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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients, et al., *Plaintiffs,* *v.* U.S. FOOD AND DRUG ADMINISTRATION, et al., *Defendants.*	Civil Action No. 2:22-cv-00223-Z

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

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I. INTERESTS OF AMICI CURIAE

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

Ensuring access to evidence-based health care and promoting health care policy that improves patient health are central to *amici*'s missions. *Amici* believe that all patients are entitled to prompt, complete, and unbiased health care that is medically and scientifically sound. *Amici* submit this brief to explain that mifepristone is exceedingly safe and effective and the Food and Drug Administration's approval of mifepristone was based in sound medical science.

Amici's ability to care for their patients in a safe and effective manner requires access to mifepristone, which has undergone rigorous testing and review and been approved for use in the United States for over twenty years. Accordingly, they have a

[1] The identities and interests of each *amicus* are explained in more detail in *amici*'s accompanying Motion for Leave.

strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is correctly understood.

II. PRELIMINARY STATEMENT

In this lawsuit, Plaintiffs have taken a position that is fundamentally ideological, not scientific. They seek to end the practice of medication abortion using mifepristone, encouraging the Court to upend the expert judgment of the Food and Drug Administration ("FDA") and overturn a *twenty-three-year-old approval*. Their request is not based on rigorous scientific review and analysis, but rather on pure speculation and the personal opinions of two physicians. As leading medical and public health societies in the fields most impacted by the present dispute, *amici* seek to center this dispute where it belongs—on the scientific evidence developed over more than two decades of study.

Medication abortion using mifepristone is safe and effective. This is not an opinion—it is a fact based on hundreds of medical studies and vast amounts of data amassed over the course of two decades and millions of uses of mifepristone for medication abortion. The risks of using mifepristone are comparable to taking Advil for a headache. The FDA based its initial approval on robust evidence which showed mifepristone was extremely safe. And the evidence collected and studies performed since that decision in 2000 have only served to confirm this. Serious side effects occur in ***less than 1%*** of patients, and major adverse events—significant infection, blood loss, or hospitalization—occur in ***less than 0.1%*** of patients. The risk of death is almost non-existent—and is ***fourteen times lower*** than childbirth.

Mifepristone is also recommended for the safe and effective treatment of miscarriage, which can be dangerous if left untreated. Indeed, in some cases, they can prove life threatening. Recent research has shown that mifepristone prescribed to treat a miscarriage, in conjunction with misoprostol, improves safety outcomes.

Plaintiffs also do not (and cannot) provide any evidence of negative psychological impacts from mifepristone. In fact, more than 95% of patients report being happy with their choice of a medication abortion. Medication abortion also offers advantages over procedural abortion, as it is less invasive and far more accessible, particularly to underserved patient populations. Again, Plaintiffs offer no scientific evidence to support any of their claims about mifepristone's safety (or purported lack thereof).

To the contrary—reversing the FDA's approval of Mifepristone, in whole or in any part, would cause profound harm to patients across the country. This will be particularly true for people of color and low-income patients who have higher rates of maternal mortality and morbidity and less access to alternative procedures. Plaintiffs claim that taking away mifepristone will somehow reduce the burden on our healthcare system is nonsensical. Medication abortion actively *reduces* any burden, as patients are able to take mifepristone at home without physician supervision. And the suggestion that complications are so frequent as to burden medical providers simply has no evidentiary basis. Finally, mifepristone has a significant (and growing) number of uses entirely outside the medication abortion context. Enjoining its use would cause irreparable harm

to the patients prescribed mifepristone off-label for management of miscarriages and a variety of other pregnancy-related conditions.

In short, the Court should reject Plaintiffs' attempt to overturn scientific judgment on the basis of personal opinion rather than medical evidence, and deny their request for a preliminary injunction.

III. Both Mifepristone and Medication Abortion Are Safe and Effective.

Medication abortion refers to a two drug regimen where mifepristone is used in conjunction with misoprostol to end an early pregnancy by emptying the contents of the uterus.[2] Mifepristone followed by misoprostol is used both to induce abortion,[3] and in the treatment of early pregnancy loss or miscarriage, a term which includes spontaneous abortion, a missed abortion, an incomplete abortion, or an inevitable abortion. Indeed,

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[2] Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are more effective than misoprostol-only regimens. ACOG Practice Bulletin No. 225, Medication Abortion Up to 70 Days of Gestation, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation; ACOG Practice Bulletin No. 200, Early Pregnancy Loss, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss

[3] Many factors influence or necessitate an individual's decision to have an abortion. They include but are not limited to contraceptive failure, barriers to contraceptive use and access, rape, incest, intimate partner violence, fetal anomalies, and exposure to teratogenic medications. Additionally, pregnancy complications such as placental abruption, bleeding from placenta previa, preeclampsia or eclampsia, chorioamnionitis, and cardiac or renal conditions may be so severe that an abortion is the only measure to preserve a patient's health or save their life. All terminations are considered medically indicated. ACOG Committee Opinion No. 815, Increasing Access to Abortion, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion.

mifepristone use is recommended for the safe and effective treatment of miscarriage,[4] which can be life-threatening.[5] To date, more than four million people in the United States have used mifepristone as part of a medication abortion.[6]

The scientific evidence supporting mifepristone's safety and efficacy is overwhelming. Mifepristone is one of the most studied medications prescribed in the United States with a safety profile comparable to ibuprofen. Hundreds of studies and more than two decades of medical practice show that: (1) mifepristone is safe and effective; (2) medication abortion offers specific benefits compared with other abortion methods; (3) additional safeguards around mifepristone's use are medically unnecessary. Plaintiffs point to no sound scientific evidence to support their scaremongering, relying instead on anecdotes, unsupportable theories, and wild exaggerations.

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

Decades of evidence demonstrates that medication abortion is safe and effective, with exceptionally low rates of major adverse events. Mifepristone's safety profile is on

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[4] ACOG Practice Bulletin No. 200, Early Pregnancy Loss, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss; World Health Organization, Medical Management of Abortion, https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1.

[5] Insert several news articles about failure to treat miscarriages post Dobbs.

[6] Need a citation for the 4 million number. Can use 3.7 and cite https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

par with common painkillers like ibuprofen and acetominephen, which more than 30 million Americans take in any given day.[7]

After rigorous testing, the FDA first approved the use of mifepristone over 20 years ago in 2000—a decision based on extensive clinical trials and sound research proving the medication's safety and efficacy.[8] This included an independent and unbiased review of the manufacturer's preclinical research and clinical test results to ensure that mifepristone was safe, effective, and that the health benefits outweighed the known risks.[9] In revising its guidance on mifepristone use in 2016, the FDA's safety analysis relied on 12 independent clinical studies conducted between 2005 and 2015, covering "well over 30,000 patients."[10] Those studies conclusively demonstrated that "serious adverse events . . . are rarely reported . . . with rates ***generally far below 1.0%***."[11]

In the two decades since mifepristone's initial approval, hundreds of additional studies have reaffirmed that medication abortions have been and continue to be safe. To date, mifepristone has been discussed in more than 780 medical reviews, and been used in more than 630 published clinical trials—of which more than 420 were randomized

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7 *See* R. Morgan Griffin, *Making the Decision on NSAIDs,* WEBMD, Oct. 17 2005, https://www.webmd.com/arthritis/features/making-decision-on-nsaids; https://pubmed.ncbi.nlm.nih.gov/10569383/#:~:text=The%20observed%20incidence%20of%20hospitalization,CI%20%3D%204.1%20to%207.0

8 *See* Complaint Ex. 24, MPI App. 518 (2000 FDA Approval Memo).

9 *Development & Approval Process | Drugs*, U.S. Food & Drug Administration, https://www.fda.gov/drugs/development-approval-process-drugs (visited Jan. 30, 2023).

10 FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 50 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf

11 *Id.* at 56 (emphasis added).

controlled studies (the gold standard in research design). At a high level, these studies have repeatedly concluded that even minor complications arising from medication abortion are extremely rare.[12]

Major adverse events — which includes hospitalization and serious infection or bleeding — are also "exceedingly rare, generally ***far below 0.1%***."[13] Studies have suggested that between 0.04% to 1.1% of patients require hospitalization,[14] with an even

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[12] Nat'l Acads. of Sci., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) ("NASEM Report"), at 58, http://nap.edu/24950 ("These reported risks [of medication abortion, including via telemedicine] are both low and similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications," comparing the risks with those from non-steroid anti-inflammatories); *id.* at 79 ("The risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDS."); Winikoff B, Dzuba IG, Chong E, Goldberg AB, Lichtenberg ES, Ball C, et al. Extending outpatient medical abortion services through 70 days of gestational age. Obstet Gynecol. 2012;120(5):1070-6. (http://www.ncbi.nlm.nih.gov/pubmed/23090524); Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception. 2015;92(3):197-9. (http://dx.doi.org/10.1016/j.contraception.2015.06.018).

[13] *See* Ushma D. Upadhyay, et al., Incidence of Emergency Department Visits and Complications After Abortion, 125(1) Obstetrics & Gynecology 175-83 (2015), available at https://journals.lww.com/greenjournal/Fulltext/2015/01000/Incidence_of_Emergency_Department_Visits_and.29.aspx (study of complications rate of over 55,000 abortions found a major complications rate of 0.23% – 0.31% for medication abortion; 0.16% for surgical abortion); FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 8, 47 (Mar. 29, 2016), at 47, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.; *See U.S. studies on medication abortion without in-person clinician dispensing of mifepristone, Advancing New Standards in Reproductive Health*, Issue Brief October 2021, https://www.ansirh.org/sites/default/files/2021-10/Issue%20Brief_Summary%20of%20U.S.%20studies_MA%20w-o%20in-; Elizabeth G. Raymond et al., First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review, 87 Contraception 26, 30 (2013) (addressing rates at which major complication occur for medication abortion).

[14] FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 53 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf

smaller number, between 0.014% and 0.07% of patients, experiencing serious infection.[15] The FDA has made clear that the complications observed can occur following a miscarriage, surgical abortion and medical abortion—i.e., any time the pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established." [16] Put simply, medication abortion is among the safest medical interventions in any category – whether related to pregnancy or not.

The risk of death from medication abortion is near-zero.[17] A 2019 analysis of FDA data by the University of San Francisco Medical Center found only 13 deaths possibly or probably related to medication abortion from 3.7 million cases, i.e., only 0.00035% of medication abortions.[18] When including deaths that are not likely related to medication abortion, the number rises to only 0.0065%. [19] In fact, there is a greater risk of complications or mortality for procedures like wisdom-tooth removal, cancer-screening

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15 *Id.* at 54.

16 Mifeprex Prescribing Information, Ex. __.

17 See Katherine Kortsmit et al., U.S. Dep't of Health & Human Servs., Ctrs. for Disease Control and Prevention, Abortion Surveillance – United States, 2019, 70 Morbidity & Mortality Weekly Rep. No. 9, 29 tbl. 15 (Nov. 26, 2021) (Kortsmit) (finding mortality rate from 0.00041% to 0.00078% for approximately five-year periods from 1978 to 2014); Suzanne Zane et al., Abortion-Related Mortality in the United States, 1998-2010, 126 Obstetrics & Gynecology 258, 261 (2015) (noting an approximate 0.0007% mortality rate for abortion).

18 https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf; *see also* FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 8, 47, 51 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

colonoscopy, plastic surgery and Viagra than by abortion by any method, procedural or medication.[20] By comparison, Viagra was associated with 4.9 deaths per 100,000 prescriptions,[21] and death by colonoscopy occurs in about 0.03% of cases.[22] By contrast, the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[23]

Because of medication abortion's proven safety and effectiveness and the demonstrated need for access to its two-drug regimen, medication abortion has been and continues to be very common today—with the FDA reporting 3.7 million U.S. uses of mifepristone by U.S. women.[24] As of 2020, medication abortions account for most

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[20] Advancing New Standards in Reproductive Health, Safety of Abortion in the United States, Issue Brief No. 6, at 2 (Dec. 2014) (2.1% of abortions result in complications—with 1.88% resulting in minor complications and 0.23% resulting in major complications—compared to 7% of wisdom-tooth extractions, 8-9% of tonsillectomies, and 29% of childbirths); Am. Soc'y for Gastrointestinal Endoscopy, Complications of Colonoscopy, 74 Gastrointestinal Endoscopy 745, 747 (2011) (33% of colonoscopies result in minor complications); Frederick M. Grazer & Rudolph H. de Jong, Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons, 105 Plastic & Reconstructive Surgery 436, 441 (2000) (mortality rate from liposuction in late 1990s was 20 per 100,000); Kortsmit 29 tbl. 15 (mortality rate from legal induced abortion was between 0.52 and 0.63 per 100,000 in late 1990s, dropping to 0.41 in the years 2013-2018). 18 ACOG, Practice Bulletin No. 135, Second Trimester Abortion, 121 Obstetrics & Gynecology 1394, 1394 (2013, reaff'd 2021).

[21] Mitka M. Some Men Who Take Viagra Die—Why? JAMA. 2000;283(5):590–593. doi:10.1001/jama.283.5.590-JMN0202-2-1

[22] https://www.asge.org/docs/default-source/education/practice_guidelines/doc-56321364-c4d8-4742-8158-55b6bef2a568.pdf?sfvrsn=8

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

[24] https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf

abortions in the United States,[25] while maintaining an exceptionally low rate of complications.

Plaintiffs' inaccurate characterization of mifepristone as an 'endocrine-disruptor' notwithstanding, Plaintiffs' purported concerns that mifepristone will affect adolescents because it briefly blocks progesterone receptors in the uterus is completely unfounded. Adolescents who are pregnant have abnormally high levels of progesterone compared with their non-pregnant counterparts. There is no reason to think, nor is there evidence to show, that preventing the absorption of progesterone for a brief window would have any effects on adolescent development.[26]

Additionally, studies have shown that patients who seek an abortion, including medication abortion, do not suffer from emotional distress or negative mental health outcomes and experience better long-term outcomes than those who seek abortion care but are denied. For instance, one recent long-term study found that women who obtain abortions had "similar or better mental health outcomes than those who were denied a

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[25] https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions

[26] Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BJM, April 20, 2011 "(medication abortion seems to be at least as safe in adolescents as it is in adults"). *See also* Letter from Michael Munger, Board Chair, American Academy of Family Physicians to Norman Sharpless, Acting Commissioner, FDA (June 20, 2019), https://www.aafp.org/dam/AAFP/documents/advocacy/prevention/women/LT-FDA-MifepristoneREMS-062019.pdf; MIFEPREX™ (mifepristone) Tablets, 200 mg For Oral Administration Only, https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm#:~:text=Following%20a%20distribution%20phase%2C%20elimination,half%2Dlife%20of%2018%20hours (explaining that the effects of mifepristone are temporary and do not have a lasting effect on the body).

wanted abortion."[27] Another study observed that 95% of participants who received abortion care believed that doing so had been the "right decision for them" in the years that followed.[28] Plaintiffs' argument to the contrary—that patients frequently regret their medical decisions or go so far as to seek "reversal" treatment (discussed *infra)* is contrary to the scientific evidence.

Nor is it accurate to suggest that patients suffer emotionally because the FDA has created an "inaccurate and false safety profile" for mifepristone.[29] Mifepristone's safety has been evident for decades thanks to rigorous scientific study. And that risk profile has not changed since its approval, despite ongoing and robust study, testing, and monitoring of market data.[30]

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27 *See, e.g.*, M. Antonia Biggs et al., *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169 (2017); *see also* M. Antonia Biggs et al., *Does Abortion Increase Women's Risk for Post-Traumatic Stress? Findings from a Prospective Longitudinal Cohort Study*, 6 BMJ Open e009698 (2016); M. Antonia Biggs et al., *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States*, 105 Am. J. Pub. Health 2557 (2015); Diana G. Foster et al., *A Comparison of Depression and Anxiety Symptom Trajectories Between Women Who Had an Abortion and Women Denied One*, 45 Psychol. Med. 2073 (2015).

28 Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLoS ONE 1, 7 (2015); *see also* Corinne H. Rocca, et. al., *Emotions and decision rightness over five years following an abortion: An examination of decision difficulty and abortion stigma,* Social Science and Medicine 248 (2020) (finding no evidence of negative emotions or decision regret among those surveyed and that the prevailing sentiment post-abortion was relief).

29 Mot. at 8.

30 *See* MPI App. 651 (2016 FDA Approval) ("[A]fter 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged. Therefore, I agree that reporting of labeled serious adverse events other than deaths can be collected in the periodic safety update reports and annual reports to the Agency.").

B. Medication Abortion Offers Comparative Benefits Against Other Forms of Abortion or Miscarriage Management.

Patients eligible for medication abortions also have the option of obtaining a procedural abortion (sometimes referred to as a "surgical abortion" despite the fact that it does not involve "surgery" as that term is generally understood). The reasons patients choose medication abortion over procedural abortion are varied, and can include a desire to avoid physical contact due to prior sexual assault or trauma; a desire to be able to have the abortion, in the company of family; or simply a desire for privacy. Patients suffering miscarriage may choose to take mifepristone and misoprostol for the same reason, rather than to opt for an in-clinic suction procedure to treat the miscarriage. In fact expectant management (wait and see) of a miscarriage results in a complete abortion approximately 80% of the time, while the use of the two-drug medication abortion regimen has a higher rate of complete abortion.[31]

1. While Medication and Procedural Abortions Are Safe and Effective, Medication Abortion Offers Additional Benefits for Patients.

As demonstrated above, the incidence of major complications from all abortion, including medication abortion, are exceedingly low. Yet, in an attempt to suggest that medication abortion is dangerous, Plaintiffs argue that "surgical abortion" is a far safer alternative.[32] The reality is, when it comes to major complications from either

[31] https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss

[32] Mot. at 16.

medication abortion or procedural abortion, one is ultimately comparing exceedingly small numbers, as both methods of abortion have a comparable safety profile to acetaminophen or ibuprofen.

While both methods of abortion are safe and effective, medication abortion offers unique benefits over procedural abortion for some patients. Medication abortion allows patients to avoid an in-office procedure that may be perceived as more invasive[33] Patients who have experienced rape or sexual abuse especially may prefer medication abortion to avoid the trauma of having instruments inserted into their vagina in an office visit.[34] Patients may perceive medication abortion as safer, more natural and private compared with uterine aspiration.[35] Medication abortion also allows patients to complete the termination of their pregnancy at home, in a private and comfortable setting with the support friends or loved-ones of their choosing.

Additionally, given the increasing number of care deserts throughout the United States, medication abortion may be the only option that is accessible to patients, which may be seeking an abortion for a myriad of reasons, including a life-threatening condition or early pregnancy loss. This is especially true for patients from historically-marginalized populations, patients with low incomes and patients living in rural areas or long distances

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[33] *Medical Versus Surgical Abortion*, University of California San Francisco Health, https://www.ucsfhealth.org/education/medical-versus-surgical-abortion (visited Sept. 7, 2020).

[34] *See* Sharkansky, *Sexual Trauma: Information for Women's Medical Providers*, U.S. Dep't of Veterans Affairs, https://www.ptsd.va.gov/professional/treat/type/sexual_trauma_women.asp (visited Feb. 9, 2021); *see also* Clark Decl. ¶ [9].

[35] ACOG Practice Bulletin No. 225, Medication Abortion Up to 70 Days of Gestation.

from a medical facility that can provide needed care.[36] Even when a medical facility is accessible to patients, a significant number of medical facilities that provide abortions offer only medication abortion.[37] For patients with certain medical conditions, disabilities, or other extenuating life circumstances (such as a lack of access child care or the inability to take time off work or travel long distances to receive care), medication abortion is by far the safest and most accessible option.[38] Given the dearth of accessible health care in large portions of this country, the FDA's recent decision to permanently remove the in-person dispensing requirement for mifepristone is not only correct but critical to ensure these patients can access necessary and potentially life-saving medication abortion.

2. Medication Abortion Is Far Safer Than Carrying a Pregnancy to Term.

Plaintiffs claim that "pregnancy rarely leads to complications that threaten the life of the mother or the child"[39]—but they base this assertion on a study that does little more

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[36] March of Dimes, Maternity Care Desert: Idaho (June 2021), available at https://www.marchofdimes.org/peristats/data?reg=99&top=23&stop=641&lev=1&slev=4&obj=9&sreg=99&cregLyndsey S. Benson et al., Early Pregnancy Loss in the Emergency Department, J. AM. C. OF EMERGENCY PHYSICIANS OPEN (2021); Anthony Mazzeo et. al, Delivery of Emergency Care in Rural Settings (2017).

[37] *See* Compl. ¶ 51.

[38] Plaintiffs argue that medication abortion does not offer a meaningful benefit over procedural abortion, because some patients require surgical intervention following medication abortion. But the need for surgical intervention following medication abortion is a very rare complication. Patients face only a 2% chance of needing a follow-up intervention. Ireland et. Al., *Medical Compared with Surgical Abortion for Pregnancy Termination in the First Trimester* at 56, https://pubmed.ncbi.nlm.nih.gov/26241252/..

[39] *See* Compl. ¶ 15

than critique the FDA's process for tracking post-abortion complications,[40] and on a political opinion piece.[41] As one expert put it, "[e]very major professional organization representing obstetricians and gynecologists and family planning professionals agrees that abortion care in the United States is extremely safe—far safer than the alternative of carrying a pregnancy to term and giving birth."[42] Extensive empirical evidence shows that women are 10-15 times more likely to die during childbirth than during any abortion

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40 *See* Pl. Ex. 11, Byron Calhoun, *The maternal mortality myth in the context of legalized abortion*, 80 The Linacre Quarterly 264, 264–276 (2013).

41 *See* James Studnicki & Tessa Longbons, *Pregnancy Is Not More Dangerous Than Abortion*, Nat'l Rev. (Aug. 28, 2022, 6:30 AM), https://www.nationalreview.com/2022/08/pregnancy-is-not-moredangerous-than-abortion/.

42 Expert Report of Steven J. Ralston at 5, Planned Parenthood of Montana v. State of Montana, No. DV-21-00999 (Mont. DATE FILED); see also Am. Coll. of Obstetricians & Gynecologists, Committee Op. No. 815: Increasing Access to Abortion, 136 Obstetrics & Gynecology e107, e108 (2020) (stating that the "risk of death associated with childbirth is approximately 14 times higher than that with abortion."); Soc'y for Maternal-Fetal Med., Access to Abortion Servs. 1, 1-2 (approved Dec. 2017, revised, re-titled, and reaffirmed June 2020), https://s3.amazonaws.com/cdn.smfm.org/media/2418/Access_to_Abortion_Services_(2020).pdf (stating that "[i]n pregnancies in which complications arise or there are preexisting medical comorbidities (including mental illness), abortion may be required and may be medically safer than carrying a pregnancy to term").

procedure,[43] and are at an increased risk of experiencing hemorrhaging, infection, and injury to other organs during pregnancy and childbirth as well.[44]

Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying preexisting conditions and can severely compromise health, sometimes permanently.[45] Pregnancy, particularly when coupled with a preexisting condition, can quickly evolve into a life-threatening situation necessitating critical care, including abortion. This phenomenon is particularly apparent in the United States, which has the highest maternal mortality rate among developed countries, with rates increasing the most for Black and Hispanic patients.[46]

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43 *See* Raymond & Grimes, The *Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216–17 & fig.1 (2012). The U.S. mortality rate associated with live births from 1998 to 2005 was 8.8 deaths per 100,000 live births. *Id*. at 216. Rates have sharply increased since then. MacDorman et al., *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 Obstetrics & Gynecology 447 (2016). In contrast, the mortality rate associated with abortions performed from 1998 to 2005 was 0.6 deaths per 100,000 procedures. Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, *supra* at 216. A committee of the National Academies in a 2018 peer-reviewed, evidence-based report similarly concluded that abortion is safer than pregnancy; specifically, "the risk of death subsequent to a legal abortion (0.7 per 100,000) is a small fraction of that for childbirth (8.8 per 100,000)." Nat'l Acads. of Scis. Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* at 74 (2018).

44 Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States,* 119 Obstetrics & Gynecology 215, 216–17 & fig.1 (2012).

45 *See e.g.* ACOG Practice Bulletin No. 190, *Gestational Diabetes Mellitus* (Feb. 2018); ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (Dec. 2018); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017); ACOG Obstetric Care Consensus, *Placenta Accreta Spectrum* (July 2012, reaff'd 2021); ACOG Practice Bulletin No. 198, *Prevention and Management of Obstetric Lacerations at Vaginal Delivery* (Sept. 2018, reaff'd 2022); ACOG Clinical Consensus No. 1, *Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management* (Sept. 2021).

46 Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, THE COMMONWEALTH FUND,

C. The FDA's Recent Decisions Concerning Mifepristone Have Been Amply Supported by Evidence of Safety.

Plaintiffs' concerns regarding the supposed lack of "safeguards" with respect to mifepristone are contradicted by evidence. The FDA's decision in 2016 to make mifepristone available for use in pregnancies up to 10 weeks was supported by substantial evidence of safety, including a wide-ranging systemic review, [47] a randomized control trial, [48] and three observational studies, [49] all of which demonstrated the safety and effectiveness of mifepristone up to ten weeks' of pregnancy.[50] More recent studies have

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https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries (Nov. 18, 2020), ("The U.S. has the highest maternal mortality rate among developed countries."); https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/e-stat-maternal-mortality-rates-2022.pdf.

[47] MPI App 631 (citing Chen MJ, Creinin MD. *Mifepristone with Buccal Misoprostol for Medical Abortion Obstet Gynecol: a Systematic Review*. Obstet Gynecol 2015; 126(1):12-21).

[48] MPI App 631 (citing Olavarrieta CD, Ganatra B, Sorhaindo A, Karver TS, Seuc A, Villalobos A, Garcia SG, Perez M, Bousieguez M, Sanhueza P., *Nurse versus physician provision of early medical abortion in Mexico: a randomized controlled non-inferiority trial.* Bull World Health Organ 2015; 93:249-258).

[49] MPI App 631 (citing Winikoff B, Dzuba IG, Chong E, et al., *Extending outpatient medical abortion services through 70 days of gestational age*, Obstet Gynecol 2012; 120:1076-6; Boersma AA, Meyboom-de Jong B, Kleiverda G., *Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curacao*, Eur. J. Contracept Reprod Health Care 2011; 16:61-6; Sanhueza Smith P, Pena M, Dzuba IG, et al., *Safety, efficacy and acceptability of outpatient mifepristone-misoprostol medical abortion through 70 days since last menstrual period in public sector facilities in Mexico City*, Reprod Health Matters 2015; 22:75-82.)

[50] Gouk EV, Lincoln K, Khair A, Haslock J, Knight J, Cruickshank DJ. Medical termination of pregnancy at 63 to 83 days gestation. BJOG. 1999;106(6):535-9. (http://www.ncbi.nlm.nih.gov/pubmed/10426609); Boersma AA, Meyboom-de Jong B, Kleiverda G. Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curacao. Eur J Contracept Reprod Health Care. 2011;16(2):61-6. (http://dx.doi.org/doi:10.3109/13625187.2011.555568); Winikoff B, Dzuba IG, Chong E, Goldberg AB, Lichtenberg ES, Ball C, et al. Extending outpatient medical abortion services

confirmed this. For example, a 2020 study concluded yet again that medication abortion can safely and effectively be used up to 70 days of gestation.[51] Plaintiffs cite no scientific support for their conclusion to the contrary, and instead rely entirely on the declarations of Drs. Jester and Wozniak—one of which does not even consider, let alone analyze, the relevance of gestational age with respect to mifepristone use.[52]

Similarly, the FDA's decision to drop the ultrasound requirement was based on sound medicine. Simply put, it is medically unnecessary to perform an ultrasound on the vast majority of medication abortion patients, and clinicians, as a result of their medical expertise, are perfectly capable of ordering an ultrasound when that is, in their experience and judgment, advisable.[53] Although an ultrasound can help determine gestational age and can identify an ectopic pregnancy, studies have shown that both of these goals can be accomplished just as effectively by taking the patient's medical history—even via a

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through 70 days of gestational age. Obstet Gynecol. 2012;120(5):1070-6. (http://www.ncbi.nlm.nih.gov/pubmed/23090524); Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception. 2015;92(3):197-9. (http://dx.doi.org/10.1016/j.contraception.2015.06.018).

[51] *Medication Abortion up to 70 Days of Gestation*, Contraception Journal (Aug. 14, 2020), https://www.contraceptionjournal.org/article/S0010-7824(20)30301-2/fulltext.

[52] *See* Compl. ¶ 265 (citing Ex. 9, Wozniak Decl. ¶ 10; Ex. 52, Jester Decl. ¶ 17). The Jester declaration cited by Plaintiffs does not discuss gestational age.

[53] Elizabeth Raymond et al., *Simplified Medical Abortion Screening: A Demonstration Project*, 97 Contraception 292 (2018); *see also* Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG 1464, 1469 (2021); Holly A. Anger, *Clinical and Service Delivery Implications of Omitting Ultrasound Before Medication Abortion Provided via Direct-to-Patient Telemedicine and Mail in the US*, 104 Contraception 679 (2021); Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43, 46 (2021) ("Preabortion ultrasounds are usually unnecessary for safe and effective medication abortion ….").

telemedicine appointment.[54] As the FDA determined more than 20 years ago, the choice of whether to perform an ultrasound should be left to the provider's reasonable judgment, on a case-by-case basis.[55] The "safeguards" promoted by Plaintiffs are medically unnecessary, and mifepristone and medication abortion continue to be safe and effective.

Plaintiffs also seek to rehash their position with respect to the FDA's decision to eliminate certain restrictions in 2016—for instance, its revision to the "adverse event reporting" mandate, which requires physicians to report adverse events and injuries to the FDA under certain circumstances.[56]

In 2016, the FDA eliminated a requirement that providers report *all* adverse events on mifepristone to the FDA, noting that "after 15 years of reporting serious adverse events, the safety profile for [mifepristone] is essentially unchanged." On this basis, the FDA determined it was sufficient to continue requiring the reporting of patient deaths, but that

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[54] *See* MPI App 522 (2000 FDA Approval Memo) ("In practice, dating pregnancies occurs through using other clinical methods, as well as through using ultrasound."); Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 Contraception 212, 214 (2015) (finding that gestational dating using last monthly period rather than ultrasound may be reasonable for selected patients before medication abortion); *see also* Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182(5) Journal of the American Medical Association Internal Medicine 482, 1469 (2022) (finding no statistical difference between the use of ultrasound and medical history in identifying ectopic pregnancy).

[55] *See* MPI App 522 (2000 FDA Approval Memo) ("The role of an ultrasound was carefully considered. In the clinical trial, ultrasound was performed to ensure proper data collection on gestational age. In practice, dating pregnancies occurs through using other clinical methods, as well as through using ultrasound. Ultrasound information can be provided to the prescribing physicians to guide treatment, but this information can be obtained through consultation referral from an ultrasound provider and does not necessarily need to be obtained by the prescriber him/herself. The labeling recommends ultrasound evaluation as needed, leaving it to the medical judgment of the physician.").

[56] *See e.g.*, Complaint at ¶¶ 250, 304, Brief in Support of Motion for PI at 25.

information regarding any other "serious adverse events" could be collected on a reduced basis through "periodic safety update[s]" and "annual reports."[57] By the time this decision was made, mifepristone had been studied extensively for over 15 years and was proven to be safe time and time again. Plaintiffs offer no support for their suggestion that eliminating the requirement was unsupported by the medical evidence at the time, or resulted in any harm to patients or their providers. Instead, Plaintiffs speculate, based on no evidence, that the lack of a more robust reporting requirement will harm the doctor-patient relationship.[58] There is no justification to revisit the FDA's reasoned decision now.

IV. Enjoining the Use of Mifepristone Will Harm Pregnant Patients and Have Severe Negative Impacts on the Broader Healthcare System.

A. Patients Will Suffer if Denied Access to a Safe and Effective Treatment.

Making mifepristone unavailable – nationwide, even in states where abortion remains legal – will impose a severe, almost unimaginable cost on pregnant people throughout the United States. There is no evidence that people are harmed by having access

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[57] Mot. at 9. *See* footnote 12 supra.

[58] For instance, Plaintiffs speculate that a "lack of accurate information on adverse events" will cause patients to mistrust their doctors. But the FDA removed the reporting requirement because it was determined to be unnecessary upon review of more than 15 years of reporting data on mifepristone. Doctors had in 2016, and continue to have now, all the information they need to make accurate assessments with respect to prescribing mifepristone to any given patient and to adequately inform patients about what to expect when taking the medication. Plaintiffs also speculate, without evidence, that doctors will face or have faced increased malpractice liability because mifepristone can be prescribed via telehealth and ingested at the patient's home, thus increasing the likelihood of an emergent situation or serious side effects. As discussed above, medication abortion, whether taken at home or elsewhere, rarely results in any serious complications, let alone those requiring hospitalization or an emergency-room visit, and there is no evidence that malpractice liability rates have been affected by the accessibility of medication abortion.

to safe and effective medication abortion. To the contrary, there is substantial evidence that the *denial* of abortion care causes harm.

Abortion care can be life-saving care, including for people suffering from life-threatening pregnancy complications or experiencing an early pregnancy loss. Medication abortion's relative availability makes it more accessible to patients who otherwise face challenges to access medical care, including low-income patients and patients of color[59] — the very people that are most likely to experience severe maternal morbidity and more likely to die from pregnancy-related complications.[60] Pregnant people of color are also more likely to experience early pregnancy loss or miscarriage, the treatment for which can include procedural or medication abortion.[61] Patients who are denied abortions

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[59] *See* Christine Dehlendorf and Tracy Weitz, *Access to Abortion Services: A Neglected Health Disparity*, 22 J. HEALTH CARE FOR THE POOR & UNDERSERVED 415 (May 2011) ("Poor and minority women experience both greater need for and reduced access to abortion services than their white and more affluent counterparts, and have negative health and social consequences as a result."); Rachel K. Jones et al., *COVID-19 Abortion Bans and Their Implications for Public Health*, PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH (May 14, 2020) ("Nationally, three-quarters of abortion patients are poor or low income …black women and those with limited financial resources already face numerous economic and structural hurdles that delay access to abortion); Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, GUTTMACHER INST. (May 2016) https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014; Ctr. for Medicare & Medicaid Serv. , *CMS Rural Health Strategy* 2 (2018) https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf ("[R]ural Americans are more likely to be living in poverty, unhealthy, older, uninsured or underinsured, and medically underserved.").

[60] CMS, *Advancing Rural Maternal Health Equity*, at1 (May 2022), available at: https://www.cms.gov/files/document/maternal-health-may-2022.pdf ("CMS, *Advancing Rural Maternal*") *see also Juanita Chinn, et al., Health Equity Among Black Women in the United States, 30(2) J. Women's Health 212, 215 (2021) ("Chinn, Health Equity")*

[61] Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department*, J. AM. C. OF EMERGENCY PHYSICIANS OPEN, 1, 1–2 (2021) ("Benson, *EPL*").

experienced an increase in violence from romantic partners compared with patients who were able to obtain an abortion.[62] Studies have repeatedly shown that being denied an abortion exacerbated patients' economic hardships, revealing "large and statistically significant differences in the socioeconomic trajectories of women who were denied requested abortions compared with women who received abortions—with women denied abortions facing more economic hardships."[63]

Aside from the psychological toll of being denied needed medical care without justification, the physical consequences of restricting mifepristone use would also be devastating. Mifepristone is used to treat a wide array of off-label conditions entirely unrelated to induced abortion (and many conditions unrelated to pregnancy at all). As explained infra, these uses include miscarriage or the management of early pregnancy loss for patients experiencing a spontaneous, missed, inevitable or incomplete abortion. For people that do not have access to procedural abortion or adequate medical facilities, there may be no other options to obtain critical care.

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62 Roberts et al., *Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion* (2014), https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-014-0144-z.

63 Diana Greene 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, 412 (2018).

B. Physicians and Hospitals Will Experience Significant Costs and Burdens Without Any Medical Justification.

Overturning mifepristone's approval will, at a macro level, increase the burden on the nation's healthcare system, particularly women's health and OBGYN care.[64] Should the use of mifepristone be proscribed or limited, medical facilities will experience an increased strain on already-limited resources.[65] Medication abortion allows a patient to ingest their prescription safely at home, freeing physicians and in-patient resources to focus on addressing emergent situations and hospitalizations. To the extent a patient does require follow-up care in a clinician's office or medical facility (which is, again, exceedingly rare and utilizes, at most minimal hospital resources) providers may focus on the needs of these patients, rather than expending resources to unnecessarily supervise patients taking their medication in the office (and then traveling home to complete the process) or see patients during follow-up appointments that are not medically necessary.

Plaintiffs also suggest that medication abortion is a drain on in-patient resources because physicians must frequently counsel patients on "reversal" or regret.[66] To start,

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[64] Plaintiffs go so far as to claim that medication abortion is a driving factor in the "national blood supply shortage" due to the purportedly high number of patients who experience hemorrhaging or sepsis as a result. See Compl. ¶ 82 There is absolutely no evidence of this—as explained above, medication abortion is extremely safe and rarely results in complications requiring a blood transfusion.

[65] *See* Alexander Janke, *An Emergency in U.S. Emergency Care: Two Studies Show Rising Strain*, U. Mich. Inst. of Healthcare Policy & Innovation (Oct. 7, 2022), https://ihpi.umich.edu/news/emergency-us-emergency-care-two-studies-show-rising-strain; Steven Ross Johnson, *Hospitals Face Strain as Respiratory 'Tripledemic' Wanes,* US NEWS & WORLD REPORT (Jan. 25, 2023), https://www.usnews.com/news/health-news/articles/2023-01-25/hospitals-face-strain-as-tripledemic-wanes.

[66] Mot. at 9 (speculating that doctors may need to divert resources to assist patients seeking to reverse medication abortion).

there is *no* medical evidence or even sound medical theory to support the idea that a medication abortion can be "reversed."[67] The reversal "treatment" described in the Complaint is the invention of one of the Plaintiffs—George Delgado.[68] The only peer-reviewed, randomized controlled study to ever attempted with respect to Mr. Delgado's "treatment" was stopped in the middle of the study for safety reasons after three out of the twelve participants were transported to the emergency room via ambulance after experiencing hemorrhages as a result of not following the established two-drug medical abortion regimen.[69] Indeed, this supposed "treatment" has not even been proven safe or effective in animal studies. Moreover, as previously noted, patients who obtain abortions, including medication abortion, overwhelmingly report satisfaction with their decision to obtain abortion care. Plaintiffs have offered no sound evidence to the contrary.[70] Indeed,

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[67] *See* D. Grossman et al., *Continuing Pregnancy After Mifepristone and 'Reversal' of First-Trimester Medical Abortion: A Systematic Review*, 92 CONTRACEPTION 206–211 (Jun. 2015); Hal C. Lawrence, *The American College of Obstetricians and Gynecologists Supports Access to Women's Health Care*, 125 OBSTETRICS & GYNECOLOGY 1282, 1283 (Jun. 2015); G. Delgado & M. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 ANNALS OF PHARMACOTHERAPY (Dec. 2012); Mitchell D. Creinin, *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion*, 135 OBSTETRICS & GYNECOLOGY 158-165 (Jan. 2020), https://journals.lww.com/greenjournal/pages/articleviewer.aspx?year=2020&issue=01000&article=00021&type=Fulltext.

[68] *Planned Parenthood of Tennessee & N. Mississippi v. Slatery*, 523 F. Supp. 3d 985, 991 (M.D. Tenn. 2021) ("The theory … that progesterone can 'reverse' the effects of mifepristone – is primarily based on two papers co-authored by Dr. George Delgado.").

[69] Creininet al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion, A Randomized Controlled Trial*, 135 Obstetrics & Gynecology 158 (2020), https://journals.lww.com/greenjournal/Abstract/2020/01000/Mifepristone_Antagonization_With_Progesterone_to.21.aspx.

[70] In his declaration, Dr. George Delgado claims that he treats women with so-called abortion reversal. *See* Delgado Decl. ¶ 13. However, there is no evidence that women seek such "treatment" (which is not medically-supported) with any degree of frequency. His perspective

as noted supra, the evidence shows that patients report satisfaction with their decision to obtain care in this manner.

C. Mifepristone Has a Growing Range of Critical Uses Outside of Medication Abortion.

Mifepristone has many uses outside of medication abortion. Enjoining its use will cause irreparable harm to many patients who are prescribed mifepristone by their physician to treat a range of conditions related to pregnancy and beyond. As with many medications, mifepristone has "off label"[71] applications beyond medication abortion. Off label drug use is a critically important tool in any physician's toolbox, and even become the clinical standard of care for treating certain conditions.[72] Mifepristone is already widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable and incomplete abortions.[73] Studies have also examined its use for a range of other maternal health purposes, including treatment of uterine fibroids (tumorous growths of uterine muscle), and treatment of endometriosis (abnormal tissue growth outside the uterus, which can cause severe pain and infertility). Mifepristone is also used off label to reduce

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is purely anecdotal and based on the experience of treating patients one day a week – he is primarily an administrator. Delgado Decl. ¶ 12.

71 Off Label Drug Use is defined as "prescribing currently available and marketed medications but for an indication (e.g., a disease or a symptom) that has never received Food and Drug Administration (FDA) approval." Wittich et al., *Ten common questions (and their answers) about off-label drug use*, Mayo Clin Proc. 2012 Oct. 87(10), 982-90, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/. Off label use is extremely common, with approximately one in five prescriptions being written for off-label use. *Id.*

72 *Id.*

73 Mara Gordon et. al., « A drug that eases miscarriages is difficult for women to get," *NPR*, (10 January 2019) <https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.>

the duration of bleeding or hemorrhaging during certain serious pregnancy complications, and may have beneficial effects on the cervix in full-term pregnancies, which in turn may affect the likelihood of successful labor, as opposed to cesarean delivery. Outside of pregnancy and related conditions, mifepristone has been studied and considered for use in treating mood disorders and depression, alcohol use disorders, PTSD, Cushing's Disease and even some types of brain tumors.

Mifepristone is the focus of hundreds of currently active studies exploring its potential for the off-label uses described above—and many more. Requiring the FDA to withdraw or suspend its approval of mifepristone[74] would hamstring those studies and have devastating down-stream consequences.

V. CONCLUSION

For these reasons and those articulated in Defendant's Brief, the balance of the equities strongly disfavors an injunction. We strongly urge the Court to deny the relief sought in the Complaint.

[74] *See* Motion for Preliminary Injunction, 18 November 2022, p.2.