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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Other Authorities

I. INTERESTS OF AMICI CURIAE

Amici curiae are leading medical and public health societies representing physicians, clinicians, and public health professionals who serve patients in 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 professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies.

Amici also include the American Academy of Family Physicians ("AAFP"), one of the largest national medical organizations representing nearly 128,000 family physicians and medical students; the American Gynecological & Obstetrical Society ("AGOS"), comprised of prominent scholars in obstetrics, gynecology, and women's health; the American Society for Reproductive Medicine ("ASRM"), a professional organization with over 8,000 members dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals; the Council of University Chairs of Obstetrics and Gynecology ("CUCOG"), which promotes excellence in medical education in Obstetrics and Gynecology through leadership development and more; the North American Society for Pediatric and Adolescent Gynecology ("NASPAG"), which provides multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive

health of youths; the National Association of Nurse Practitioners in Women's Health ("NPWH"), a professional community of over 12,500 clinicians who provide women's health and gender-related care; the Society of Family Planning ("SFP"), which represents more than 1,400 clinicians, scholars, and other individuals seeking to advance the science and clinical care of family planning; the Society of Gynecologic Oncology ("SGO"), which, among other things, collaborates with domestic and international organizations to advance women's cancer care; and the Society for OB/GYN Hospitalists ("SOGH"), a growing group of physicians and others in the healthcare field who support a "hospitalist" model for OB/GYN care.[1]

Ensuring access to evidence-based health care and promoting healthcare 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 ("FDA") approval of mifepristone was and continues to be based on sound medical science.

Amici's ability to safely and effectively care for patients requires access to mifepristone, which has undergone rigorous testing and review and has been approved for use in the United States for over twenty years. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is correctly understood.

---

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

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 FDA and overturn a *twenty-three-year-old approval*. Their request is not based on rigorous scientific review and analysis but on 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 including 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. 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 0.3%*** of patients. The risk of death is almost non-existent.

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

Plaintiffs also do not (and cannot) provide any evidence that mifepristone has any negative psychological impact on patients. In fact, the vast majority of patients report being happy with their decision to have an 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).

Plaintiffs' claim that mifepristone somehow increases the burden on our healthcare system is upside down. Medication abortion actively ***reduces*** any burden, as patients are able to take mifepristone at home following consultation with their healthcare provider. The suggestion that complications are so frequent as to burden medical providers has no evidentiary basis. To the contrary, because mifepristone has a significant (and growing) number of uses beyond medication abortion and is used as an effective treatment for miscarriage and other pregnancy-related conditions, enjoining its use would ***increase*** the burden on patients, clinicians, and the healthcare system as a whole by eliminating an established and effective form of care.

Reversing the FDA's approval of mifepristone, in whole or in any part, would cause profound and irreparable harm to patients across the country. This harm will be most severe for people of color and low-income patients who have higher rates of maternal mortality and morbidity and less access to alternative procedures (i.e., procedural abortion). In short, the Court should reject Plaintiffs' attempt to overturn

scientific judgment in a manner contrary to medical evidence and deny their request for a preliminary injunction.

III. Mifepristone and Medication Abortion Are Safe and Effective.

The most common method of medication abortion in the United States 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 miscarriage or early pregnancy loss (which can be life threatening),[4] a term which includes spontaneous abortion, missed abortion, incomplete abortion, or inevitable abortion.

---

[2] Combined mifepristone–misoprostol regimens are 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*, 1, 4 (Oct. 2020) ("ACOG Practice Bulletin No. 225").

[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." ACOG Committee Opinion No. 815, *Increasing Access to Abortion*, e107, e108 (Dec. 2020) ("ACOG Committee Opinion 815").

[4] ACOG Practice Bulletin No. 200, *Early Pregnancy Loss*, e197, e203 (Nov. 2018, reaff'd 2021) ("ACOG Practice Bulletin No. 200"); Amy Steigerwald, *Northwest Ohio Mom Speaks Out About Abortion Care After Second Miscarriage*, WTOL 11: TOLEDO NEWS (Sept. 7, 2022), https://www.wtol.com/article/news/health/toledo-area-mom-speaks-about-access-to-abortion-care-after-second-miscarriage/512-64be010c-293f-419f-9a87-8c5f3ea59d17; Pam Belluck, *They Had Miscarriages, and New Abortion Laws Obstructed Treatment*, NY TIMES (July 17, 2022); Rosemary Westwood, *Bleeding and in Pain, She Couldn't Get 2 Louisiana ERs to Answer: Is it a Miscarriage?*, NPR (Dec. 29, 2022), https://www.npr.org/sections/health-

The scientific evidence supporting mifepristone's safety and efficacy is overwhelming. Mifepristone is one of the most studied medications prescribed in the United States and has 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 for some patients; and (3) additional safeguards around mifepristone's use are medically unnecessary. Plaintiffs point to no sound scientific evidence to support their arguments, relying instead on anecdotes, unsupported theories, and speculation.

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

Decades of evidence demonstrate that medication abortion is safe and effective, with exceptionally low rates of major adverse events. Mifepristone's safety profile is on par with common painkillers like ibuprofen and acetaminophen, which more than 30 million Americans take in any given day.[5]

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.[6] This included an independent and unbiased review of the manufacturer's preclinical research and clinical test results to ensure that mifepristone was safe and effective, and

---

shots/2022/12/29/1143823727/bleeding-and-in-pain-she-couldnt-get-2-louisiana-ers-to-answer-is-it-a-miscarria. *See also* Oriana Gonzalez & Ashley Gold, *Abortion Pill Demand Soaring Following Roe's Demise*, AXIOS (July 19, 2022), https://www.axios.com/2022/07/18/abortion-pills-mifepristone-misoprostol-demand.

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

[6] *See* Compl. Ex. 24, Mot. for Prelim. Injunction App. 518 ("2000 FDA Approval").

that the health benefits outweighed the known risks.[7] 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."[8] Those studies conclusively demonstrated that "serious adverse events . . . are rarely reported . . . with rates ***generally far below 1.0%***."[9]

In the two decades since mifepristone's 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 used in more than 630 published clinical trials—of which more than 420 were randomized controlled studies (the gold standard in research design).[10] At a high level, these studies have repeatedly concluded that even minor complications arising from medication abortion are extremely rare.[11] As a result, medication abortion has been and continues to be very

---

7 Development & Approval Process | Drugs, U.S. FOOD & DRUG ADMINISTRATION (Aug. 08, 2008), https://www.fda.gov/drugs/development-approval-process-drugs (visited Jan. 30, 2023).

8 FDA Ctr. For Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020*, 1, 50 (Mar. 29, 2016) ("2016 FDA Approval"), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

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

10 Based on a review of PubMed, the National Institute of Health's sponsored database of research studies.

11 Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States*, WASHINGTON D.C. THE NAT'L ACADEMIES PRESS 45, 58 (2018) ("NASEM Report"), 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-

common today.[12] As of 2020, medication abortions account for most abortions in the United States,[13] while maintaining an exceptionally low rate of complications.

Major adverse events—which include hospitalization and serious infection or bleeding—are "exceedingly rare," occurring in approximately 0.3% of cases.[14] Studies have shown an even smaller number, finding between 0.014% and 0.07% of patients

---

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."); Beverly Winikoff, et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 (5) OBSTET. GYNECOL. 1070, 1070-76 (2012); Dina Abbas et al., *Outpatient Medical Abortion is Safe and Effective Through 70 Days Gestation*, 92(3) CONTRACEPTION 197, 197-99 (Sept. 2015).

[12] Advancing New Standards in Reproductive Health ("ANSIRH"), *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone US Post-marketing Adverse Events Summary through 6/30/2021*, UNIV. OF CAL., S.F. 1,1 (Nov. 2022), https://www.ansirh.org/research/brief/analysis-medication-abortion-risk-and-fda-report-mifepristone-us-post-marketing.

[13] Rachel K. Jones et al, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INSTITUTE (Feb. 24, 2022, *last updated* Dec. 21, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions.

[14] 2016 FDA Approval, *supra* n.8, at 56; *see also* Ushma D. Upadhyay, et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125(1) OBSTETRICS & GYNECOLOGY 175, 175-83 (Jan. 2015) (study of over 55,000 abortions found a major complications rate of 0.23% – 0.31% for medication abortion; 0.16% for procedural abortion (i.e., abortion by aspiration); ANSIRH, *U.S. Studies on Medication Abortion without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. (Oct. 2021), https://www.ansirh.org/research/brief/us-studies-medication-abortion-without-person-clinician-dispensing-mifepristone; 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).

experience serious infection.[15] The FDA has made clear that the same complications can be observed following a miscarriage, procedural abortion, or medication 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]

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, yielding an approximate mortality rate of 0.00035%.[18] Even when including deaths that followed a medication abortion but did not appear to be related to mifepristone use, that number rises to only 0.00065%.[19] Indeed, there is a greater risk of complications or mortality for procedures like wisdom-tooth removal, cancer-screening, colonoscopy, plastic surgery, and the use of Viagra,

---

15 *Id.* at 53-54.

16 Mifeprex Prescribing Information, U.S. FOOD & DRUG ADMIN. 1, 2,5 (Mar. 2016) https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

17 *See* Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, Morbidity & Mortality Weekly Report, 70(9) U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION 1, 29, tbl. 15 (Nov. 26, 2021) (finding mortality rate of 0.00041% to 0.00078% from 1978 to 2018); Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998-2010*, 126 OBSTET. GYNECOL. 258, 261 (Aug. 2015) (noting a mortality rate of approximately 0.0007% mortality rate for abortion).

18 ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, UNIV. OF CAL., S.F., 1, 1-2 (April 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.; *see also* 2016 FDA Approval, *supra* n.8, at 8, 47, 51.

19 *Id.*

than by any abortion method (medication or procedural).[20] To illustrate, studies have shown Viagra to be associated with 4.9 deaths per 100,000 prescriptions,[21] that death by colonoscopy occurs in about 0.03% of cases,[22] and the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[23] Put simply, medication abortion is among the safest medical interventions in any category—related to pregnancy or not.

Notwithstanding Plaintiffs' inaccurate characterization of mifepristone as an "endocrine-disruptor," their purported concerns that mifepristone will affect adolescents

---

[20] ANSIRH, *Safety of Abortion in the United States*, UNIV. OF CAL., S.F. 1, 1-2 (Dec. 1, 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf (complication rate for wisdom-tooth extraction is approximately 3.5x higher than abortions; complication for tonsillectomies is approximately 4x higher than abortions); ASGE Standards of Practice Committee, *Complications of Colonoscopy*, 74(4) AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY 745, 745 (2011) ("ASGE, Complications of Colonoscopy") (33% of colonoscopies result in minor complications); Frederick M. Grazer & Rudolph H. de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeon*s, 105 PLASTIC & RECONSTRUCTIVE SURGERY 436, 441 (2000) (mortality rate from liposuction in late 1990s was 20 deaths per 100,000 patients); Kortsmit, *supra* n.17, at 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).

[21] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283(5) JAMA NETWORK, 590, 590–593 (Feb. 02, 2000).

[22] ASGE, Complications of Colonoscopy, *supra* n.20, at 747.

[23] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTET. GYNECOL. 215, 216 (Feb. 2012) ("Raymond & Grimes"). Data from the Centers for Disease Control and Prevention indicates that the risk of death associated with childbirth is increasing. *See* Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2020*, NCHS HEALTH E-STATS (Feb. 2022), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/e-stat-maternal-mortality-rates-2022.pdf.

because it briefly blocks progesterone receptors in the uterus is completely unfounded. Adolescents who are pregnant have extremely 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.[24]

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 it. 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 wanted abortion."[25] 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

---

[24] Maarit Niinimaki et al., *Comparison of Rates of Adverse Events in Adolescent and Adult Women Undergoing Medical Abortion: Population Register Based Study*, BJM, 1,1 (April 19, 2011) ("medical 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.

[25] 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(2) JAMA PSYCHIATRY, 169, 177 (Feb. 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(2) BMJ OPEN (2016); M. Antonia Biggs et al., *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States*, 105(12) AM. J. PUB. HEALTH 2557, 2557 (Dec. 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., 1, 6 (July 2015).

that followed.[26] 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.[27] Mifepristone's safety has been evident for decades thanks to rigorous scientific study. And that risk profile has not changed since its approval, confirmed by ongoing and robust study, testing, and monitoring of market data.[28]

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

Patients eligible for medication abortions also have the option to obtain a procedural abortion (sometimes referred to as a "surgical abortion," though that it does not involve "surgery" as that term is generally understood). While both methods are exceedingly safe, medication abortion offers unique benefits over procedural abortion for some patients. In *amici's* experience, patients choose medication abortion over

---

[26] Corrine H. Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLOS ONE 1, 7 (July 8, 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*, SOC. SCI. & MED. (March 2020) (finding no evidence of negative emotions or decision regret among those surveyed and that the prevailing sentiment post-abortion was relief).

[27] *See* Compl. ¶ 272.

[28] *See* 2016 FDA Approval, *supra* n.8, at 8 ("FDA has received such reports for 15 years, and it has determined that the safety profile of Mifeprex is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely.").

procedural abortion for a variety of reasons, which can include a desire to avoid physical contact or the trauma of having instruments inserted into their vagina due to prior sexual assault or trauma; a desire to be able to have the abortion in the company of family or loved ones; or simply a desire for privacy. Patients experiencing miscarriage may choose to take mifepristone and misoprostol for the same reasons, rather than to opt for an in-clinic procedure for treatment.

Additionally, medication abortion may be the only option that is reasonably accessible to patients, even in states that have chosen to keep abortion legal. This is especially true for patients from historically marginalized populations, those with low incomes, and patients living in rural areas or long distances from medical facilities.[29] Even when medical facilities are reasonably accessible to patients, a significant number that provide abortion care offer only medication abortion.[30] For patients with certain medical conditions, disabilities, or other extenuating life circumstances (such as a lack of access child care, the inability to take time off work, or not being able to travel long distances), medication abortion is by far the safest and most accessible option.[31] Given

---

[29] *See* March of Dimes, *Maternity Care Desert* (Oct. 2022), https://www.marchofdimes.org/peristats/data?reg=99&top=23&stop=641&lev=1&slev=4&obj=9&sreg=99&creg; Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department*, 2 J. AM. C. EMERGENCY PHYSICIANS OPEN. (2021); Anthony Mazzeo et. al, *Delivery of Emergency Care in Rural Settings*, ACEP EMERGENCY MEDICINE PRAC. COMM. (July 2017).

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

[31] 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

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 critical to ensuring patient access to necessary and potentially life-saving medication abortion.

C. The FDA's Recent Decisions Removing Restrictions on Mifepristone Are Amply Supported by Evidence of Safety.

Plaintiffs' concerns regarding the supposed lack of "safeguards" with respect to mifepristone are contradicted by the evidence. The FDA's 2016 change to the mifepristone label was supported by substantial evidence, including a wide-ranging systemic review,[32] a randomized control trial,[33] and several observational studies,[34] all of which demonstrated the safety and effectiveness of mifepristone up to the ten-week

---

abortion is very rare. Patients face only a 2.1% chance of needing a follow-up intervention. *See* Luu Ireland et. al., *Medical Compared with Surgical Abortion for Pregnancy Termination in the First Trimester*, 126 OBSTET. GYNECOL., 22-28 (2015).

[32] *See* 2016 FDA Approval, *supra* n.8, at 16 (citing M.J. Chen & M.D. Creinin, *Mifepristone with Buccal Misoprostol for Medical Abortion Obstet Gynecol: A Systematic Review*, MNP26 OBSTET. GYNECOL. 12-21 (2015)).

[33] *See id.* at 79 (citing C.D. Olavarrieta et al., *Nurse Versus Physician Provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial*, 93 BULL. WORLD HEALTH ORGAN. 249-58 (2015)).

[34] *See e.g.*, *id.* at 18 (citing Winikoff, *supra* n.11; A.A. Boersma et al., *Mifepristone Followed by Home Administration of Buccal Misoprostol for Medical Abortion Up to 70 Days of Amenorrhoea in a General Practice in Curacao*, 16 EUR. J. CONTRACEPT. REPROD. HEALTH CARE 61-66 (2011)); 2016 FDA Approval, *supra* n.8, at 35 (citing P. Sanhueza Smith 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*, 22 REPROD. HEALTH MATTERS 75-82 (2015)).

gestational period.[35] More recent studies have confirmed these results. For example, a 2020 evidence review recognized yet again that medication abortion can safely and effectively be used up to at least 70 days of gestation.[36] Plaintiffs cite no scientific support for their conclusion to the contrary, and instead rely entirely on the declarations of Drs. Jester and Wozniak—neither of which offers any meaningful analysis of gestational age with respect to mifepristone use.[37]

Similarly, the FDA's decision not to require an ultrasound was based on sound medicine. Simply put, it is medically unnecessary to perform an ultrasound for 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.[38] Although an ultrasound can help determine gestational age

---

35 *See* E.V. Gouk, *Medical Termination of Pregnancy at 63 to 83 Days Gestation*, 106 BR. J. OBSTET. GYNAECOL. 535-39 (1999); Boersma, *supra* n.34; B. Winikoff, *supra* n.11; Abbas, *supra* n.11.

36 *See* ACOG Practice Bulletin No. 225, *supra* n.2.

37 *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 beyond mentioning dissatisfaction with the FDA's 2016 approval of mifepristone at later gestational age.

38 *See* 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); Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 CONTRACEPTION 43, 46 (2021) ("Preabortion ultrasounds are usually unnecessary for safe and effective medication abortion.").

and can identify an ectopic pregnancy, studies have shown that both of these goals can be accomplished just as effectively by discussing the patient's medical history—even via a telemedicine appointment.[39] 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.[40] The "safeguards" promoted by Plaintiffs are medically unnecessary.

Plaintiffs also express discontent with respect to the FDA's decision to eliminate certain restrictions in 2016—for instance, its revision to the "adverse event reporting" mandate, which required physicians to report adverse events and injuries to the FDA under certain circumstances.[41]

---

[39] *See* 2000 FDA Approval, *supra* n.6 ("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 J. AM. MED. ASS'N INTERNAL MED. 482, 489 (2022) (finding that "if pregnancy duration can be reasonably estimated by history and if no symptoms or risk factors for ectopic pregnancy are present," ultrasonography should not be required).

[40] *See id.* ("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.").

[41] *See e.g.*, Compl. ¶¶ 250, 304; Pl.'s Br. Supp. Mot. Prelim. Inj. at 18-19.

In 2016, the FDA eliminated a requirement that providers report *all* adverse events relating to mifepristone to the FDA, noting that after 15 years of reporting, the safety profile for mifepristone was "well-characterized" and that "serious risks occur rarely."[42] On this basis, the FDA determined it was sufficient to continue requiring the reporting of patient deaths, but that information regarding any other "serious, unexpected adverse events" could be collected on a reduced basis through periodic reports.[43] By the time this decision was made, mifepristone had been studied extensively for over 15 years and was proven to be safe time and again. Plaintiffs offer no support for their suggestion that eliminating the requirement was unsupported by the medical evidence, 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.[44] There is no justification to revisit the FDA's reasoned decision now.

---

42 2016 FDA Approval, *supra* n.8, at 48-49.

43 *See id.* at 8.

44 For instance, Plaintiffs speculate that a "lack of accurate information on adverse events" will cause patients to mistrust their doctors. Compl. ¶ 309. 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

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.

Abortion care can be lifesaving, especially for people suffering from serious health conditions or experiencing 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[45]—the very people who are most likely to experience severe maternal morbidity and more likely to die from

---

that malpractice liability rates have been affected by the accessibility of medication abortion.

[45] *See* Christine Dehlendorf & 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* at 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.").

pregnancy-related complications.[46] 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.[47] Enjoining the use of mifepristone would only harm these patients by removing a relatively accessible and entirely safe treatment from the marketplace—resulting in more people being denied requested abortion care.

Indeed, there is substantial evidence that the *denial* of abortion care alone causes harm. Patients who are denied abortions experience an increase in violence from intimate partners compared with patients who were able to obtain an abortion.[48] Studies have repeatedly shown that being denied an abortion also 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."[49]

In arguing otherwise, Plaintiffs claim continuing a pregnancy is somehow a safer alternative, arguing that "pregnancy rarely leads to complications that threaten the life of

---

[46] *See* Ctr. for Medicare & Medicaid Serv., *Advancing Rural Maternal Health Equity* at 1 (May 2022), https://www.cms.gov/files/document/maternal-health-may-2022.pdf; *see also* Juanita Chinn, et al., *Health Equity Among Black Women in the United States*, 30 J. WOMEN'S HEALTH 212, 215 (2021).

[47] *See* Benson, *supra* n.29.

[48] *See* Sarah Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, BMC MEDICINE (2014).

[49] 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).

the mother or the child."[50] This statement is not founded in scientific evidence. Instead, Plaintiffs cite a lone opinion piece and a study of post-abortion complications. Empirical evidence shows that women are at least 14 times more likely to die during childbirth than during any abortion procedure[51] and are at an increased risk of experiencing hemorrhage, infection, and injury to other organs during pregnancy and childbirth as well.[52] 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.[53] Pregnancy, particularly when coupled with a preexisting condition, can quickly evolve into a life-

---

50 *See* Compl. ¶ 51.

51 *See* Raymond & Grimes, *supra* n.23, at 216-17 & fig. 1. 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. David Boulware, *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 OBSTETRICS & GYNECOLOGY 447 (2016). By contrast, the mortality rate associated with abortions performed from 1998 to 2005 was 0.6 deaths per 100,000 procedures. Raymond & Grimes, *supra* n.23 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 [deaths] per 100,000 [patients]) is a small fraction of that for childbirth (8.8 [death] per 100,000 [patients])." Nat'l Acads. of Sci., Eng'g. & Med., *supra* n.11 at 74.

52 Raymond & Grimes, *supra* n.23, at 215, 216–17 & fig.1.

53 *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).

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.[54]

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.[55] Should the use of mifepristone be proscribed or limited, medical facilities will experience an increased strain on already-limited resources.[56] Medication abortion allows a patient to ingest their prescription safely at home after consultation with their healthcare providers, freeing clinicians and in-patient resources to focus on providing other needed medical care. The same is true of prior restrictions on mifepristone use that the FDA has now

---

[54] Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, THE COMMONWEALTH FUND (Nov. 18, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries.

[55] 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. ¶ 286. There is absolutely no evidence of this—as explained above, medication abortion is extremely safe and rarely results in complications requiring a blood transfusion.

[56] *See* Alexander Janke, *An Emergency in U.S. Emergency Care: Two Studies Show Rising Strain*, U. MICH. INST. OF HEALTHCARE POL'Y & 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.

lifted, like requiring patients to take the medication in front of a physician or making patients travel to a facility for a medically unnecessary follow-up appointment.

Plaintiffs also suggest that medication abortion is a drain on in-patient resources because physicians must frequently counsel patients on "reversal" or regret.[57] To start, there is *no* medical evidence or even sound medical theory to support the idea that a medication abortion can be "reversed."[58] The reversal "treatment" described in the Complaint is the invention of one of the Plaintiffs—George Delgado.[59] The only randomized controlled study that has attempted to analyze 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 regimen.[60] Indeed, this supposed "treatment" has not even been proven safe or effective in animal studies. Moreover, as noted *supra*, patients who obtain abortions, including medication abortion, overwhelmingly report satisfaction with their decision to obtain abortion care.

---

57 Pl.'s Br. Supp. Mot. Prelim. Inj., *supra* n.41 at 9 (speculating that doctors may need to divert resources to assist patients seeking to reverse medication abortion).

58 *See, e.g.*, D. Grossman et al., *Continuing Pregnancy After Mifepristone and 'Reversal' of First-Trimester Medical Abortion: A Systematic Review*, 92 CONTRACEPTION 206–211 (Jun. 2015).

59 *Planned Parenthood of Tennessee & N. Mississippi v. Slatery*, 523 F. Supp. 3d 985, 991-92 (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.").

60 Mitchell Creinin, et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion, A Randomized Controlled Trial*, 135 Obstet. & Gynecol. 158, 158 (2020).

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 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"[61] applications beyond abortion. Off-label drug use is a critically important tool in any clinician's toolbox and is very common for treating certain conditions.[62] Mifepristone is already widely prescribed for management and treatment of miscarriages, including spontaneous, missed, inevitable, and incomplete abortions.[63] 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).[64] Mifepristone is also used off-label to reduce the

---

61 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*, 87(10) MAYO CLINIC PROC. 982, 982 (Oct. 2012). Off label use is extremely common, with approximately one in five prescriptions being written for off-label use. *Id.* at 983.

62 *Id.* at 982-90.

63 Mara Gordon & Sarah McMannon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.

64 Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYST. REV. (Aug. 2012); Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, Clin. and Exp. Obstetrics & Gynecology 350, 350-53 (2016); *see also* Neelofar Shaikh et al., *Mifepristone in Fibroids: Comparative Study of Safety and Efficacy of Dosage Vs Daily Dosage Struggle*, 12 J. MIDLIFE HEALTH 39 (2021).

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.[65] Outside of pregnancy and related conditions, mifepristone has been used as a treatment for certain patients with Cushing's Syndrome and studied and considered for use in treating mood disorders and depression, alcohol use disorders, post-traumatic stress disorder, and even some types of brain tumors.[66] Enjoining the use of mifepristone will have a significant impact on treatments entirely unrelated to pregnancy.

V. CONCLUSION

For these reasons and those articulated in Defendant's Brief, we strongly urge the Court to deny the relief sought in the Complaint.

---

65 *See* Yanxia Cao et al., *Efficacy of Misopristol Combined with Mifepristone on Postpartum Hemorrhage and its Effects on Coagulation Function*,13 INT. J. CLIN. EXP. MED. 2234, 2234-240 (2020); Shaikh, *supra* n.64, at 39-45; Zhang, *supra* n.64, at 350-53; Kanan Yelikar et al., *Safety and Efficacy of Oral Mifepristone in Pre-Induction Cervical Ripening and Induction of Labour in Prolonged Pregnancy*, 65 J. OBSTET. GYNAECOL. INDIA 221-25 (2015).

66 Scripps Research Inst., *Mifepristone Treatment of Alcohol Use Disorder*, NO. NCT02179749 CLINICALTRIALS.GOV (2022); Monserrat Llaguno-Munive et al. *Mifepristone Repurposing in Treatment of High-Grade Gliomas*, Front. Oncol. (2021); Farah H. Morgan & Marc J. Laufgraben, *Mifepristone for Management of Cushing's Syndrome,* 33 PHARMACOTHERAPHY 319, 319-29 (2013); Peter Gallagher & Allan H. Young, *Mifepristone (RU-486) Treatment for Depression and Psychosis: A Review of the Therapeutic Implications*, 2 NEUROPSYCHIATRY DISEASE & TREATMENT 33, 33-42 (2006).

Dated: February 10, 2023

Respectfully submitted,

/s/ Matt W. Sherwood

Shannon Rose Selden (*pro hac vice pending*)
Adam Aukland-Peck (*pro hac vice pending*)
Megan McGuiggan (*pro hac vice forthcoming)*
DEBEVOISE & PLIMPTON LLP
919 Third Ave.
New York, NY 10022
Tel.: 212-909-6000
srselden@debevoise.com
aauklandpeck@debevoise.com
mmcguiggan@debevoise.com

Molly Megan (*pro hac vice pending*)
Jessica Morris (*pro hac vice forthcoming*
AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS
409 12th Street, SW
Washington, DC 20024
mmeegan@acog.org
jmorris@acog.org

Matt W. Sherwood
State Bar No. 24066063
msherwood@mwlawfirm.com
MCCARN & WEIR, P.C.
905 S. Fillmore, Suite 530
Amarillo, Texas 79101
Tel: (806) 350-5395
Fax: (806) 350-5388

Counsel for Amici

CERTIFICATE OF SERVICE

I certify that on February 10, 2023, I electronically filed the foregoing document with the Court, using the CM/ECF system. The electronic case filing system will send a notice of electronic filing to the attorneys who have consented in writing to accept service by electronic means.

/s/ Matt W. Sherwood
Matt W. Sherwood