FOR RELIEF

COUNT I

(Administrative Procedure Act – Agency Action in Excess of Statutory Authority and Contrary to Law)

144. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

145. FDA's continued imposition of the REMS, and its promulgation of the mifepristone 2023 REMS, was a final agency action that is causing Plaintiffs irreparable harm for which they have no other adequate remedy under 5 U.S.C. § 704.

[85] 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), attached hereto as Ex. Q.

[86] Ex. O (ACOG Citizen Petition); Ex. P (ACOG Citizen Petition Denial).

146. This Court must "hold unlawful and set aside agency action" that is, among other things, "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "without observance of procedure required by law." 5 U.S.C. § 706(2).

147. Through the actions set out above, Defendants violated 5 U.S.C. § 706(2)(C) by acting in excess of statutory authority and contrary to law in continuing to impose the REMS and promulgating the mifepristone 2023 REMS contrary to its authorization in the FDCA.

COUNT II

(Administrative Procedure Act – Agency Action that is Arbitrary and Capricious)

148. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

149. FDA's continued imposition of the REMS, and its promulgation of the mifepristone 2023 REMS, was a final agency action that is causing Plaintiffs irreparable harm for which they have no other adequate remedy under 5 U.S.C. § 704.

150. This Court must "hold unlawful and set aside agency action" that is, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" 5 U.S.C. § 706(2)(A).

151. Through the actions set out above, Defendants violated 5 U.S.C. § 706(2)(A) by acting arbitrarily and capriciously in continuing to impose the REMS and promulgating the mifepristone 2023 REMS.

COUNT III

(Administrative Procedure Act—Action Contrary to Constitutional Right)

152. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

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

154. This Court must "hold unlawful and set aside agency action" that is, among other things, "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

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

COUNT IV

(Equal Protection)

156. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

157. As described above, Defendants violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the United States Constitution.

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

PRAYER FOR RELIEF

159. WHEREFORE, Plaintiffs pray that the Court:

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

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

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

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

e. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from taking any action under the REMS against any providers in Virginia, Montana, or Kansas.

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

DATED this 8th day of May, 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:

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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
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