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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF CALIFORNIA,

Plaintiff,

v.

HEARTBEAT INTERNATIONAL, INC., and REALOPTIONS, INC.,

Defendants.

Case No.: 23CV044940

DECLARATION OF ELENA KRAUS, M.D., PH.D.

Judge: Hon. Patrick McKinney
Dept: 18

Action filed: September 21, 2023

I, Elena Kraus, M.D., Ph.D., declare and state as follows:

1. I am over the age of eighteen (18), of sound mind, and competent to make the statements contained in this declaration.

I. PROFESSIONAL BACKGROUND, QUALIFICATIONS, AND MATERIALS REVIEWED

2. I am board-certified in Obstetrics and Gynecology and Maternal Fetal Medicine (MFM). MFM is a subspecialty of OB/GYN focusing on the care of women and babies at increased risk for morbidity and mortality during and after pregnancy. I am currently licensed to practice medicine in Missouri and Nebraska. I have practiced Obstetrics and Gynecology and/or Maternal Fetal Medicine for the last 9 years. I currently practice as a MFM Specialist in Saint Louis, Missouri.

3. I have been employed by Mercy Clinic as an MFM Specialist since September 2024. Prior to that, I worked for CHI Health in Lincoln and Omaha, Nebraska as a MFM Specialist from 2022-2024. I also worked as the Medical Director for the CHI Health Birth Center in Lincoln, Nebraska. I was on faculty in the department of Obstetrics and Gynecology at Creighton University in Omaha, Nebraska.

4. Currently, I function as faculty for the graduate medical education programs at Mercy, including their residency in Obstetrics and Gynecology and with medical students from Ponce Health Sciences University. Within these roles, I serve as a supervising and/or collaborating physician and clinical educator to Certified Nurse Midwives, Nurse Practitioners, medical students, and resident physicians in Obstetrics and Gynecology and Family Medicine. I also participate in and support the research activities of residents in Obstetrics and Gynecology.

5. I have a PhD in Health Care Ethics, which included substantial education, training, and experience in both theoretical and clinical applications of medical ethics. I have additional education in the philosophical, theological, legal, and social frameworks through which to interpret a variety of ethical issues in health care and health research.

6. As part of my PhD training, and my fellowship in Maternal Fetal Medicine, I received additional instruction and performed research in informed consent, ethical behavior in

medicine, medical teamwork, and family planning in women with medical conditions that contribute to high-risk pregnancies.

7. I have a Master of Science in Clinical Investigation, with additional education, training and practice in research design and research methods, statistics, and performing quantitative and qualitative research and analysis.

8. My practice includes caring for patients with a wide range of medical and surgical complications that put them at increased risk for adverse pregnancy and delivery outcomes.

9. As part of my practice, I monitor fetal life and development from very early pregnancy until delivery through ultrasound. I perform fetal genetic screening and diagnosis through laboratory and ultrasound assessments including in utero sampling of fetal tissue. I diagnose, monitor, and coordinate appropriate delivery and postnatal care for babies with a variety of genetic and other prenatal diagnoses.

10. As part of my practice, I am regularly consulted to provide assessment and counseling concerning the safety of a wide variety of medications used to treat medical diagnoses in pregnancy. Based on available data and an assessment of fetal safety risks and maternal risks and benefits, I determine with patients whether medications should be discontinued and/or changed due to potential abortifacient, teratogenic, and other adverse fetal or maternal effects.

11. As a Maternal Fetal Medicine Specialist, I supervise labor and delivery, attend deliveries, and perform cesarean sections. My practice also includes care for miscarriages and stillbirth, and cesarean section hysterectomies. I perform cerclages and ultrasound-guided needle procedures for genetic diagnosis and intrauterine fetal therapy that include amniocentesis, intrauterine blood transfusions, and removal of excess fluid from the fetal lungs, abdomen, bladder, and amniotic cavity. I work in both the outpatient and inpatient setting to provide high risk obstetric care. I currently see patients referred to and transferred to our facilities from across the states of Missouri and Illinois.

12. In addition to my clinical and educational responsibilities, I have served on several state and national committees in areas of maternal and perinatal health, including the Perinatal Safety and Quality Committee and Maternal Morbidity and Mortality Review Committee for CHI

Health, the Nebraska Perinatal Quality Improvement Collaborative (NPQIC), and the Women and Infants Clinical Institute (WICI) from 2022-2024. These committees aimed to monitor maternal and fetal outcomes and to perform and evaluate research and implement healthcare initiatives across the CHI Health system to improve maternal and fetal outcomes.

13. I conduct original research and have authored or co-authored peer-reviewed and other publications in multiple areas of medicine and health care ethics. My primary areas of investigation have been in ethical behavior in clinical medicine and medical research, medical business ethics, conflicts of interest and bias in medicine and research, interprofessional teamwork in medicine, trial of labor after cesarean section, and family planning in women with medical comorbidities. My research during my Maternal Fetal Medicine Fellowship was supported by a National Institute of Health Loan Repayment Program (NIHLRP) Award from the National Institute of Child Health and Human Development.

14. To prepare this declaration, I reviewed the complaints filed in *People of the State of California v. Heartbeat International Inc. and RealOptions, Inc.*, No. 23-cv-44940 (Cal. Super. Ct., Alameda Cnty., Sep. 21, 2023), and *Culture of Life Family Services, Inc. v. Attorney General Rob Bonta*, No 24-cv-1338 (S.D. Cal. July 30, 2024). Based on those complaints, I have been asked to provide expert testimony regarding the history, efficacy, and safety of providing women with supplemental progesterone following initiation of a medication abortion in order to increase the likelihood of a continuing pregnancy, otherwise known as abortion pill reversal.

15. Based on my review of the scientific literature, I conclude to a reasonable degree of scientific certainty that providing pregnant women with supplemental progesterone following the initiation of a mediation abortion is safe and efficacious at increasing the likelihood of continuation of pregnancy.

16. A copy of my curriculum vitae (CV) is attached as Exhibit A. I make this declaration based on 16 years of formal post-baccalaureate education and training, 14 years of clinical education and practice, experience and interaction with colleagues and patients, and my own clinical and social sciences research and ongoing familiarity with relevant medical and other literature. The opinions contained herein are based on this education, training, and experience.

These opinions are my own and do not represent the opinions of my employer or any professional or other group.

II. EXPERT OPINIONS

A. Background on Medication Abortions

17. Medication abortions involve the use of medications rather than a surgical procedure to induce an abortion. Data from the Guttmacher Institute indicates there were approximately 642,700 medication abortions in the United States in 2023. They are increasingly more common than surgical abortions, accounting for approximately 63% of all abortions last year.[1]

18. The U.S. Food and Drug Administration (FDA) has approved two abortion-inducing medications, mifepristone (RU-486) and misoprostol. These medications are used individually and combined in regimens that induce abortion and are FDA-approved for use until 70 days of gestation. In the United States, the preferred regimen includes a dose of Mifepristone 200mg taken orally, followed by a variable dose and route (oral or vaginal) of Misoprostol 24 – 48 hours later. These medications together act to prevent and break down the connection between a developing pregnancy and the uterine lining, and expel the pregnancy due to uterine contractions and cervical opening.[2]

19. Mifepristone is a selective progesterone receptor modulator. It acts by binding the progesterone receptor with an affinity greater than endogenous progesterone. When it binds to the receptor, it inhibits the activity of endogenous progesterone, but does not activate the receptor, thereby acting as an anti-progestin. The action of endogenous progesterone is critical to becoming pregnant and sustaining early pregnancy. The subsequent effects of this sequestration of the receptor on the uterus include decidual necrosis, cervical softening, increased uterine contractility,

[1] Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All U.S. Abortions in 2023—An Increase from 53% in 2020*, Guttmacher Institute (Oct. 18, 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

[2] American College of Obstetricians and Gynecologists' Committee on Practice Bulletins-Gynecology SoFP, *Medication Abortion Up to 70 Days of Gestation: ACOG Practice Bulletin, Number 225*, 136 Obstet. Gynecol. e31-e47 (2020).

and prostaglandin sensitivity.[3] Mifepristone was developed as an abortifacient because of its ability to compete with progesterone at the receptor level. Early in vitro animal studies showed that increased progesterone concentrations could displace mifepristone from the progesterone receptor, characteristic of what is called a competitive inhibitor. Its effects could also be overcome with increasing the substrate concentration, in this case progesterone, leading the drug's inventor to conclude that it acts "reversibly."[4] There has been no evidence to suggest that mifepristone is teratogenic, that is, it has not been shown to cause birth defects when taken in the first 12 weeks of pregnancy above the baseline 2-3% risk of fetal anomalies in any pregnancy.[5]

20. Misoprostol is a prostaglandin E1 analogue that causes cervical softening and uterine contractions. It helps the uterus expel an early pregnancy and is used both to complete spontaneous and elective abortions in the first trimester.[6] In addition to being used in medication abortions, it is commonly used in obstetrics to induce labor in the second and third trimesters. However, it is not FDA-approved for cervical ripening or labor induction indications, and up until 2002 had an absolute contraindication from the FDA for use in pregnancy.[7] When used in the first trimester, it has been associated with birth defects, specifically limb deficiency and Mobius sequence (facial nerve paralysis).[8,9] However, other case series have not shown an increase in these birth defects.[10] This is likely because the malformations are so rare, that bigger studies are needed in order to see this outcome occur.

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[3] *Id.*

[4] Emile-Etienne Baulieu, *RU 486: An Antiprogestin Steroid with Contragestive Activity in Women*, *in* The Antiprogestin Steroid RU486 and Human Fertility Control 1 (Baulieu & Segal eds., 1985).

[5] Niyomugabo Bernard, et al., *Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study*, 120 BJOG 568-74 (2013).

[6] ACOG, *supra* note 2.

[7] American College of Obstetricians and Gynecologists ACOG Committee Opinion Number 283, *New U.S. Food and Drug Administration labeling on Cytotec (misoprostol) use and pregnancy*, 101 Obstet. Gynecol. 1049-1050 (2003).

[8] Anne L. Pasturszak et al., *Use of Misoprostol during Pregnancy and Mobius' Syndrome in Infants*, 338 N. Engl. J. Med. 1881-1885 (1998).

[9] Claudette H. Gonzalez, et al., Case Notes, *Limb deficiency with or without Mobius sequence in seven Brazilian children associated with misoprostol use in the first trimester of pregnancy*, 47 Am. J. Med. Genet. 59-64 (1993).

[10] Bernard, et al., *supra* note 5.

21. Rates of effectiveness in completing an abortion for the combined mifepristone with misoprostol regimen range from approximately 92% to more than 99% with various misoprostol regimens. The protocol is less effective when used at later gestational ages. Rates of ongoing pregnancy are 0-5%, with more pregnancies continuing when the medications are provided after 57 days gestation.[11] If Mifepristone is not available, Misoprostol is sometimes used alone, but is less effective.[12] Mifepristone alone, even when given at high doses of 600mg, has been shown to have an abortion completion rate of only approximately 87%.[13] Another study at this same dose reported that, for up to 49 days gestation, Mifepristone alone had a 70% completed abortion rate, 20% incomplete abortion rate (residual tissue), and 10% fetal survival rate. For up to 70 days gestation, Mifepristone alone had a 50% completed abortion rate, 35% incomplete abortion rate, and 15% fetal survival rate.[14] However, at the lower doses used in the U.S., one review of data indicated that approximately 8-46% of pregnancies continue after mifepristone alone.[15] Another review assessing early mifepristone studies concluded the rate of continued pregnancy after mifepristone alone at 200mg doses was approximately 23%, explaining that the 8-46% range failed to distinguish between incomplete abortions with a deceased fetus and continued pregnancies.[16] This review is consistent with a more recent review of 16 studies, concluding rates of less than 25% for gestational ages less than 49 days.[17] Failure rates are higher with lower doses and at more advanced gestational ages.

22. If a pregnancy continues, a woman must choose whether to proceed with more medications or a procedure, or to continue the pregnancy. If a woman desires to continue the pregnancy after taking mifepristone, or both mifepristone and misoprostol, the most commonly

[11] Elizabeth G. Raymond, et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 Contraception 26-37 (2012).
[12] ACOG, *supra* note 2.
[13] Bernard Maria, et al., *Termination of early pregnancy by a single dose of mifepristone (RU 486), a progesterone antagonist*, 28 Eur. J. Obstet. Gynecol. Reprod. 249-255 (1988).
[14] Baulieu, *supra* note 4, at p.24.
[15] Daniel Grossman, et al., *Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review*, 92 Contraception 206-211 (2015).
[16] Mary Davenport, et al., *Embryo Survival after Mifepristone: A Systematic Review of the Literature*, 33 Issues L. & Med. 3-18 (2017).
[17] Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, 90 Linacre Q. 395-407 (2023).

provided care is expectant management with serial evaluation of the pregnancy.[18] The American College of Obstetricians and Gynecologists (ACOG) recommends that "all patients with a continuing pregnancy after using mifepristone and misoprostol should be provided with all the pregnancy options and a thorough discussion of the risks and benefits of each."[19] Ultimately, approximately 95-99% of women who take both mifepristone and misoprostol will ultimately complete their abortions, either through additional medications or a surgical procedure.[20] Overall, ACOG recommends "patients should be supported in their choice of how to proceed."[21]

23. The experience of a medication abortion with these two agents almost invariably involves bleeding and cramping "which are necessary for the process to occur," and frequently much heavier bleeding and more severe cramping than menses.[22] Adverse effects are more common with misoprostol, and include nausea, vomiting, diarrhea, headache, dizziness, and fevers and/or chills. With mifepristone alone, bleeding is the most common side effect. Serious bleeding can also be experienced, but bleeding requiring a blood transfusion is approximately 0.1%, and overall less than 1% of patients will require an additional intervention for excessive bleeding. In patients who use mifepristone and misoprostol as prescribed, approximately 0.25% will require additional medical interventions or hospitalization due to adverse events related to the medication abortion, like bleeding or infection.[23,24]

B. Data Surrounding the Experience of Abortions

24. Pregnancy is difficult, as is making a decision about abortion. Unfortunately, women often make a decision to end their pregnancy when they are sick, scared, or otherwise stressed. Many feel immense pressure from family, partners, or even their healthcare providers. Many others come to believe they must choose between their own life and that of their unborn child, and feel like abortion is their only option. There have been many studies on the short and

[18] Grossman, et al., *supra* note 15.
[19] ACOG, *supra* note 7.
[20] Mary Gatter, et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269-273 (2015).
[21] ACOG, *supra* note 7.
[22] ACOG, *supra* note 2.
[23] Raymond, et al., *supra* note 11.
[24] Gonzalez, et al., *supra* note 9.

long-term psychological effects of abortion. Although it is often suggested by abortion advocates that the vast majority of women are satisfied with their decision to have an abortion,[25,26] the results are more complicated. Some women do not have worse mental health outcomes, but others do.[27] One study concluding most women do not have regrets about their choice to have an abortion has been called into question due to methodological flaws, bias, and reliance on unvalidated and inadequate assessment of decision satisfaction.[28,29]

25. Instead, data indicates that approximately one third of women who choose to have abortions persistently believe the choice was consistent with their values and preferences, but that approximately two thirds of women who choose abortions feel the choice was unwanted, coerced, or in other ways inconsistent with their values and preferences.[30] These dynamics increase the chances of emotional disturbance following the abortion, including regret, depression, shame, grief, relationships strain and difficulty bonding with subsequent children.[31] Depression is increased in women after having abortions with an overall rate of approximately 35%,[32] significantly above baseline rates of depression in reproductive age women (7-14%).[33]

26. In my experience asking thousands of women their obstetric histories, many spontaneously express regret at the abortions they had, and many others avoid discussing them due to feelings of shame. It is not a stretch to consider then, that many women, even after taking the first part of their medication abortion (mifepristone), may have immediate regrets and wish there was a way to reverse the medicine and not complete the abortion. Of women who take mifepristone

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[25] Diana Green Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (Scribner 2021).
[26] Corinne H. Rocca, et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLoS ONE e0128832 (2015).
[27] Brenda Major, et al., *Abortion and Mental Health: Evaluating the Evidence,* 64 Am. Psychologist 863-890 (2009).
[28] David C. Reardon, et al., *The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health*, 15 Cureus e38882 (2023).
[29] Major, et al., *supra* note 27.
[30] *Id.*
[31] *Id.*
[32] Natnael A. Gebeyehu, et al., *Global prevalence of post-abortion depression: systematic review and Meta-analysis*, 23 BMC Psychiatry 786 (2023).
[33] Jean Y. Ko, et al., *Depression and Treatment Among U.S. Pregnant and Nonpregnant Women of Reproductive Age*, *2005-2009*, 21 J. Womens Health (Larchmt) 830-6 (2012).

but have a continuing pregnancy, evaluation of adverse event reports for mifepristone indicates that approximately 22% will ultimately continue the pregnancy.[34] It is uncertain exactly what percent of women seek abortion pill reversal (APR) after taking mifepristone. Data from Heartbeat International, an organization that supports the Abortion Pill Rescue Network, an international group facilitating APR for women who seek it, indicates they receive approximately 150 calls a month from women seeking APR and have ultimately helped save over 5,000 lives.[35]

C. Background on Progesterone as a Hormone of Fertility

27. Progesterone is a hormone made naturally in the female body by the female adrenal cortex and ovaries. This hormone plays a critical role in the menstrual cycle of a female by building up the lining of the uterus to prepare it for implantation of a pregnancy. Progesterone plays a similar critical role in pregnancy, stabilizing the uterine lining, prohibiting contractions, and optimizing the immune system.[36] Without optimal levels, there are increased risks of miscarriage and preterm birth. It is released in the first 10 weeks by the corpus luteum (within the ovary), and later by the placenta.[37]

28. The action of endogenous progesterone is critical to becoming pregnant and sustaining early pregnancy, and thus is a target for medications used to cause abortion, like mifepristone. Due to its beneficial characteristics early in pregnancy, and its role in maintaining uterine quiescence later in pregnancy, progesterone supplementation has become widely used by reproductive endocrinologists as well as obstetricians in early pregnancy to prevent pregnancy loss (luteal phase support), and later to prevent preterm birth.[38]

29. There is some confusion about the nomenclature of progesterone and its synthetic analogs. Progesterone refers to natural, endogenous progesterone, but can also refer to synthetic

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[34] Kathi Aultman, et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues L. & Med. 3-26 (2021).

[35] Heartbeat International, *A Last Chance to Choose Life*, Heartbeat International (Oct. 30, 2024), https://www.heartbeatinternational.org/our-work/apr.

[36] Jessie K. Cable & Michael H. Grider, *Physiology, Progesterone*, StatPearls Publishing LLC (Nov. 1, 2024), https://www.ncbi.nlm.nih.gov/books/NBK558960/.

[37] *Id.*

[38] Gian Carlo Di Renzo, et al., *Progesterone: History, facts, and artifacts*, 69 Best Pract. Res. Clin. Obstet. Gynaecol. 2-12 (2020).

progesterone that is bioidentical. Bioidentical progesterone has the same chemical structure as naturally produced progesterone and has been used to support female fertility for more than 50 years.[39] Progestins are the synthetic form of progesterone. Progesterone and progestins are both used in many different medications treating a variety of pathology. In addition to those indications already mentioned, they are used in various types of birth control, as well as medications used to treat amenorrhea, abnormal uterine bleeding, and postmenopausal hormone replacement therapy.[40,41] There are also neurologic and immunologic effects that are being studied for use in medical applications.[42]

D. Progesterone in Early Pregnancy

30. Progesterone has been used for decades to support early pregnancy using various routes, including oral, vaginal, and intramuscular injection. It has been studied extensively to prevent miscarriage in the setting of luteal phase defects, recurrent pregnancy loss, and in those with threatened miscarriage (vaginal bleeding) early in pregnancy. The need is pressing. Early pregnancy loss is very common, affecting 10-15% of known clinical pregnancies and up to 31% of all pregnancies.[43] It has clinical and psychological implications, including medical and surgical morbidity and health care use and costs,[44] as well as psychological sequelae, including increased rates of posttraumatic stress disorder, depression, and anxiety.[45]

31. In a Cochrane review of 94 randomized controlled trials of progesterone supplementation in early pregnancy in women using assisted reproduction, there was no clear benefit to the use of progesterone in various administrations in terms of an improvement in

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[39] *Id.*

[40] Michael Edwards & Ahmet S. Can, *Progestins,* StatPearls Publishing LLC (Nov. 1, 2024), https://www.ncbi.nlm.nih.gov/books/NBK563211/.

[41] Lucie Kolatorova, et al., *Progesterone: A Steroid with Wide Range of Effects in Physiology as Well as Human Medicine*, 23 Int. J. Mol. Sci. 7989 (2022).

[42] *Id.*

[43] Allen J. Wilcox, et al., *Incidence of early loss of pregnancy*, 319 N. Engl. J. Med. 189 (1988).

[44] Erin C. Strumpf, et al., *The effects of early pregnancy loss on health outcomes and health care utilization and costs*, 57 Health Serv Res. 786-795 (2022).

[45] Jessica Farren, et al., *Posttraumatic stress, anxiety and depression following miscarriage and ectopic pregnancy: a multicenter, prospective, cohort study*. 222 Am. J. Obstet. Gynecol. 367 (2020).

outcomes, including ongoing pregnancy and live birth.[46] Another review assessing the use of progesterone in the first trimester to prevent recurrent miscarriage indicated a slight benefit for those receiving progesterone for live birth rates, however quality of available trials limited certainty of other benefits.[47] Another randomized control trial (RCT) had similar conclusions—that progesterone therapy in the first trimester did not lead to a significantly higher rate of live births in those with recurrent miscarriages.[48] In another RCT studying progesterone supplementation in women with vaginal bleeding in early pregnancy (threated miscarriage), there was no significant difference in the rate of live birth overall, however rates of live birth were improved in those with prior miscarriages.[49] In assisted reproductive technology (ART), progesterone supplementation in the first trimester is commonly used, as the evidence supports reduced rates of early miscarriage.[50] Despite some uncertainty as to the clear benefits of using supplemental progesterone in pregnancy, with miscarriage and use of ART being so common, it is very commonly used in early pregnancy. Furthermore, its use is frequently off-label, as several of the formulations and indications are not FDA-approved.[51]

32. The main side effects of supplemental progesterone are abdominal pain, bloating, headache, fatigue, GI disturbance, nausea, mood swings, and in those using intramuscular formulations, reactions at the site of injection.[52] Substantial evidence supports the safety of progesterone supplementation in pregnancy for both mother and fetus when using the most common forms of progesterone supplementation.[53] Although concern for genital abnormalities in

[46] Michelle van der Linden, et al., *Luteal phase support for assisted reproduction cycles*, Cochrane Database of Syst. Rev. CD009154 (2015).
[47] David M. Haas, et al., *Progestogen for preventing miscarriage in women with recurrent miscarriage of unclear etiology*, Cochrane Database of Syst. Rev. CD003511 (2019).
[48] Arri Coomarasamy, et al., *A Randomized Trial of Progesterone in Women with Recurrent Miscarriages,* 373 N. Engl. J. Med. 2141-2148 (2015).
[49] Arri Coomarasamy et al., *Progesterone to prevent miscarriage in women with early pregnancy bleeding: the PRISM RCT*, 24 Health Technology Assessment 1-70 (2020).
[50] Rebecca S. Usadi & Kathryn S Merriam, *On-label and off-label drug use in the treatment of female infertility*, 103 Fertility & Sterility 583-94 (2015).
[51] *Id.*
[52] *Id.*
[53] The Practice Committee of the American Society for Reproductive Medicine, *Progesterone supplementation during the luteal phase and in early pregnancy in the treatment of infertility: an*

neonates who were exposed to progesterone in early pregnancy has been described, the propensity of the data indicates the medication does not increase the rate of these abnormalities.[54] Studies evaluating the potential later developmental, behavioral, and health effects on children exposed to progesterone prenatally have not conclusively shown benefit or harm. However, there is a dearth of long-term evaluation of effects beyond early childhood.[55]

E. Background on Abortion Pill Reversal

33. The possibility of abortion pill reversal is based on the established maternal and fetal safety of progesterone in early pregnancy, as well as established scientific principles of early pregnancy development and the mechanism of action of mifepristone. As previously stated, mifepristone acts as a competitive binder of the progesterone receptor—it binds to progesterone receptors at twice the avidity of progesterone itself, thus blocking endogenous progesterone from acting to support a pregnancy. The scientific tenets of competitive inhibition in pharmacology are that a competitive antagonist binds a specific receptor with a high affinity, often higher than the substrate (agonist) itself.[56] However, in the presence of additional or supplemental progesterone, the available progesterone will also bind to the receptors, and can ultimately outcompete mifepristone for the receptors. The effect is a competitive inhibition of the mifepristone that curbs and even negates its effects. Competitive inhibition can be reversible or irreversible.[57] In the case of mifepristone, it is a *reversible* competitive inhibitor of progesterone. This pharmacology is behind the use of progesterone to "reverse" medication abortions after the first pill (mifepristone) is administered.[58]

34. The fact that in early pregnancy, most women normally have very high levels of

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educational bulletin, 89 Fertility & Sterility 789-92 (2008).

[54] Arri Coomarasamy et al., *PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages —a randomised, double-blind, placebo-controlled international multicentre trial and economic evaluation*, 20 Health Technology Assessment 1-92 (2016).

[55] Noor E. Simons, et al., *The long-term effect of prenatal progesterone treatment on child development, behavior and health: a systematic review*, 128 BJOG. 964-974 (2020).

[56] John W. Pelley, Elsevier's Integrated Review Biochemistry 33-34 (2d ed. 2011).

[57] *Id*. at 33.

[58] George Delgado & Mary Davenport, *Progesterone Use to Reverse the Effects of Mifepristone,* 46 Annals Pharmacotherapy 1723 (2012).

progesterone does not contravene the basic science of competitive antagonism. In cases of competitive antagonism, the inhibition by mifepristone is proportional to the amount of inhibitor bound, and the inhibitor binds reversibly. Therefore, if the substrate concentration (progesterone) is increased (that is, above normal levels in the body, which are already elevated), the understood result is that it outcompetes the inhibitor at the receptor.[59] In these cases, it is still the administration of even more competition (in this case, more progesterone) that overcomes the inhibitory action of the mifepristone bound to progesterone receptors.

35. Another example of this science in action in medical therapies in my own practice is the use of buprenorphine and other μ receptor (a primary pain receptor) antagonists for the treatment of substance use disorders in pregnancy. These medications used to treat substance use disorder act primarily by binding the μ receptor,[60] stimulating the pain receptors without the use of medical or illicit opiate medications, and decreasing cravings. However, being on these medications can make it more difficult to treat pain, because the pain receptors are already bound by buprenorphine. Therefore, one of the tenets of acute pain management (as in labor, delivery, or postoperatively) is the administration of "higher and more frequent doses of opioid analgesics to achieve adequate pain control."[61] Similar to progesterone, increasing concentrations of the substrate (in this case, opiates) can ultimately overcome the inhibitory effects of buprenorphine, leading to binding of the actual opiate to the receptor, thereby alleviating pain. Because increasing the concentration of substrate levels in these cases ultimately displaces the competitive inhibitor, this would slow and halt the inhibitory effects, and then allow the receptor to function with the normal substrate, thereby "reversing" those inhibitory effects.

36. There is limited high-quality data on mifepristone reversal with progesterone. However, taken together, multiple studies show it could be effective without significant risk to the

[59] John W. Pelley, Elsevier's Integrated Review Biochemistry 33-34 (2d ed. 2011).
[60] Mark K. Greenwald, et al., *Effects of Buprenorphine Maintenance Dose on μ-Opioid Receptor Availability, Plasma Concentrations, and Antagonist Blockade in Heroin-Dependent Volunteers*, 28 Nature Neuropsychopharm. 2000-09 (2003).
[61] Daniel P. Alford, et al., *Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy*, 144(2) Ann. Intern. Med. 127-34 (2007).

mother or fetus.[62] The highest level of clinical evidence used in medicine to establish causal associations is the randomized controlled trial (RCT). However, it is not always possible to ethically or practically conduct this level of study, and poorly designed RCTs will provide poor data. The ethics of research are challenging when participants enrolled are pregnant women, and they have to consent to taking an abortifacient medication without clear knowledge of how effective the intervention (progesterone reversal) would be.

37. Take for example the combination of mifepristone-misoprostol that is currently recommended as first line treatment for late intrauterine death and stillbirth by the Royal College of Obstetricians and Gynaecologists.[63] They base this recommendation and use in healthcare settings on a case series, and a randomized controlled trial on the use of mifepristone alone in a different medical application. In this way, they use the basic science underpinning its actions in the body, randomized controlled trials of the medication in a different setting, indication, or dosing, and case series of the specific application to support use for patients off-label. Despite the absence of large prospective randomized controlled trials and specific approval for this indication, its use in this setting is routine.

38. The FDA even has specific programs of accelerated review to approve treatments in order to expedite the availability of new drugs, particularly for conditions with unmet need, such as rare diseases or diseases that are life-threatening but may have limited treatments, like cancer.[64] There are consistently treatments that reach the market, being FDA-approved for use, without having data from randomized controlled trials.[65] The majority of these are for chemotherapy agents for the treatment of cancer, which have far more potential risks from toxicity and side effects than supplemental progesterone.

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[62] DeBeasi, *supra* note 17.

[63] Royal College of Obstetricians & Gynaecologists, *Late Intrauterine Fetal Death and Stillbirth* (2010), https://www.rcog.org.uk/media/0fefdrk4/gtg_55.pdf.

[64] U.S. Food & Drug Administration, *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review* (current as of June 12, 2023), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

[65] Anthony J. Hatswell, et al., *Regulatory approval of pharmaceuticals without a randomized controlled study: analysis of EMA and FDA approvals 1999-2014*, 6(6) BMJ Open e011666 (2016).

39. The one RCT for abortion pill reversal with bioidentical progesterone was undertaken by Mitchell D. Creinin and included women with a confirmed viable gestation between 44 and 63 days of gestation who were planning surgical abortion. Prior to the procedure, they took mifepristone alone, followed by high dose progesterone 24 hours later. The study was stopped after recruiting only 12 of the anticipated 40 due to safety concerns, specifically hemorrhage that required emergent medical treatment in 3 cases. Two of the three were in the placebo group, and one in the progesterone group. Of those studied, 4 in the progesterone group continued to have cardiac activity after 2 weeks, and 2 in the placebo group.[66]

40. A stronger RCT on progesterone after mifepristone was a 2016 study of 461 participants comparing the quick initiation of a progestin-only contraceptive (depot medroxyprogesterone acetate) at the time of mifepristone therapy for abortion, versus initiation after a completed abortion with mifepristone. There was no difference between groups in the need for surgery to complete the abortion. However, ongoing pregnancy after initial abortion treatment was significantly increased in the group receiving the progestin earlier.[67] As a result of this study, ACOG recommends that "patients who select depot medroxyprogesterone acetate (DMPA) for contraception should be counseled that the administration of DMPA on day 1 of the medication abortion regimen may increase the risk of ongoing pregnancy."[68]

41. The fact that APR involves provision of supplemental progesterone up to 72 hours after mifepristone, not at the same time as mifepristone, is irrelevant. Mifepristone is rapidly *absorbed*, but its *intended actions* do not largely occur during this time. This is based on the timing of how mifepristone is available to be active in the body. After mifepristone is absorbed, it binds a serum transport protein, alpha-1 acid glycoprotein (AAG) in the bloodstream.[69,70] As understood

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[66] Mitchell D. Creinin, et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135 Obstet. Gynecol. 158-165 (2020).

[67] Elizabeth G. Raymond, et al., *Effects of depot medroxyprogesterone acetate injection timing on medical abortion efficacy and repeat pregnancy: a randomized controlled trial*, 128 Obstet. Gynecol. 739-745 (2016).

[68] ACOG, *supra* note 2.

[69] Oskari Heikinheimo, et al., *The Pharmacokinetics of Mifepristone in Humans Reveal Insights Into Differential Mechanisms of Antiprogestin Action*, 68 Contraception 421, 422 (2003).

[70] Nikhil N. Sarkar, *Mifepristone: Bioavailability, Pharmacokinetics, and Use-Effectiveness*, 101

even in early studies on mifepristone, "only free Mifepristone is active" on the target tissues, leading to its intended effects.[71] Binding to AAG thus limits its availability to act on target tissues at the time of absorption, and instead, it is released over a longer period of time. This contributes to mifepristone's long half-life. Thus, mifepristone is absorbed quickly, but its action occurs over a more prolonged period. During this period of activity in its target areas, mostly within about 72 hours, supplemental progesterone would have time to counteract its effects, and hold potential for being applicable for effectively outcompeting mifepristone and its actions at progesterone receptors.

42. Lastly, a new RCT published in 2025 aimed to define the effects of progesterone (P4) supplementation following the postovulatory administration of mifepristone (200mg) on the endometrium (the inner lining of the uterus where implantation occurs). More specifically, the "study primarily aimed to determine whether exogenous P4 could reverse the effects of mifepristone at the gene expression level and to identify biological processes disrupted by mifepristone that might be restored by P4 supplementation."[72]

43. The timing of mifepristone administration is important, as the effects of the medication vary depending on when it is taken within a woman's menstrual cycle. Its administration 2 days after the luteinizing hormone (LH) surge means it was given soon after ovulation ("postovulatory"). It is at this time in the cycle mifepristone has the most significant effects on the endometrial lining, thus preventing implantation or causing the loss of a recently implanted embryo (a pregnancy). In these cases progesterone administration would have the greatest impact to limit or reverse these effects, allowing for the continuation of pregnancy. Within a woman's menstrual cycle, conception is most likely to occur when intercourse is timed within the "fertile window," an approximately 6 day period from about 5 days prior to ovulation until 1 day after ovulation.[73]

Eur. J. Obst. Gynecol. Reprod. Biol. 113, 113-15 (2002).

[71] Maria, et al., *supra* note 13.

[72] Alejandro Tapia-Pizarro, et al., *Progesterone Supplementation after Postovulatory Mifepristone Reduce Changes in Human Endometrial Gene Expression*, 169(4) Reproduction e240372 (2025).

[73] Allen J. Wilcox, et al., *Timing of Sexual Intercourse in Relation to Ovulation — Effects on the Probability of Conception, Survival of the Pregnancy, and Sex of the Baby*, 333(23) N. Engl. J.

44. The research study's design entailed nine healthy women aged 18-43 with proven fertility, regular menstrual cycles, and who had previously undergone surgical sterilization procedures at least 1 year prior to study enrollment. Prior sterilization as part of inclusion criteria circumvents any ethical issues related to experimentation with abortifacients in those who are or could become pregnant.

45. The study design was a placebo controlled trial. This is a type of randomized controlled trial where the control group receives a placebo, instead of no treatment or another treatment (such as standard treatment). In Group A, subjects received postovulatory mifepristone 200mg, followed by either placebo or progesterone (600mg/day vaginally) for the next 3 days, in two non-consecutive study cycles in a randomized order. A second subgroup (Group B) of 4 subjects underwent two further non-consecutive study cycles, during which they received a postovulatory placebo, then received either 600mg/day of vaginal progesterone or placebo for 3 days. Endometrial biopsies obtained 7 days after ovulation in each cycle were analyzed in two ways, histologically, and with transcriptome analysis.

46. The histological examination assessed endometrial dating, that is, a determination of the stage of the menstrual cycle by examination of the uterine lining. An endometrial maturation delay of at least 3 days was identified significantly more frequently in specimens that had received mifepristone. The inhibitory effects of mifepristone on the endometrium during the secretory phase of the menstrual cycle have been previously described in other studies.[74,75] This new study indicated further that in cycles that received progesterone after mifepristone, there were fewer endometrial samples where there was discordance from histological dating of at least 3 days. These findings suggest that exogenous progesterone may help promote the restoration of the secretory phenotype, which is the normal phenotype of the progesterone-dominant secretory phase which prepares the endometrium for implantation. This demonstrates the potential role of supplemental

Med. 1517 (1995).

[74] K. Gemzell-Danielsson & M. Hamberg, *The Effect of Antiprogestin (Ru 486) and Prostaglandin Biosynthesis Inhibitor (Naproxen) on Uterine Fluid Prostaglandin F2 Alpha Concentrations*, 9(9) Human Reprod. 1626 (1994).

[75] K. G. Danielsson, et al., *Effect of Low Daily Doses of Mifepristone on Ovarian Function and Endometrial Development*, 12(1) Human Reprod. 124 (1997).

progesterone in modulating the effects caused by mifepristone on the endometrium.

47. Transcriptome analysis is a process of describing gene expression from a specific tissue by evaluating RNA transcripts produced by cells in that tissue. RNA transcripts are the intermediary step between gene expression and protein formation and function in a living cell. By performing transcriptome analysis on endometrial cells exposed to mifepristone alone, and mifepristone + progesterone, and then comparing these expression patterns to each other and the control group of placebo alone, these authors were able to identify 266 transcripts that exhibited an opposite regulatory response in their levels of expression when comparing mifepristone + placebo and mifepristone + progesterone. This finding suggests that specific gene expression that is affected by mifepristone in the human endometrium is reversed by exogenous progesterone when administered 24 hours later. It also supports the concept of endometrial plasticity, where recovery is possible after transient reductions in progesterone stimulation, which is what happens when mifepristone binds to progesterone receptors.

48. Further studies are needed to establish a direct regulatory effect of exogenous progesterone administered after mifepristone on the proteins coded by these variably expressed transcripts. Still, this study adds to our understanding of hormonal regulation and supplementation on the histology of the human uterus and endometrium, and further supports the potential effectiveness of supplemental progesterone in reversing the effects of mifepristone when used for medication abortions.

49. In the absence of a quality RCT, other evidence is used to support the efficacy and safety of medications. Most other data on progesterone use to counteract mifepristone in the setting of medication abortion are case series on the use of progesterone in those desiring abortion pill reversal after taking mifepristone. The two initial studies each reported on only 6 women who desired to reverse their medication abortion after already taking mifepristone, but before taking misoprostol. In these two initial studies, 4/6 and 2/3 women who received progesterone ultimately carried their pregnancies to term [76,77] A third study was published in 2018, reporting on 754 who

[76] Delgado & Davenport, *supra* note 58.
[77] Deborah Garratt & Joseph V. Turner, *Progesterone for preventing pregnancy termination after*

desired to reverse their medication abortions. Outcomes with progesterone were compared with baseline ongoing pregnancy rates in those who only took mifepristone. Results indicated a statistically significant increase in pregnancy continuation, with rates of approximately 64-68%, and intramuscular and oral progesterone being the most effective. The study reported no increased risk of birth defects in those who received progesterone.[78]

F. Concerns on the Use of Progesterone in Abortion Pill Reversal

50. There have been two primary critiques of the use of progesterone in abortion pill reversal related to efficacy and safety. Initial critiques were spearheaded by Daniel Grossman. He published a systemic review in 2015 which reviewed the initial 6 patient case series from 2012 and 13 studies addressing the likelihood of continuing pregnancy following mifepristone alone. Dr. Grossman concluded that there usual care for women seeking to continue their pregnancies following mifepristone was expectant management with surveillance. He further concluded that there was inadequate evidence to establish that supplemental progesterone increased the likelihood of pregnancy continuation following mifepristone because of its small size.[79] Subsequently, Dr. Grossman published an opinion article in 2018 which reviewed the 754 patient case series from 2018 and maintained his conclusion about efficacy of abortion pull reversal because of what he perceived to be flaws in the study.[80]

51. Dr. Grossman never concludes that progesterone will not increase the likelihood of maintaining pregnancy, merely that there is inadequate evidence to believe it does. In interviews, Dr. Grossman has also explained that he did not see any safety concerns with administering supplemental progesterone, but that promoting abortion pill reversal misleads the public about the

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initiation of medical abortion with mifepristone, 22 Eur. J. Contracept. Reprod. Health Care 472-475 (2017).

[78] George Delgado, et al., *A case series detailing the successful reversal of the effects of mifepristone using progesterone*, 33 Issues L. & Med. 21-31 (2018).

[79] Grossman, et al., *supra* note 15.

[80] Daniel Grossman & Kari White, *Abortion "Reversal" - Legislating without Evidence*, 379 N. Engl. J. Med. 1491-93 (2018).

prevalence of abortion regret.[81] Dr. Grossman's concerns therefore appear to be more political then medical, which is perhaps unsurprising in this context.

52. A second critique was undertaken by Mitchell Creinin, the researcher who published the truncated randomized control trial in 2020. Dr. Creinin came to a different conclusion from Dr. Grossman with respect to the safety of efforts to maintain a pregnancy following mifepristone. He concluded that the risk of hemorrhage was too great for women to take only mifepristone without subsequently taking misoprostol, even with the addition of progesterone. Thus, he concluded that abortion pill reversal was inherently unsafe.[82]

53. Dr. Creinin's apprehension seems manufactured for many reasons. First, there were twice as many cases of hemorrhage requiring intervention in the placebo group (albeit only 2 versus 1 in the progesterone group). This result implies that it is more concerning to take mifepristone alone, as without misoprostol there is slower and reduced effectiveness of expulsion of the pregnancy, thus leading to more bleeding. However, mifepristone is considered adequate alone as an abortifacient medication, and systematic evaluation on outcome data indicates it is effective and safe in this setting and a "reasonable option for women seeking abortion in the first trimester."[83] ACOG reports that less than 1% of patients will ultimately require emergency treatment for excessive bleeding, and the need for blood transfusion occurs in 0.1% or less of patients.[84]

54. I agree that rates of hemorrhage in his study were high—much higher than previous studies on mifepristone alone—where patients tolerated 200mg and 600mg with "very few side effects."[85] And it is difficult to resolve the significant difference between rates of serious hemorrhage in his study with other studies on mifepristone alone.[86] But there does not seem to have

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[81] Amanda Marcotte, *The Newest Crisis Pregnancy Center Offer: "Abortion Reversals,"* Slate (Nov. 1, 2024, 11:23 AM), https://slate.com/human-interest/2014/12/abortion-reversals-the-latest-anti-abortion-offer-from-crisis-pregnancy-centers.html.

[82] Creinin, et al., *supra* note 66.

[83] Elizabeth G. Raymond, et al., *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, 133 Obstet. Gynecol. 137-147 (2019).

[84] ACOG, *supra* note 2.

[85] Maria, et al., *supra* note 13.

[86] Grossman, et al., *supra* note 15.

been a valid reason for halting his study since excessive bleeding is a known risk of medication abortion, and numerous studies on similar or identical protocols of mifepristone were continued and completed.

55. Vaginal bleeding is a "natural consequence of the abortion process" and occurs in 100% of women who terminate their pregnancies successfully with medication.[87] A prior systematic review of 97 trials including 47,283 treated women—including several randomized controlled trials—for medication abortion with mifepristone 200mg and misoprostol (of several doses and administrations) indicated approximately 0.3% are hospitalized, most commonly for vaginal bleeding, pain, or infection. About 0.1% received blood transfusions.[88] The actual rate of these complications is low, but persistent. If the rate of "serious adverse reactions" is truly <0.5%, as indicated by the FDA,[89] and with over 642,000 medication abortions in 2023,[90] that is still more than 3,000 people yearly that have significant medical complications from these medications, which includes severe hemorrhage. There is no evidence that progesterone leads to worse bleeding or other outcomes, either in Dr. Creinin's study, or in case series where progesterone is given after mifepristone.

56. In order to determine the efficacy of mifepristone alone at different doses, and the combination of mifepristone and misoprostol for medication abortion, researchers have published many studies on mifepristone alone for purposes of pregnancy termination.[91] Furthermore, researchers have tolerated severe bleeding necessitating blood transfusions, hospitalizations, and surgical interventions in numerous previous studies.[92] In one earlier study on 2,015 women who received mifepristone and misoprostol (using a 600mg mifepristone and 400mcg misoprostol dose, respectively) for first trimester termination, excessive bleeding necessitated blood transfusions in

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[87] Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 N. Engl. J. Med. 1241-47 (1998).

[88] Elizabeth G. Raymond, et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87(1) Contraception 26-37 (2012).

[89] *Label for Mifeprex (mifepristone) Tablets*, FDA (rev. Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[90] The Guttmacher Institute, *Monthly Abortion Provision Study* (last updated Sep. 2024), https://www.guttmacher.org/monthly-abortion-provision-study.

[91] Grossman, et al., *supra* note 15.

[92] Raymond, et al., *supra* note 88.

four women and accounted for 93% of hospitalizations (including emergency-room visits), 95% of surgical interventions, and 48% of administrations of intravenous fluid.[93]

57. Furthermore, instead of increasing regulations related to its use (which would be reasonable if there were true safety concerns), the FDA has actually made mifepristone easier to acquire and use, and ACOG "advocates the removal of REMS [risk evaluation and mitigation strategy] restrictions for mifepristone."[94] Mifepristone alone has been FDA-approved for use from 49-70 days gestation, and the dosing has been reduced from 600mg to 200mg, indicating efficacy and safety of use for this indication. In addition, the FDA removed a requirement to dispense mifepristone in clinics, medical offices, and hospitals, meaning women could access mifepristone without seeing a medical professional.[95] All of these changes encourage the expanded use of mifepristone and reduced regulations for its use. Taken together, these actions communicate a low concern for any dangers related to mifepristone and support faith in its efficacy and safety. If taking mifepristone alone was a true safety concern, monitoring of outcomes would be critical. In fact, the FDA also removed the requirement for prescribers to report adverse event reports (AER) with mifepristone except a requirement to report deaths.[96]

58. In the real world, with the reduced restrictions on mifepristone and misoprostol by the FDA, surveillance is increasingly challenging, and may lead to more complications with no physician available or responsible to provide guidance and further care.[97] In contrast, in cases of patients who pursue abortion pill reversal with progesterone, they are connected with a physician practicing near them that provides care for the duration of treatment, whether it ends in termination or continuation of the pregnancy. At this point in the United States, most bad outcomes with medication abortion (anything less than death) are not even reported, and so an ongoing and accurate assessment of the risks of these medications is difficult. Making these medications

[93] Spitz, et al., *supra* note 87.
[94] ACOG, *supra* note 2.
[95] Aultman, et al., *supra* note 34.
[96] Aultman, et al., *supra* note 34.
[97] The Associated Press, *Texas challenges shield laws by suing New York doctor who prescribed abortion pills*, National Public Radio (Dec. 13, 2024), https://www.npr.org/2024/12/13/g-s1-38240/texas-abortion-pill-lawsuit-new-york-doctor-challenge-interstate-telemedicine.

accessible without exams, without an in-person visit, and increasingly with prescriptions from a physician in another state, puts women at increased risk for more severe consequences of the known complications from these medications.[98]

59. By definition, inducing an abortion has risks—risks that have likely been de-emphasized in order to facilitate access. In attempting to understand why Dr. Creinin chose to halt his study, I suspect that due to the now regular suppression of these negative outcomes, physicians like Dr. Creinin are impressed when they occur, which may have influenced the early termination of his research study.

G. The Unique Case of Abortion Pill Reversal

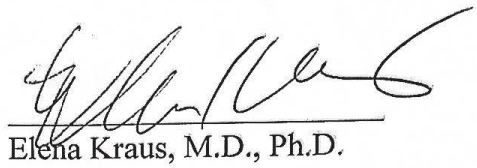
60. Abortion pill reversal is a very unique situation. In cases where women regret taking the initial pill the stakes are extraordinarily high and women will do anything to increase the chances they can save their baby's life. In these cases, they are willing to accept a very high risk to benefit ratio for an intervention—desiring anything that could increase their chances of continuing the pregnancy even in the slightest degree. In medicine, many people undergo treatments—even treatments with significantly more risks and side effects than progesterone—that are experimental. For example, in clinical trials of novel chemotherapy combinations for the treatment of cancer, patients are motivated to participate due to hope that the treatment will help and that, even if it does not, their participation could add information for the benefit of others. Research such as this is ethical as long as the methodology is sound and there is some evidence supporting potential benefit.

61. Ultimately, significant responsibility remains on the physician, who the patient trusts would not allow them to experience an investigational therapy unless he or she believed it could be helpful and not significantly harmful. Abortion pill reversal is similar—patients have significant hope of success, and may be less wavered by potential risks or safety concerns unless they are well-established and significant. In the context of a trusting relationship with a healthcare professional, shared decision making can be made in line with the patient's goals and desires. Thorough counseling is critical, describing the risks, benefits, and alternatives of intervention,

[98] *Id*.

including doing nothing, the extent of the data on efficacy, and the fact that the medication is being used off-label. In this context, they have the right to do everything possible to continue their pregnancy if that is what they desire.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed on January 16, 2025, in Saint Louis, Missouri.



Elena Kraus, M.D., Ph.D.

EXHIBIT A

ELENA MARIE (YATES) KRAUS, MD, PHD, MSCI, FACOG

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CURRENT POSITION

- Maternal Fetal Medicine Physician, Mercy Clinic Maternal & Fetal Medicine, St Louis, MO
- OB/GYN Faculty, Mercy Residency Program in Obstetrics & Gynecology
- Faculty, Ponce Health Sciences University

PAST POSITIONS

- Maternal Fetal Medicine Physician, CHI Health Clinic, St Elizabeth Hospital, Lincoln, NE and Creighton University Medical Center, Omaha, NE
- Assistant Professor in the Department of Obstetrics and Gynecology, Creighton University School of Medicine, Omaha, NE
- Medical Director, CHI Health Birth Center, Lincoln, NE

EDUCATION

University of Dallas, Irving, Texas
Bachelor of Science in Biology **2006**
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Saint Louis University, Gnaegi Center for Health Care Ethics, Saint Louis, MO
Doctor of Philosophy (PhD), Health Care Ethics **2013**
Dissertation: *Nurse Practitioners in Primary Care: A Grounded Theory Study of Physician and Nurse Practitioner Perspectives*

Saint Louis University Medical School, Saint Louis, MO
Medical Doctorate (MD) **2015**

Saint Louis University Department of Obstetrics and Gynecology, Saint Louis, MO
Residency in Obstetrics and Gynecology **2019**
Chief Resident of Academics

Saint Louis University Department of Obstetrics and Gynecology,
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Fellowship in Maternal Fetal Medicine **2022**

Washington University in Saint Louis
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Research Mentor: James Dubois, PhD, DSc
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LICENSURE

Nebraska and Missouri Medical Licenses **Current**
DEA and X-DEA licenses **Current**
Diplomate, American Board of Obstetrics & Gynecology **Current**
Diplomate, American Board of Obstetrics & Gynecology, Maternal & Fetal Medicine **Current**

SERVICE AND LEADERSHIP ACTIVITIES

Saint Louis University Medical School Admissions Committee, **2007 – 2015**
Student Representative

Book Reviewer for Doody's Enterprises **2009 – 2012**

Poster Judge, American Physician Scientists Association (APSA) **2015**
Annual Regional Conference, Saint Louis, MO

SSM Saint Mary's Hospital Ethics Committee **2019 – 2022**

Perinatal Safety and Quality Committee, CHI Health **2022 - 2024**
System-wide development and implementation of quality data and evidence-based performance improvement activities for obstetric care.

Nebraska Perinatal Quality Improvement Collaborative (NPQIC) **2022 - 2024**
State program to improve the delivery of and access to evidence-based and equitable health care for mothers and newborns.

Maternal Morbidity and Mortality Review Committee – CHI Health Nebraska **2022 – 2024**
Review of maternal morbidity and mortality cases across CHI Hospitals in Nebraska with the goal of quality and safety improvement.

Women and Infants Clinical Institute (WICI) – Common Spirit Health **2023 - 2024**
National organization of perinatal physician and nursing leaders within Common Spirit Health with the aim of improving women and infant health care across the system through research and quality improvement initiatives.

RESEARCH EXPERIENCE

Trial of Labor after Cesarean Section Research Group, Laura Vricella, MD, and William Perez, MD **2018 – 2022**
Saint Louis University, Division of Maternal Fetal Medicine, St. Louis, MO

Bander Center Coordinator, James DuBois, PhD, DSc **2008 – 2013**
Saint Louis University, Gnaegi Center for Health Care Ethics, St Louis, MO

Supported both administrative and research activities at the Bander Center. All activities focused on research and education in various areas of medical business ethics.

Research Assistant, James DuBois, PhD, DSc **2008 – 2013**
Saint Louis University, Gnaegi Center for Health Care Ethics, St Louis, MO
Supported research within the Social Sciences Research Group, including the UPWARD Program (Understanding and Preventing Wrongdoing in American Healthcare Research and Delivery).

Research assistant, Daniel Hoft, MD, PhD **2006**
Saint Louis University, Department of Molecular, Microbiology, and Immunology, Saint Louis, MO
Investigation of basic mechanisms of mucosal and systemic immunity against chronic intracellular pathogens, primary tuberculosis, with murine models

Research assistant, Julian Solway, MD, and Bahao Chen, MD **2005**
University of Chicago Pritzker School of Medicine, Department of Pulmonology and Critical Care, Chicago, IL
Characterization of GATA 5 promoters in murine models

RELATED EXPERIENCE

Guest Editor*, The AMA Journal of Ethics (*formally known as *Virtual Mentor)* **2009 – 2010**
Audiey Kao, MD, PhD, American Medical Association, Chicago, IL

Peer Reviewer for Elsevier **2016 – present**
The Journal of Nurse Practitioners and *Contemporary Nurse*

Guest Editor, *Narrative Inquiry in Bioethics* issue on Pregnancy Loss **2022**

Peer Reviewer for *AJOG MFM* **2023 - present**

PRESENTATIONS

DuBois, JM, **Kraus, EM**. (2012, May). *Physician Decision Making and the Web of Influence.* Oral presentation presented at: Saint Louis University Department of Ophthalmology Grand Rounds; Saint Louis, MO.

Kraus, EM. (2013, March). *Physician-Pharmaceutical Industry Interactions: Ethical Issues in Clinical Practice*. Oral Presentation presented at Saint Louis University Medical School Capstone Series; Saint Louis, MO.

Kraus, EM. (2014, April). *Nurse Practitioners in Primary Care: A Grounded Theory Study of Physician and Nurse Practitioner Perspectives.* Oral presentation at: Saint Louis University 3rd Annual Primary Care Research Symposium; Saint Louis, MO.

Kraus, EM. (2016, September). *Does the addition of Propranolol to oxytocin shorten the duration of*

labor and decrease the rate of cesarean sections? Oral presentation presented at: Saint Louis University Department of OB/GYN Evidence Based Medicine Series; Saint Louis, MO.

Kraus, EM. (2017, September). *Case Report: Ovarian Lymphoma in a 14-year-old with Bilateral Adnexal Massess.* Oral presentation presented at : Saint Louis University 20th Annual OB/GYN Resident Research Symposium; Saint Louis, MO.

Kraus, EM. (2018, August). *Endometriosis in Hydatid Cysts of Morgagni: A Retrospective Cohort Study of Another Atypical Manifestation of Endometriosis*. Oral presentation at: Saint Louis University Department of OB/GYN Resident Research Day; Saint Louis, MO.

Kraus, EM. (2019, April). *Physician and Industry Relationships*. Oral presentation at: Saint Louis University Department of OB/GYN Financial Grand Rounds Series; Saint Louis, MO.

Kraus, EM. (2022, May). *Reproductive Decision Making in Women with Medical Comorbidities: A Qualitative Study.* Oral presentation at: Saint Louis University Department of OB/GYN Grand Rounds; Saint Louis, MO.

Kraus, EM. (2024, July). *Reproductive Decision Making in Women with Medical Comorbidities: A Qualitative Study.* Oral presentation at: Creighton University Department of OB/GYN Grand Rounds; Omaha, NE.

POSTERS

Lawlor, M. L., Perez, W. M., **Kraus, E.,** Jacobson, J. M., Renner, K. C., & Vricella, L. K. (2019). Does gestational weight gain affect TOLAC success? *American Journal of Obstetrics & Gynecology, 220*(1, S386).

Mullan, S. J., Perez, W. M., Vricella, L. K., **Kraus, E.,** Jacobson, J. M., Renner, K. C., & Gross, G. A. (2019). Induction decreases success rates in vaginal birth after cesarean: Does indication matter? *American Journal of Obstetrics & Gynecology, 220*(1, S520).

Lawlor, M.L., **Kraus, E.,** Perez, W.M. Vricella, L.K., Kraus, E., Jacobson J.M., Renner, K.C., & Gross, G. A. (2019). High risk obstetric providers have similar VBAC success rates; an analysis by prenatal provider type. *American Journal of Obstetrics & Gynecology, 220 (1, S520*.

Kraus, E., Perez, W., Gross, G., Tomlinson, T., Vricella, L. Intrapartum variables predicting labor progress and vaginal delivery in trials of labor after cesarean [abstract]. Society of Maternal Fetal Medicine 40th Annual Pregnancy Meeting. 2020 February 3-8; Dallas, TX. Abstract nr 723748.

Kraus, E., Perez, W., Gross, G., Vricella, L., Tomlinson, T. Validation of the MFMU admission model for vaginal birth after cesarean in a modern population [abstract]. Society of Maternal Fetal Medicine 40th Annual Pregnancy Meeting. 2020 February 3-8; Dallas, TX. Abstract nr 723777.

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Kraus, EM. (2014, January). *Nurse Practitioners in Primary Care: A Grounded Theory Study of Physician and Nurse Practitioner Perspectives.* Poster presented at: Saint Louis University 3rd Annual Primary Care Research Symposium; Saint Louis, MO.

PEER REVIEWED PUBLICATIONS

Chen B, **Yates E**, Huang Y, et al. Alternative promoter and GATA5 trascripts in mouse. *American Journal of Physiology: Gastrointestinal and Liver Physiology.* 2009; 297(6):g1214-1222.

Anderson E, **Kraus E**. Re-examining Empirical Data through the Lens of Personal Narratives on Living with Conflicts of Interest in Medicine. *Narrative Inquiry in Bioethics.* 2011;1(2):91-99.

DuBois J, Anderson E, **Kraus E**, et al. Environmental Factors Contributing to Wrongdoing in Medicine: A Criterion-based Review of Studies and Cases. *Ethics and Behavior.* 2012;22(3):163-188.

DuBois J, **Kraus E**, Vasher M. The Development of a Taxonomy of Wrongdoing in Medical Practice and Research. *American Journal of Preventive Medicine.* January 2012;42(1):89-98.

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DuBois J, **Kraus E**, Gursahani K, Mikulec A, Bakanas E. Curricular priorities for business ethics in medical practice and research: recommendations from Delphi consensus panels. *BMC Med Educ.* November 15 2014;14(235).

Kraus E, Bakanas E, Gursahani K, DuBois J. Establishing the need and identifying goals for a curriculum in medical business ethics: a survey of students and residents at two medical centers in Missouri. *BMC Research Notes.* 2014;7(708).

Kraus E, DuBois JM. Knowing Your Limits: A Qualitative Study of Physician and Nurse Practitioner Perspectives on NP Independence in Primary Care. *J Gen Intern Med.* 2017;32(3):284-290.

Gupta S, Gavard JA, **Kraus E**, P. Yeung J. Endometriosis in Hydatid Cysts of Morgagni: A Retrospective Cohort Study of Another Atypical Manifestation of Endometriosis. *J Minim Invasive Gynecol.* 2017;24(4):653-658.

Gee A, **Kraus E**, Bilyeu A. Female Genital Cutting: Considerations for the Western Physician. *Missouri Medicine.* 2019;116(1):32-34.

Kraus E. An Exploratory Analysis of US Nurse Practitioner Perspectives on Training and Credentialing. *Narrative Inquiry in Bioethics*. 2019;9(3):233-246.

Powel JE, **Kraus E**, Reddy C, Lannaman K. Treatment of Severe Fetal Ebstein's Anomaly with Prenatal Nonsteroidal Anti-Inflammatory Therapy. *Fetal Diagn Ther.* 2022;49(5-6):245-249.

Kraus E. Humanizing the Language and Experience of Pregnancy Loss in Health Care. *Narrative Inquiry in Bioethics.* 2022;12(3):235-240. doi:10.1353/nib.2022.0059.

Kraus, EM, Chavan NR, Whelan V, Goldkamp J, DuBois JM. Reproductive decision making in women with medical comorbidities: a qualitative study. *BMC Pregnancy Childbirth.* Dec 11 2023;23(1):848. doi:10.1186/s12884-023-06093-4

OTHER PUBLICATIONS

Yates E. Job Description: Nurse 2010. Virtual Mentor. 2010;12(1):3-5.

Dubois J, **Kraus E**, Bakanas E. Will Concierge Medicine's Image Improve as it Evolves? *American Medical News.* September 3, 2012; Ethics Forum.

Dubois JM, **Kraus E**. The ghost of veterinary medicine yet to come: Lessons learned from medical business ethics. *Proceedings of the 59th annual convention: American Association of Equine Practitioners* 2013;45(s45).

Kraus EM. Ethical drug pricing. *Healthcare Finance News.* October 25, 2013; Quality and Safety.

Kraus E. Case 4: Observing questionable medical business practices. In: Volpe R, Bakanas E, Dineen K, Dubois J, eds. *Exploring integrity in medicine: The Bander Center for Medical Business Ethics Casebook*. St. Louis: Saint Louis University; 2016.

Kraus E. Pregnancy Loss. *Narrative Inquiry in Bioethics.* 2022;12(3):183-186. doi:10.1353/nib.2022.0055.

GRANTS AND SCHOLARSHIPS

Sister Clodovia Lockett Scholarship	**2005 – 2006**
Fellowship Award, Graduate Student Association Saint Louis University, Saint Louis, MO	**2012**
Bander Business Ethics in Medical Research Funding Program Administered by the Institute for Clinical and Translational Science (ICTS) at Washington University, Saint Louis, MO	**2012**
Research Grant, Graduate Medical Education at Saint Louis University School of Medicine	**2020**
National Institute of Health Loan Repayment (NIHRP) Award, National Institute of Child Health and Human Development	**2020-2022**

HONORS AND AWARDS

University of Dallas Student Athlete Award	**2005 and 2006**
Frank J Doe Summer Scholar	**2005**
Ann Heller Mayberry Award	**2006**
Phi Beta Kappa, Liberal Arts Honors Society	**2006**
Alpha Sigma Nu, Jesuit Honors Society	**2010**
Athletics Hall of Fame, University of Dallas	**2011**
American Board of Internal Medicine Professional Article Prize (For: A Humble Task: Restoring virtue in Medicine in an Age of Conflicting Interests)	**2014**
Residency Program Award for Excellence in Obstetrics	**2018**

Resident Research Award	**2018**
Finalist for Resident Teaching Award	**2019**
Alpha Omega Alpha Honor Medical Society	**2019**
Residency Excellence Award	**2019**
Melanie McCleave, MD, Memorial Award for Compassion in Medicine	**2019**
MFM Fellow Resident Teaching Award	**2022**

PROFESSIONAL AFFILIATIONS AND ASSOCIATIONS

American College of Obstetricians and Gynecologists (ACOG)
Society of Maternal Fetal Medicine (SMFM)
American Institute of Ultrasound in Medicine (AIUM)