IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, on behalf of itself, its physicians and staff, and its patients; MEMPHIS CENTER FOR REPRODUCTIVE HEALTH, on behalf of itself, its physicians and staff, and its patients; KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH, on behalf of itself, its physicians and staff, and its patients; FEMHEALTH USA, INC., d/b/a CARAFEM, on behalf of itself, its physicians and staff, and its patients; and AUDREY LANCE, M.D., M.S., on behalf of herself and her patients,

Plaintiffs,

v.

HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; LISA PIERCEY, M.D., Commissioner of the Tennessee Department of Health, in her official capacity; RENE SAUNDERS, M.D., Chair of the Board for Licensing Health Care Facilities, in her official capacity; W. REEVES JOHNSON, JR., M.D., President of the Tennessee Board of Medical Examiners, in his official capacity; HONORABLE AMY P. WEIRICH, District Attorney General of Shelby County, Tennessee, in her official capacity; GLENN FUNK, District Attorney General of Davidson County, Tennessee, in his official capacity; CHARME P. ALLEN, District Attorney General of Knox County, Tennessee, in her official capacity; and TOM P. THOMPSON, JR., District Attorney General for Wilson County, Tennessee, in his official capacity,

Defendants.

CIVIL ACTION

CASE NO. 3:20-cv-00740

JUDGE CAMPBELL

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

I. PRELIMINARY STATEMENT

This case concerns a law, Tenn. Code Ann. § 39-15-218 (effective October 1, 2020) ("the Act"), that compels physicians, upon threat of criminal prosecution and imprisonment, to provide their patients with inaccurate, misleading, and irrelevant information that a medication abortion can be "reversed." In so doing, the Act violates Plaintiffs' First Amendment rights by compelling them to endorse an unproven, potentially harmful medical treatment that the American College of Obstetricians and Gynecologists ("ACOG") and Society of Family Planning ("SFP") have found "no evidence" to support. Ex. 1, Declaration of Courtney A. Schreiber, M.D., M.P.H. ("Schreiber Decl.") Ex. D ("ACOG/SFP Guidelines") at 3. And alarmingly, the Act's mandated communications are so misleading as to undermine informed consent, giving women[1] the false impression that they need not be certain in their decision before beginning a medication abortion, because the process can be "reversed." The Act thus forces Plaintiffs to either breach their ethical obligations to patients or subject themselves to potential criminal, civil, and licensure penalties.

The Act also violates Plaintiffs' patients' Fourteenth Amendment rights to choose abortion without being subjected to statements that are untruthful, misleading, and irrelevant to their decision. Indeed, the Act's requirements actively impede the decision-making process and expose patients to potential harm. Finally, the Act violates Plaintiffs' and their patients' equal protection rights, by imposing harmful requirements not imposed on others similarly situated.

Patients rely on their doctors to tell them the truth and to provide accurate, non-misleading, and evidence-based medical information. If the government could compel physicians to mislead their patients with inaccurate medical statements about unproven treatments, it would undermine

[1] Plaintiffs use "woman," "women," "she," or "her" in this brief to refer to people who are or may become pregnant, but they note that people of all gender identities, including gender non-conforming people and transgender men, may also become pregnant and seek abortion services and would thus also suffer irreparable harm as a result of the Act.

the trust between patients and physicians. Public health and the integrity of the medical profession depend on patients being able to trust that their physicians are communicating honestly and in their best interest. Ex. 2, Declaration of Steven Joffe, M.D., M.P.H. ("Joffe Decl.") ¶ 18.

Plaintiffs therefore seek a temporary and/or preliminary injunction to preserve the status quo and prevent irreparable harm to themselves, their physicians and staff, and their patients. Absent intervention from this Court, the Act will go into effect on **October 1, 2020**.

II. STATEMENT OF FACTS

A. Plaintiffs' Provision of Medication Abortion in Tennessee

Plaintiffs Planned Parenthood of Tennessee and North Mississippi ("PPTNM"), Memphis Center for Reproductive Health ("CHOICES"), Knoxville Center for Reproductive Health ("KCRH"), and FemHealth USA, Inc., d/b/a carafem, operate health centers throughout Tennessee. Plaintiffs' health centers provide a full range of reproductive health services, including, *inter alia*, wellness visits; cancer screenings; human papillomavirus vaccines; annual gynecological exams; contraception; adoption referral; health-care services for lesbian, gay, and transgender individuals; miscarriage management; and abortion care, including medication abortion available through eleven weeks measured from the first day of a patient's last menstrual period ("LMP"). Ex. 3, Declaration of Melissa Grant ("Grant Decl"). ¶ 4; Ex. 4, Declaration of Ashley Coffield ("Coffield Decl.") ¶ 5; Ex. 5, Declaration of Corinne Rovetti ("Rovetti Decl.") ¶ 2; Ex. 6, Declaration of Rebecca Terrell ("Terrell Decl.") ¶ 9. Plaintiff Dr. Audrey Lance is a physician who provides health care including medication abortion care to patients in Tennessee at health centers operated by Plaintiff PPTNM. Ex. 7, Declaration of Audrey Lance, M.D., M.S. ("Lance Decl.") ¶ 2.

Abortion is one of the safest and most common medical procedures performed in the United States. Schreiber Decl. ¶ 16. Plaintiffs' patients seek abortions for a variety of medical,

psychological, emotional, familial, economic, and personal reasons. Lance Decl. ¶ 9; Terrell Decl. ¶ 12. Nationwide, nearly one in four women will obtain an abortion by age forty-five. Schreiber Decl. ¶ 16. Patients seeking abortions at or before seventy-seven days LMP generally can choose between a procedural abortion, which takes place in the health center, or a medication abortion, which involves only medicine and begins at the health center but can be completed at home. Coffield Decl. ¶¶ 6–7. Approximately 40–60% of Plaintiffs' abortion patients obtain medication abortions; Plaintiffs have observed an increasing preference for medication abortion during the COVID-19 pandemic, presumably because it requires less in-person contact than procedural abortion. Rovetti Decl. ¶ 2; Terrell Decl. ¶ 11; Coffield Decl. ¶ 7.

The most common form of medication abortion is a regimen of two prescription medications, mifepristone and misoprostol. *See* Schreiber Decl. ¶ 19. Mifepristone works by temporarily blocking the hormone progesterone, which is necessary to maintain pregnancy; by triggering the release of prostaglandins, which can cause uterine contractions; and by increasing the efficacy of misoprostol, the second medication in the regimen. *See id.* ¶¶ 21–22. Misoprostol, typically taken between twenty-four to forty-eight hours after mifepristone, causes the uterus to contract and expel its contents. *Id.* ¶ 22. The pregnancy is passed at a location of the patient's choosing—usually her home—in a process similar to miscarriage. *See id.* ¶¶ 19, 22. The combined use of these two medications is known collectively as "medication abortion," and its use is evidence-based for early pregnancy termination through eleven weeks (seventy-seven days) LMP. *Id.* ¶¶ 19, 23. Medication abortion is safe and highly effective, with an efficacy rate of up to 97.4%.[2] While mifepristone and misoprostol are each independently capable of terminating a pregnancy,

[2] Medication abortion has been shown to have a 97.4% efficacy rate when used up through ten weeks LMP. Schreiber Decl. ¶ 19. There is also evidence for the safe and effective use of medication abortion up through seventy-seven days LMP. *Id.*

the two-drug combined regimen is used for maximum efficacy and safety. *See* Schreiber Decl. ¶¶ 19–23, 61–62. Since 2000, more than four million patients in the United States have had a medication abortion.[3]

Consistent with their ethical obligations and values, Plaintiffs obtain informed consent from patients before providing any medical care, including abortion. Coffield Decl. ¶ 8; Grant Decl. ¶ 5; Lance Decl. ¶ 15; Rovetti Decl. ¶ 7; Terrell Decl. ¶ 13; *see* Joffe Decl. ¶¶ 19–23. As part of the informed consent process, Plaintiffs discuss with each patient accurate and relevant information to assist her with her decision whether to have an abortion and, if so, by which method. Coffield Decl. ¶¶ 8, 14; Grant Decl. ¶ 5; Lance Decl. ¶¶ 17–18; Rovetti Decl. ¶ 7; Terrell Decl. ¶ 13. Plaintiffs discuss all of the patient's options and alternatives (parenting, adoption, and abortion), the methods of abortion that are available to her, and the risks and benefits associated with each. Coffield Decl. ¶¶ 8, 11; Grant Decl. ¶ 5; Lance Decl. ¶ 17; Rovetti Decl. ¶ 7; Terrell Decl. ¶ 15. The goal of the informed consent process is for patients to have the information necessary to make the right decision for them. Coffield Decl. ¶ 9; Joffe Decl. ¶ 22; Grant Decl. ¶ 5; Lance Decl. ¶¶ 16–17; Rovetti Decl. ¶ 7; Terrell Decl. ¶ 13.

Plaintiffs advise each patient that the decision to have an abortion is hers alone to make, and not to start any abortion, medical or procedural, unless and until she is firm in her decision to terminate the pregnancy. Coffield Decl. ¶¶ 10–11; Grant Decl. ¶ 6; Lance Decl. ¶¶ 20–22; Rovetti Decl. ¶ 7; Terrell Decl. ¶ 14. Plaintiffs encourage patients to take the time they need to be certain in their decisions. Coffield Decl. ¶ 11; Lance Decl. ¶ 23. Prior to providing medication abortion, Plaintiffs counsel each patient to be certain in her decision before starting the regimen, given that

[3] *Mifeprex Effectiveness and Advantages*, Danco Laboratories, https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/ (last visited Aug. 27, 2020).

mifepristone alone will terminate a majority of pregnancies. Grant Decl. ¶ 10; Lance Decl. ¶ 22; Rovetti Decl. ¶ 10; Coffield Decl. ¶ 20; Terrell ¶ 14; *see* Schreiber ¶¶ 22, 24, 80. While most patients are already sure of their decision when they first come to the health center, in the rare instance that a patient is unsure, Plaintiffs will not provide an abortion (medication or procedural). Coffield Decl. ¶¶ 10–11; Terrell Decl. ¶ 14; Rovetti Decl. ¶ 10; Lance Decl. ¶¶ 21–22.

Plaintiffs' mission and core values dictate that they provide accurate, relevant information and evidence-based health care to all their patients. Coffield Decl. ¶¶ 8, 28; Grant Decl. ¶¶ 3, 8–9; Lance Decl. ¶¶ 24-26, 43; Rovetti Decl. ¶¶ 6, 8; Terrell Decl. ¶ 2.

B. Existing Tennessee Abortion Requirements and the Act

Existing Tennessee law requires physicians who provide medical treatments to first obtain voluntary and informed consent, consistent with recognized practice standards in the relevant medical specialty. Tenn. Code Ann. § 29-26-118. Separate from this generally applicable requirement, Tennessee also mandates that, before a patient can obtain an abortion, she must meet with a physician at least forty-eight hours beforehand and be told the probable gestational age of the pregnancy, the risks and benefits of abortion and childbirth, the alternatives to abortion, and the information, services, and agencies available to assist with adoption and parenting. *Id.* §§ 39-15-202(b), (d). Tennessee further requires that prior to an abortion, a physician or qualified technician must perform an ultrasound and, *inter alia*, display and describe the images to the patient in State-specified detail, and auscultate (*i.e.*, produce the sounds of) fetal cardiac activity if it is audible. *Id.* § 39-15-215(b).

The Act would radically alter Tennessee's existing generally applicable informed-consent requirements, as well as Plaintiffs' practices, by compelling Plaintiffs to convey scientifically unsupported and misleading information to their patients in three ways.

First, the Act compels Plaintiffs' physicians to inform patients at least forty-eight hours before a medication abortion, that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone[4] if the woman changes her mind" and that "information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." *Id*. § 39-15-218(e).[5]

Second, the Act requires any waiting room and patient consultation room used by patients obtaining an abortion (whether medication or procedural) to "conspicuously" post signs "clearly visible to patients" with the following state-ordered text in large, boldfaced type: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately." *Id*. §§ 39-15-218(b), (c).

Third, after the mifepristone and misoprostol regimen is provided to the patient, the physician or physician's agent must provide written medical discharge instructions that include the same state-mandated statement about reversing medication abortion as is required on the signs. *Id.* § 39-15-218(f).

Violation of the Act is a Class E felony, punishable by one to six years in prison. *Id.* § 39-15-218(j).[6] In addition, Plaintiff clinics may be fined $10,000 per day if the Department of Health

[4] As defined by the Act, this refers to medication abortion. Tenn. Code Ann. § 39-15-218(a)(2).
[5] The Act further directs the Tennessee Department of Health to publish, by December 30, 2020, information "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and providing "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion." *Id.* §§ 39-15-218(h), (i).
[6] The Act specifies that penalties for failure to comply with the requirement that physicians refer patients to the Department of Health website for "reversal" information will not be assessed

determines they negligently failed to post the mandated sign. *Id.* § 39-15-218(k). Physicians who provide, or attempt to provide, a medication abortion without the state-mandated disclosures are also subject to actual and punitive damages in a lawsuit brought by the patient, the "father" of the embryo or fetus, or the parents of a minor patient or a deceased patient. *Id.* § 39-15-218(l).

C. The Scientifically Unsupported Abortion Reversal Theory

There is no credible scientific evidence supporting the theory that medication abortion can be "reversed." Schreiber Decl. ¶¶ 25–55; Joffe Decl. ¶¶ 44–56. This theory originated from two physicians, Dr. George Delgado and Dr. Mary Davenport, who posit that administering high doses of progesterone after patients have taken mifepristone but before they have taken misoprostol can counteract the effects of mifepristone and thus "reverse" the abortion. Schreiber Decl. ¶ 25. However, after reviewing the medical evidence, both the American College of Obstetricians and Gynecologists ("ACOG")—the premier professional organization for OBGYNs—and the Society of Family Planning ("SFP") have recognized that "[t]here is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing." ACOG/SFP Guidelines at 3. Medical papers published over the last several years in highly respected journals, including a systematic review of the research on medication abortion "reversal," also conclude that this theory is unsupported. Schreiber Decl. ¶ 50; Schreiber Decl. Ex's. F, G. The American Medical Association ("AMA") was so opposed to a law with mandated physician communications strikingly similar to the Act that it sued to enjoin the law. *See* Complaint, *Am. Med. Ass'n v. Stenehjem*, No. 1:19-cv-125, 2019 WL 2601802 (D.N.D. June 25, 2019).

"unless the department of health has made the information available on the website at the time the physician is required to inform the woman." Tenn. Code Ann. § 39-15-218(j).

Delgado and Davenport's theory is described in two ethically problematic papers[7] that contain serious methodological problems, making their purported conclusions wholly unreliable. Schreiber Decl. ¶¶ 25, 28–49, 52–55, 68–70; *see also* Joffe Decl. ¶¶ 46–54. Their 2012 paper describes outcomes from just six patients; their 2018 paper discusses data from 547 patients in various countries who took mifepristone, called an "abortion pill reversal" hotline Delgado helps run, and were referred to unknown providers who administered progesterone in varying amounts, via differing methods, and for varying durations.[8] *See* Schreiber Decl. ¶¶ 29, 34, 44, 56-57; Schreiber Decl. Ex.'s B, C. Neither paper was published in a respectable medical journal and neither appears to have undergone proper Institutional Review Board ("IRB")[9] vetting for ethical research on human subjects. Schreiber Decl. ¶¶ 30, 39–40; *see* Joffe Decl. ¶ 58–60.

Critically, neither paper used a control group of patients who took mifepristone and then received a placebo rather than progesterone treatments. Schreiber Decl. ¶¶ 31–32, 41–42. This is a major flaw, as mifepristone alone (without misoprostol) is known to frequently be insufficient to terminate a pregnancy. *Id*. ¶¶ 22, 24. Without a control group with which to compare the result of the experimental progesterone treatment, it is impossible to draw any inferences about whether the treatment had any effect (or the size of such effect, if any). *See id*. ¶¶ 35, 42. In fact, despite

[7] These studies were the subject of hearings concerning H.B. 2568 (which, as amended, is codified as the Act). *Hearing on H.B. 2568 Before the H. Health Comm.*, 111th General Assembly (Mar. 10, 2020) (statement and questioning of Dr. Brent Boles, Medical Advisor to Abortion Pill Rescue Network) (starting at time 00:04:16)), http://tnga.granicus.com/MediaPlayer.php?view_id=414&clip_id=22077.

[8] Indeed, Davenport and Delgado acknowledge that further research employing "randomized controlled trials comparing progesterone doses and routes of administration are needed" to "confirm" which protocol "is most efficacious." Schreiber Decl. Ex. C at 24. This makes their willingness to recommend the administration of two progesterone protocols at the end of the paper even more irresponsible and egregious.

[9] The professional norm and expectation is that research on human subjects should be approved by an IRB, which is a committee that performs an ethical review of proposed research and is designed to protect human subjects of research. Schreiber Decl. ¶ 40 n.35.

methodological flaws that likely inflated the rate of continuing pregnancy after "reversal" treatment, Schreiber Decl. ¶¶ 35–37, 43, 46–48, 51; Joffe Decl. ¶ 49 & n.14, Delgado and Davenport were *still* unable to show any statistically significant difference between the rate of continuing pregnancy with or without progesterone treatment, *see* Schreiber Decl. ¶¶ 49–50; *see also* Schreiber Decl. Ex. G at 1492.

The only scientifically controlled study of the effects of progesterone treatment after mifepristone, conducted in 2019 with IRB approval, was halted early due to serious safety concerns when a number of study participants experienced hemorrhage. *See* Schreiber Decl. ¶¶ 63–66. Because the study was halted early, the effect or lack thereof of progesterone treatment was not demonstrated, resulting instead in the conclusion that, due to a "void in high-quality research . . . such [reversal] treatment is experimental and should be offered only in [IRB]-approved human clinical trials to ensure proper oversight."[10] The study involved women who were willing to delay their abortions for two weeks for study purposes, took mifepristone, and were randomly assigned to take either progesterone or a placebo thereafter. *Id*. ¶ 64. The researchers halted the study after three of the twelve enrolled participants had to be transported to the emergency room by ambulance due to severe hemorrhage, with one requiring a blood transfusion. *Id.* ¶ 65. These patients came from both the progesterone and the placebo groups, suggesting that the hemorrhages were related the patients not having taken misoprostol, the second medication in a medication abortion regimen. *Id*. As a result, ACOG and SFP caution that "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage." ACOG/SFP Guidelines at 3.

[10] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medication Abortion: A Randomized Controlled Trial*, 135 Obstetrics & Gynecology 158, 164 (Jan. 2020).

D. The Impact of the Act

The Act requires Plaintiffs, their physicians and their staff to violate their ethics, values, and organizational missions, and potentially harm their patients. It does so in three primary ways.

First, the Act forces Plaintiffs and their physicians and staff to communicate inaccurate and misleading medical information to their patients. *See* Joffe Decl. ¶¶ 3, 34–37, 44–56; Schreiber Decl. ¶¶ 27, 38, 56–58, 71, 82. This requirement itself violates medical ethics, as it requires Plaintiffs' physicians and staff to communicate a message they *know* is scientifically unsupported and potentially harmful to patients. Joffe Decl. ¶¶ 25–31, 39–43, 56; Lance Decl. ¶¶ 37–43; Grant Decl. ¶ 8; Rovetti Decl. ¶ 6; Terrell Decl. ¶ 20. The Act thus harms patients, by forcing them to receive inaccurate and misleading medical information from their healthcare providers, and also undermines the relationship of trust between patient and provider which is crucial to the effective provision of medical care and the integrity of the medical profession. Joffe Decl. ¶¶ 18, 30–34, 39–43; Lance Decl. ¶¶ 19, 34.

Second, the Act forces Plaintiffs' physicians to undermine their patients' informed consent and decision-making, potentially resulting in severe harm to their patients. As detailed above in Section II.A, consistent with ethical informed consent practice, Plaintiffs emphasize to patients that they must come to a firm decision before beginning the abortion process because the first medication (mifepristone) will terminate a majority of pregnancies regardless of whether the second medication is taken. The Act forces Plaintiffs' physicians to directly contradict this message, and to do so in advance of the abortion. As a result, Plaintiffs' patients will have been told *both* that they must be firm in their decision before starting the abortion process, *and* that, should they not be, they can simply "reverse" the process later. Knowingly creating this kind of profound confusion is unethical and directly undermines the informed consent process. Joffe Decl. ¶¶ 26–28, 43.

Third, the Act forces Plaintiffs and their physicians and staff to unethically direct patients towards an unproven treatment that has not been demonstrated to be safe or effective and that may harm patients. When healthcare providers discuss a possible treatment with their patients, patients trust that the physician reasonably believes the treatment is safe, effective, and in the patient's best interest. *See* Lance Decl. ¶¶ 17–19. This trust is undermined by the Act. *Id*. ¶ 34. As noted above, the only scientifically controlled study on so-called reversal treatment was discontinued after three out of twelve patients hemorrhaged. *See supra* Section II.C. Moreover, the treatment involves administering large doses of progesterone for potentially substantial periods of time, which is not without risks. *See* Schreiber Decl. ¶¶ 29, 37, 59. In addition, the effects of the "reversal" protocol on ongoing pregnancy have not been adequately studied—neither the effects of large doses of progesterone, or of the combination of large doses of progesterone with misoprostol. *Id.* ¶ 60. Indeed, it is "almost impossible that it would be acceptable per current federal standards" concerning experimentation on pregnant women to even conduct an experiment with such regimen "without intensive safety and monitoring board oversight," *id.*, let alone to routinely direct patients to such treatment, as the Act requires, *id*. ¶ 27; Joffe Decl. ¶ 30. Notably, the Delgado and Davenport studies that purport to demonstrate the efficacy of "reversal" treatment appear to constitute unethical experimentation on human subjects. Schreiber Decl. ¶¶ 68–70; Joffe Decl. ¶¶ 57–62.

III. ARGUMENT

A. Applicable Legal Standards

Plaintiffs seek a temporary restraining order and/or preliminary injunction to prevent the Act from inflicting constitutional, medical, ethical, and other harm on Plaintiffs and their patients. In ruling on such a motion, the court considers: "(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the

injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction." *Am. C. L. Union Fund of Mich. v. Livingston Cnty*., 796 F.3d 636, 642 (6th Cir. 2015) (internal quotation marks omitted).

As set out below and in the accompanying declarations, Plaintiffs meet the test.

E. Plaintiffs Are Likely to Succeed on the Merits

Plaintiffs are highly likely to prevail on their First and Fourteenth Amendment claims. The Act infringes on Plaintiffs' First Amendment rights by compelling them to speak a state-mandated message about an experimental medical practice that has not been proven safe or effective and that "does not facilitate informed consent." *Nat'l Inst. of Fam. & Life Advocates v. Becerra* ("*NIFLA*"), 138 S. Ct. 2361, 2373–74 (2018); *see also EMW Women's Surgical Ctr., P.S.C. v. Beshear* ("*EMW*"), 920 F.3d 421, n.6 (6th Cir. 2019), *cert. denied sub nom. EMW Women's Surgical Ctr., P.S.C. v. Meier*, 140 S. Ct. 655 (2019). The Act further violates Plaintiffs' First Amendment rights and Plaintiffs' patients' Fourteenth Amendment rights because the Act's state-mandated message is untruthful, misleading, and not relevant to the decision whether to have an abortion. Moreover, the Act unconstitutionally singles out Plaintiffs and their patients for differential treatment compared with others similarly situated, in violation of the Fourteenth Amendment's guarantee of equal protection.

The only two other courts to consider similar laws have preliminarily enjoined them. *See Am. Med. Ass'n v. Stenehjem,* 412 F.Supp.3d 1134 (D.N.D. 2019); Journal Entry of Judgment*, Tulsa Women's Reprod. Clinic v. Hunter*, No. CV-2019-2176 (Okla. Dist. Ct. Oct. 29, 2019).[11]

[11] A third court also entered a preliminary injunction against an Arizona law mandating an identical disclosure. Order Granting Prelim. Inj. & Vacating Hr'g, *Planned Parenthood Ariz., Inc. v. Brnovich*, No. CV-15-01022 (D. Ariz. Oct. 16, 2015), ECF No. 107. In that case, the State stipulated to the injunction after preliminary discovery; thereafter, the Arizona legislature repealed the challenged law. Stipulation to Dismiss, *Planned Parenthood Ariz. v. Brnovich*, No. CV-15-0122 (D. Ariz. Aug. 18, 2016), ECF No. 133.

1. (i) The Act Unconstitutionally Compels Speech That Undermines Informed Consent

The First Amendment protects "both the right to speak freely and the right to refrain from speaking at all," *Wooley v. Maynard*, 430 U.S. 705, 714 (1977), and requires the presumption "that speakers, not the government, know best both what they want to say and how to say it," *Riley v. Nat'l Fed'n of the Blind of N. C., Inc.*, 487 U.S. 781, 790–91 (1988). In recent years, the Supreme Court has further emphasized the "damage" done when "individuals are coerced into betraying their convictions" through compelled speech. *Janus v. Am. Fed'n of State, Cnty., & Mun. Employees Council 31*, 138 S. Ct. 2448, 2464 (2018). As noted above, *see supra* Section II.A, the Act would force Plaintiffs to violate their core ethics, values, and principles, which center evidence-based medicine, patient-centered healthcare, and the provision of accurate, scientifically sound information.

A statute that "compel[s] individuals to speak a particular message . . . 'alter[s] the content of their speech.'" *NIFLA*, 138 S. Ct. at 2371 (internal alterations and quotations omitted). Such content-based restrictions are "presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests." *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015). In particular, the Supreme Court has held that a compelled speech statute is unconstitutional where "licensed clinics must provide a government-drafted script about the availability of . . . services, as well as contact information about how to obtain them." *NIFLA*, 138 S. Ct. at 2371.

The Supreme Court has recognized narrow exceptions to this prohibition on content-based speech regulation where a state "regulate[s] professional conduct that incidentally involves speech" by requiring physicians to provide information necessary to obtain informed consent for a medical procedure. *NIFLA*, 138 S. Ct. at 2366, 2377; *EMW* 920 F.3d at 428–29. However,

"[s]peech is not unprotected merely because it is uttered by 'professionals'" such as physicians. *NIFLA*, 138 S. Ct. at 2371–72. Indeed, the Supreme Court has "stressed the danger of content-based regulations 'in the fields of medicine and public health, where information can save lives.'" *Id.* at 2374 (quoting *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011)).

Where a law compels physicians to communicate messages that "do[] not facilitate informed consent to a medical procedure" and "provide[] no information about the risks or benefits" of the procedure, the regulation does not meet the narrow exception for speech restrictions incidental to the regulation of professional conduct.[12] *See NIFLA*, 138 S. Ct. at 2373–74; *see also EMW*, 920 F.3d at n.6. In considering a statute similar to the one at issue here, a federal district court in North Dakota found that the statute "violates the First Amendment rights of physicians" because, *inter alia*, it "undermines informed consent and the standard of care" and does not "focus on relevant medical information designed to assist a woman in making a free choice." *See Am. Med. Ass'n,* 412 F.Supp.3d at 1150.

The statute in *NIFLA* required certain licensed clinics to "inform women how they can obtain state-subsidized abortions," even though the clinics did not provide abortions and actively sought to dissuade women from having abortions. *NIFLA*, 138 S. Ct. at 2371. The Supreme Court struck the statute down because the mandated information "d[id] not facilitate informed consent to a medical procedure" and provided "no information about the risks or benefits" of any procedure. *Id.* at 2373–74; *EMW*, 920 F.3d at 437–38 ("[T]he very reason that the required disclosure in *NIFLA* did 'not facilitate informed consent' was because it *provided* no information about the risks or benefits of a medical procedure." (quoting *NIFLA* 138 S. Ct. at 2373)).

[12] Nor does the Act fall within the only other exception identified in *NIFLA* for commercial speech related to "purely factual and uncontroversial information." *See NIFLA*, 138 S. Ct. at 2372 (internal citations omitted).

The Act here similarly mandates speech that does "not facilitate informed consent" because it does not inform patients "about the nature of the [medication abortion] procedure, the attendant health risks and those of childbirth, [or] the probable gestational age of the fetus." *EMW*, 920 F.3d at 427 (quoting *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 882 (1992) (internal quotation marks omitted)). Rather, the statements compelled by the Act relate to an entirely different and medically unsupported treatment—medication abortion "reversal"—that Plaintiffs do not provide and that their patients are not seeking. And while it is central to the mission of Plaintiffs' medical practices to provide evidence-based information and health care to their patients, *see supra* Section II.B, the Act forces Plaintiffs to make statements and endorse treatments contrary to medical evidence—"the very practice that [Plaintiffs] . . . oppos[e]." *NIFLA*, 138 S. Ct. at 2371.

The Act is in stark contrast with the information required by the informed consent statute upheld by the Supreme Court in *Casey*, which was "aimed at ensuring a decision [to have an abortion] that is mature and informed." *Casey*, 505 U.S. at 883; *see also EMW*, 920 F.3d at 442 (noting that the law analyzed in *Casey* "furthers the State's legitimate interest . . . of ensuring that the patient understands the full implications of her decision"). The Court further noted that the statute at issue in *Casey* "further[ed] the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later . . . that her decision was not fully informed." *EMW*, 920 F.3d at 442 (quoting *Casey*, 505 U.S. at 882).

The Act here will, if anything, do the opposite, *increasing* the risk that a woman will start the medication abortion process under the misimpression that "it may be possible to reverse" the procedure if she "changes her mind," only to discover later that this was not the case and that her pregnancy has been terminated. Tenn. Code. Ann. § 39-15-218(e)(1). In so doing, the Act actively

impedes informed consent by undermining Plaintiffs' counseling of patients that they must be certain in their decision before starting a medication abortion. Joffe Decl. ¶¶ 32-38, 63; Schreiber Decl. ¶¶ 79–82; *see also supra* Section II.A.

Indeed, far from being an informed consent statute, the Act constitutes "the most aggressive form of viewpoint discrimination—compelling an individual 'to utter what is not in her mind' and indeed what she might find deeply offensive." *Ward v. Polite*, 667 F.3d 727, 733 (6th Cir. 2012) (quoting *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 634 (1943) (internal alterations omitted)). As such, the Act is subject to the "stringent standard" of strict scrutiny: justifiable "only if the government proves that [it is] narrowly tailored to serve compelling state interests." *NIFLA*, 138 S. Ct. at 2371. The Act fails this test. If the state wishes to inform women of the supposed "reversibility" of medication abortions, "[m]ost obviously, it could inform the women itself with a public-information campaign" and "could even post the information on public property." *Id.* at 2376. There is no justification for, instead, "co-opt[ing] [Plaintiffs] to deliver its message for it." *Id.* Because the Act compels Plaintiffs to communicate a message they oppose,[13] and further because such a message impedes, rather than facilitates, informed consent, the Act is an unconstitutional content-based speech restriction.

[13] The Act further requires Plaintiffs to refer all medication abortion patients to the Tennessee Department of Health website, which in turn is required to post "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion." Tenn. Code Ann. § 39-15-218(h). While Plaintiffs do not yet know what the Department of Health intends to put on its website, the only such "resource" of which Plaintiffs are aware is the Abortion Pill Rescue Network. Coffield Decl. ¶ 27. That organization's website, in turn, is rife with medical misinformation. *See, e.g.*, *Can the Abortion Pill Be Reversed?* Abortion Pill Rescue (2020), abortionpillreversal.com/abortion-pill-reversal ("Can the abortion pill be reversed? The simple answer is yes! If done in time. There is an effective process called abortion pill reversal that can . . . allow you to continue your pregnancy, but time is of the essence.").

2. (ii) The Act's Compelled Speech is False, Misleading, and Not Relevant to Decision-Making

Regardless of whether the Act is an informed-consent law, it is still unconstitutional because it forces physicians to give, and patients to receive, information that is untruthful, misleading, and not relevant to their decision to choose whether to have an abortion. As the Sixth Circuit has made clear, an informed-consent law "should be upheld *so long as* the disclosure is truthful, non-misleading," and "relevant to the patient's decision whether to undertake the procedure." *EMW*, 920 F.3d at 424, 428 (emphasis added) (citing *Casey*, 505 U.S. at 882); *see also NIFLA*, 138 S. Ct. at 2373–74 ("Doctors help patients make deeply personal decisions, and their candor is crucial.") (internal quotations and citations omitted). Thus, even if the Act could be considered an informed consent law, which it cannot, it would nonetheless violate both Plaintiffs' First Amendment rights against compelled speech and their patients' Fourteenth Amendment rights under *Casey*.

a. The Act's Mandatory Statements Are Untruthful

As discussed extensively above and in detail in Plaintiffs' expert declarations, there exists no treatment that has been demonstrated to "reverse," "cease," or "avoid" the effects of mifepristone taken as part of a medication abortion. *See supra* Section II.C. The "reversal" theory has been put forth in two ethically-problematic and methodologically flawed papers, both of which have been rejected by the mainstream medical community. *See supra* Section II.C. These papers, by Drs. Delgado and Davenport, concern individuals who called an abortion "reversal" hotline run by Abortion Pill Rescue, an organization of which Dr. Delgado is listed as a Founder and Medical Advisor. *See* Schreiber Decl. Ex. C at 24; *see also* Schreiber Decl. ¶ 57. These patients were then referred to unknown practitioners in unknown locations around the world, who were given differing doses of progesterone, over different periods of time, and by different methods of

administration. *See* Schreiber Decl. ¶¶ 37, 44; *see also* Schreiber Decl. Exs. B, C. While the Delgado and Davenport's analyses suffer from substantial methodological flaws that would result in an *overestimation* of the supposed efficacy of "reversal"—such as screening out patients whose pregnancies had already been terminated after taking mifepristone—they nevertheless were unable to show a significant difference between the effects of "reversal" treatment after mifepristone and the effects of mifepristone alone. Schreiber Decl. ¶¶ 35–37, 43, 46–51; *see also* Schreiber Decl. Ex. G at 3.

Indeed, ACOG and SFP have unequivocally confirmed that there is "no evidence" that medication abortion "reversal" treatments have *any* effect other than to possibly increase the risk of hemorrhage. ACOG/SFP Guidelines at 2; *see also* Schreiber Decl. ¶¶ 26, 50, 65–66; Schreiber Decl. Ex. G. Indeed, ACOG has been vocal that "[c]laims regarding abortion 'reversal' treatment are not based on science and do not meet clinical standards," and thus ACOG "does not support prescribing progesterone to stop a medical abortion." Schreiber Decl. Ex. E at 1. The AMA was similarly so opposed to having to provide such patently false information to patients that it sued North Dakota to enjoin a law virtually identical to the Act. *See* Complaint at 2, *Am. Med. Ass'n*, 2019 WL 2601802 ("the Compelled Reversal Mandate . . . force[s] physicians to speak medically inaccurate messages"); *id.* at 18 ("the Compelled Reversal Mandate . . . compels Physicians to lie to their patients").

b. The Act's Mandatory Statements Are Misleading

The Act's compelled statements are also highly misleading, with the potential to cause severe harm to patients. The Act creates a serious and unacceptable risk that a patient will be misled into believing that a medication abortion can be "reversed" once begun and thus that she may take mifepristone and thereby terminate her pregnancy before she is certain in her decision. Schreiber Decl. ¶¶ 79–82; Joffe Decl. ¶¶ 32–34, 37; Coffield Decl. ¶ 22; Lance Decl. ¶ 35. The

Act also threatens to mislead patients into believing that medication abortion itself is less effective than it has been proven to be, and thus may compel patients to choose procedural abortion despite otherwise preferring medication abortion. Coffield Decl. ¶ 24. Plaintiffs have an ethical obligation not to mislead their patients at all, let alone when doing so may have such harmful consequences. *See supra* Section II.D.

The Act's requirements will further mislead patients into believing that their physicians are endorsing as sound medical practice what, in reality, is an unproven and potentially harmful treatment. *See supra* Section II.C; Schreiber Decl. ¶¶ 59–60, 63–70, 75. Because of the lack of scientific support, "reversal" treatment has been rejected as not evidence-based by the general medical community and is not generally offered by medical practitioners. *See* Lance Decl. ¶ 39.

The dubious nature of this "reversal" practice and the practitioners willing to offer it is demonstrated by the experience of a patient of Plaintiff KCRH, who, after taking mifepristone as part of a medication abortion, saw a sign promoting so-called "reversal" treatments. Rovetti Decl. ¶ 12. Feeling suddenly overwhelmed, she called the number provided, where she was pressured to immediately visit an address and obtain "reversal" treatment. *Id.* The patient arrived at the address to discover she had not been referred to a medical office, but rather to the residential home of a man who administered an injection and then instructed her to not take the second medication abortion pill. *Id.* ¶ 13. The patient's pregnancy did not continue. *Id*. ¶ 14. The patient was so upset by the entire experience that she called Plaintiff KCHR's offices crying, expressing her profound distress that she had been pressured to seek "treatment" at the home of someone she knew nothing about, rather than taking the second medication abortion drug. *Id.*

c. The Act's Required Statements Are Irrelevant to a Patient's Decision to Have an Abortion

As discussed *supra* at Section III.B(ii), information about how to "reverse" an abortion is not "relevant to the patient's decision whether to undertake the procedure." *EMW*, 920 F.3d at 428. The Act's mandated information does not concern the risks or benefits of, or alternatives to, having an abortion, but rather constitutes misleading statements about the efficacy of an entirely *different* medical procedure that Plaintiffs do not provide or recommend and the patient is not seeking. Not only is this information unrelated to the decision to have an abortion, but that decision itself must be made based on an understanding that the abortion is intended to be, and in a majority of cases *will* be, effective and irreversible—an understanding that is directly undermined by the mandated information. Schreiber Decl. ¶¶ 79–81; Joffe Decl. ¶¶ 32–33.

Moreover, the Act requires that signs with misleading statements about reversal be posted in any waiting room and procedure room that any abortion patient might use. Thus, Plaintiffs are required to communicate these false and misleading statements to many patients who are not seeking a medication abortion or an abortion at all. Coffield Decl. ¶ 23; Grant Decl. ¶ 12; Rovetti Decl. ¶ 9; Terrell Decl. ¶ 24. Indeed, patients obtaining procedural abortions may well also be misled by the Act's mandatory signage, as they may not understand exactly what a "chemical abortion utilizing mifepristone" means and whether it applies to them. Coffield Decl. ¶ 23.

In short, the Act's requirements are untruthful, misleading, and irrelevant to the decision to have an abortion, and are thus unconstitutional under the First and Fourteenth Amendments. *See EMW*, 920 F.3d at 424, 428 (emphasis added) (citing *Casey*, 505 U.S. at 882). A federal district court in North Dakota preliminarily enjoined a law requiring state-mandated information almost identical to the Act, holding that the mandated information was "untrue," "devoid of scientific support," and "misleading." *Am. Med. Ass'n*, 412 F.Supp.3d at 1150.

3. (iii) The Act Violates Plaintiffs' and Their Patients' Equal Protection Rights

The Act is also unconstitutional because it violates the equal protection rights of Plaintiffs and their staff and physicians, as well as their patients, by imposing burdens on them that are not imposed upon others similarly situated. The Act requires providers to undermine their patients' informed consent to an abortion through state-compelled provision of inaccurate information—a requirement not imposed on providers or patients in *any* other medical context.

The Act requires physicians and health centers to communicate to medication abortion patients that their procedure "may be . . . revers[ible]," despite there being no evidence to support such statement. Tennessee does *not*, however, require physicians providing sterilization procedures to undermine *their* patients' informed consent by communicating that the sterilization procedure "may be . . . reverse[ible]." Yet, sterilization procedures, unlike medication abortions, *are* reversible a significant percentage of the time. *See* Joffe Decl. ¶¶ 35–36. Nevertheless, as with abortion, ethical informed consent practice requires that healthcare providers communicate to the patient that the sterilization procedure is intended to be permanent, because while sterilization may be reversible for many, any individual patient runs the risk that the procedure will be permanent.

Indeed, this understanding of the requirements for ethical informed consent—that physicians emphasize the permanence of sterilization procedures, even though they may not be permanent for everyone—is reflected in federal Medicaid regulations concerning federally-subsidized sterilization procedures. 42 C.F.R. § 441.257 (1)(iii). Tennessee has not required that the ethical informed consent process for sterilization be undermined by any required countervailing disclosures concerning the reversibility of sterilization procedures.

Nor are sterilization patients—or any patients other than medication abortion patients—required to be misled about and steered towards unproven treatments of questionable safety. *See,*

e.g., Grant Decl. ¶ 13; Rovetti Decl. ¶ 15; Terrell Decl. ¶ 29; *see also* Schreiber Decl. ¶¶ 68–70; Joffe Decl. ¶ 38. Tennessee forces such unethical and harmful requirements only on medication abortion patients and their healthcare providers.

While heightened scrutiny should apply where states are singling out abortion over other procedures,[14] Tennessee's differential treatment of providers and patients of medication abortion cannot withstand even rational basis scrutiny. "[E]ven in the ordinary equal protection case calling for the most deferential of standards, [the Court] insist[s] on knowing the relation between the classification adopted and the object to be attained." *Romer v. Evans*, 517 U.S. 620, 632 (1996). "[R]equiring that the classification bear a rational relationship to an independent and legitimate legislative end . . . ensure[s] that classifications are not drawn for the purpose of disadvantaging the group burdened by the law." *Id*. at 633; *accord City of Cleburne, Tex. v. Cleburne Living Ctr.*, 473 U.S. 432, 448–50 (1985); *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973).

The Act's singling out of medication abortion is not rationally related to any legitimate state interest. By misleading patients into believing that their decision to have an abortion need not be final, and promoting experimental treatments rejected by mainstream medicine, the Act cannot reasonably be said to advance a state interest in fetal life or childbirth. Indeed, the misleading nature of the Act's requirements actually *increases* the chances that someone will terminate a pregnancy before she has fully decided to do so. For the same reasons, the Act cannot be said to

[14] Because the Act interferes with the exercise of the fundamental right to abortion, it should be reviewed under strict scrutiny. *See Mass Bd. of Ret. v. Murgia*, 427 U.S. 307, 312 & n.3 (1976) (noting that the right to an abortion is a "fundamental right," and that classifications burdening fundamental rights are reviewed under strict scrutiny); *Craigmiles v. Giles*, 312 F.3d 220, 223 (6th Cir. 2002) ("When a statute regulates certain 'fundamental rights' (*e.g.* voting or abortion) . . . the statute is subject to 'strict scrutiny.'" (citation omitted) (emphasis in original)). "Under strict scrutiny, a regulation infringing upon a fundamental right will only be upheld if it is narrowly tailored to serve a compelling state interest." *Dubay v. Wells*, 506 F.3d 422, 429 (6th Cir. 2007).

advance any interest in women's health or decisional certainty. When there is "no rational relationship to any of the articulated purposes of the state, [the court is] left with the more obvious illegitimate purpose." *Craigmiles v. Giles*, 312 F.3d 220, 228 (6th Cir. 2002) (applying rational basis review to strike down licensing requirement as "inapposite and counterproductive" to the state's asserted interest).

F. Absent an Injunction, Plaintiffs and Their Patients Will Suffer Irreparable Injury

Plaintiffs and their patients will suffer irreparable harm unless the Act is enjoined. The deprivation of constitutional rights unquestionably constitutes irreparable injury. *See, e.g.*, *Elrod v. Burns*, 427 U.S. 347, 373 (1976) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury"); *Am. C. L. Union of Ky. v. McCreary Cnty.*, *Ky.*, 354 F.3d 438, 445 (6th Cir. 2003) ("[I]f it is found that a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated."); *Mich. State A. Philip Randolph Inst. v. Johnson*, 833 F.3d 656, 669 (6th Cir. 2016); *Taubman Co. v. Webfeats*, 319 F.3d 770, 778 (6th Cir. 2003); *Planned Parenthood Ass'n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1400 (6th Cir. 1987).

The Act further threatens to harm patients by impeding informed consent, directing them to an unproven and potentially unsafe treatment, and undermining their trust in their healthcare providers. *See supra* Sections II.C, D. These threats to Plaintiffs' patients' health and wellbeing, as well as their constitutional rights, constitute irreparable harm. *See, e.g.*, *Harris v. Bd. of Supervisors, L.A. Cnty.*, 366 F.3d 754, 766 (9th Cir. 2004) (finding likelihood of irreparable harm where delayed medical treatment would cause pain, complications, and other adverse effects); *Planned Parenthood of Wis. v. Van Hollen*, 963 F. Supp. 2d 858, 868 (W.D. Wis. 2013) (holding

that an abortion restriction caused irreparable harm to patients by *inter alia* imposing increased health risks through delay).

The threat of the Act's onerous penalties, including confinement in jail, licensure penalties, and civil penalties of $10,000 per day, likewise constitutes irreparable harm. *See, e.g.*, *A Choice for Women v. Butterworth*, 54 F. Supp. 2d 1148, 1158 (S.D. Fla. 1998); *Planned Parenthood of Cent. N.J. v. Verniero*, 41 F. Supp. 2d 478, 504 (D. N.J. 1998), *aff'd sub nom Planned Parenthood of Cent. N.J. v. Farmer*, 220 F.3d 127 (3d Cir. 2000).

G. An Injunction Would Not Harm Defendants and Would Serve the Public Interest

As set forth above, Plaintiffs and their patients will suffer serious harm without an injunction, whereas Defendants only stand to temporarily lose the ability to enforce a law that is not in effect, does not serve any state interest, and is likely to be held unconstitutional. *See Planned Parenthood Ass'n of Cincinnati*, *Inc.*, 822 F.2d at 1400 (finding it "questionable" whether state "has any 'valid' interest in enforcing" an unconstitutional law); *see also Chamber of Com. of U.S. v. Edmondson*, 594 F.3d 742 (10th Cir. 2010) (noting that defendant "does not have an interest in enforcing a law that is likely constitutionally infirm"). Where Plaintiffs' requested relief will simply preserve the status quo, the balance of equities tips in favor of an injunction. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *Preterm-Cleveland v. Yost*, 394 F.Supp.3d 796, 803 (S.D. Ohio 2019). The balance of harm thus weighs decisively in Plaintiffs' favor.

Finally, granting an injunction in this case will serve the public interest. As the Sixth Circuit has made clear, "[w]hen a constitutional violation is likely . . . the public interest militates in favor of injunctive relief because it is always in the public interest to prevent violation of a party's constitutional rights." *Am. C. L. Union Fund of Mich.*, 796 F.3d at 649 (alteration in original)

(internal quotation marks omitted); *see also Am. Freedom Def. Initiative v. Suburban Mobility Auth. for Reg'l Transp. (SMART)*, 698 F.3d 885, 896 (6th Cir. 2012); *Planned Parenthood Ass'n of Cincinnati,* 822 F.2d at 1400 ("[T]he public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional.").

It is also unquestionably in the public interest, especially during a global pandemic, to protect people's ability to trust that their doctors are providing truthful, evidence-based medicine, rather than becoming mere government mouthpieces for unscientific viewpoints. The only way to prevent the public harm resulting from this far-reaching, ongoing constitutional violation is to enjoin enforcement of the Act.

IV. CONCLUSION

For all of the foregoing reasons, Plaintiffs' motion for a temporary restraining order and/or preliminary injunction should be granted. Defendants should be enjoined from enforcing the Act pending the final determination of Plaintiffs' claims.[15]

Dated: September 1, 2020

Respectfully submitted,

/s/ Thomas Castelli
Thomas H. Castelli (No. 24849)
Stella Yarbrough (No. 33637)
American Civil Liberties Union
Foundation of Tennessee
P.O. Box 12160
Nashville, TN 37212
Tel: (615) 320-7142
tcastelli@aclu-tn.org

[15] Because Plaintiffs and their patients face a loss of constitutional rights, and Defendants are not faced with any monetary injury if a preliminary injunction is issued, this Court should exercise its discretion to waive the Fed. R. Civ. P. 65(c) bond requirement. *See Appalachian Reg'l Healthcare, Inc. v. Coventry Health and Life Ins. Co.*, 714 F.3d 424, 431 (6th Cir. 2013); *see also Moltan Co. v. Eagle-Picher Indus., Inc*., 55 F.3d 1171, 1176 (6th Cir. 1995) (affirming district court decision to require no bond "because of the strength of [the plaintiff's] case and the strong public interest involved"); *Preterm-Cleveland v. Yost*, 394 F. Supp. 3d 796, 804 (S.D. Ohio 2019) (waiving bond).

syarbrough@aclu-tn.org

Attorneys for Plaintiffs

Christine Clarke*
Jennifer Sandman*
Planned Parenthood Federation of America
123 William St., 9th Floor
New York, NY 10038
Tel: (212) 261-4749
Tel: (212) 261-4405
Fax: (212) 247-6811
christine.clarke@ppfa.org
jennifer.sandman@ppfa.org

Attorneys for Plaintiffs Planned Parenthood of Tennessee and North Mississippi and Audrey Lance, M.D., M.S.

Andrew Beck*
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
Tel: (212) 549-2633
abeck@aclu.org

Attorneys for Plaintiffs Knoxville Center for Reproductive Health and FemHealth USA, Inc.

Michelle Moriarty*
Center for Reproductive Rights
199 Water St., 22nd Floor
New York, NY 10038
Tel: (917) 637-3695
mmoriarty@reprorights.org

Marc Hearron*
Center for Reproductive Rights
1634 Eye St., N.W., Suite 600
Washington, DC 20006
Tel: (202) 524-5539
mhearron@reprorights.org

Attorneys for Plaintiff Memphis Center for Reproductive Health

*Application for admission *pro hac vice* forthcoming

CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify that on September 1, 2020, a true and correct copy of the foregoing has been served by e-mail according to the agreement and instructions from the Attorney General's Office to tnattygen@ag.tn.gov and on the Attorney for Defendants listed below.

ALEXANDER S. RIEGER
Assistant Attorney General
Office of the Attorney General
Public Interest Division
P.O. Box 20207
Nashville, TN 37202
(615) 741-2408
Alex.Rieger@ag.tn.gov

/s/ Thomas Castelli
Thomas H. Castelli (No. 24849)
American Civil Liberties Union
Foundation of Tennessee
P.O. Box 12160
Nashville, TN 37212
Tel: (615) 320-7142
tcastelli@aclu-tn.org

Attorney for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al.*, Plaintiffs, v. HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF COURTNEY A. SCHREIBER, M.D., M.P.H. IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Courtney A. Schreiber, M.D., M.P.H., declares and states as follows:

1. I am over 18 years of age and competent to make this declaration.

2. I submit this declaration in support of Plaintiffs' Motion for a Temporary Restraining Order and/or Preliminary Injunction preventing enforcement of Section 39-15-218 of H.B. 2263/S.B. 2196 (the "Act"), which would require physicians providing medication abortions to inform patients at least forty-eight hours prior to their having a medication abortion that "(1) [i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence; and

(2) [i]nformation on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." Act § 39-15-218(e).[1]

3. I understand that a separate section of the Act requires that any private office, ambulatory surgical treatment center, other facility, or clinic that provided more than fifty "elective" abortions during the previous calendar year (other than abortions necessary to prevent the death of the patient) must "conspicuously post a sign" in numerous locations that states: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately." Act §§ 39-15-218(b),(d).

4. I understand that the sign must be "printed with lettering that is legible and at least three quarters of an inch (0.75") boldfaced type." Act § 39-15-218(c).

5. I understand that for private offices or ambulatory surgical treatment centers, this sign must be posted in each patient waiting room and patient consultation room used by patients on whom abortions are performed. Act § 39-15-218(d). For hospitals and other facilities, the sign must be posted in each patient admission area used by patients on whom abortions are performed. *Id.*

6. I understand that the Act requires that after the "first drug involved in the two-drug process is dispensed in a chemical abortion utilizing mifepristone, the physician or an agent

[1] The Act defines "chemical abortion" as "the use or prescription of an abortion-inducing drug dispensed with intent to cause the death of the unborn child." Act § 39-15-218(a)(2). I understand the use of the term "chemical abortion" in the Act to refer to medication abortion using mifepristone and misoprostol, as I describe in detail in this declaration. *See infra* at ¶¶ 18-24.

of the physician" must "provide written medical discharge instructions" to the patient which include the same statement reproduced in paragraph 3 of this Declaration. Act § 39-15-218(f).

7. I understand that within ninety days after the Act's effective date of October 1, 2020, the Tennessee Department of Health must publish and make available on its website materials "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind and information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion." Act §§ 39-15-218(h),(i). I understand that these materials have not yet been published.

8. Finally, I understand that any physician who performs a medication abortion using mifepristone in violation of the Act would commit a felony criminal offense and be liable for damages in a civil lawsuit filed by the patient, the "father" of the fetus or embryo, or a minor or deceased patient's parents. Act §§ 39-15-218(j),(l). I also understand that medical facilities that violate the signage requirement may be fined $10,000 per day. Act § 39-15-218(k).

9. I am aware of a similar law that passed in Arizona several years ago but was later repealed, a similar law that recently passed in North Dakota and has been enjoined, and another similar law that recently passed in Oklahoma and has also been enjoined. Until the law in Arizona passed, I had never heard or read of "reversing" mifepristone or any other abortion-inducing drugs, and as an abortion provider and professor, I keep up to date with new research about medication abortion.

10. As I explain below, it is my opinion that the Act would force physicians to deviate from the best practice of medicine and the current medical evidence by providing information to patients that: (1) is medically unsupported, and is therefore false, misleading, and irrelevant to patients; (2) undermines the patient-provider relationship that is the cornerstone of the medical

profession in that it forces physicians to violate their ethical duty by providing false information to patients; and (3) poses real harm to both physicians and patients. I base these opinions on my expertise in the fields of obstetrics and gynecology; my experience in providing a broad range of reproductive health care to patients, including abortions; my expertise as a clinical researcher in the field of reproduction; and my familiarity with the body of scientific literature concerning medication abortion, including the few published papers regarding so-called "reversal."

My Expert Credentials

11. I am a board-certified obstetrician/gynecologist at the University of Pennsylvania Health System ("Penn Medicine") and a Professor of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania. I am Chair of the Division of Complex Family Planning for the American Board of Obstetrics and Gynecology. I am also a Fellow of the American College of Obstetricians and Gynecologists ("ACOG").[2] At Penn Medicine and the Perelman School of Medicine, I serve as Chief of the Division of Family Planning, the Director of the Pregnancy Early Access Center, and Program Director of the Fellowship in Family Planning. I also serve as an attending physician at the Hospital of the University of Pennsylvania.

12. At Penn Medicine, I teach medical students as well as residents, including those training in obstetrics/gynecology and family medicine, among others, both didactically and clinically. Among the subjects I teach is abortion, including medication abortion and procedural abortion. In addition, I direct the Fellowship in Complex Family Planning at Penn, which involves teaching advanced family planning and abortion techniques to doctors who have completed their residencies and seek sub-specialization. I am an expert in the provision of abortion services, having provided this procedure to over 5,000 patients as an integral component

[2] ACOG is also known as the American Congress of Obstetricians and Gynecologists.

of my practice. In so doing, I use various approaches to abortion care, including medication abortion, vacuum aspiration, and dilation and evacuation. I provide general gynecology and expert contraceptive management as well as expert care in early pregnancy loss (or miscarriage), and I have been practicing in this way as an attending physician for fourteen years at the Perelman School of Medicine.

13. In addition to being an obstetrician/gynecologist, I hold a master's degree in public health with a concentration in epidemiology (the study of the incidence, distribution, and possible control of diseases and other factors relating to health). I also have expertise in the conduct of human-subjects research in reproduction.

14. A copy of my curriculum vitae ("CV") is annexed hereto as Exhibit A. As indicated on my CV, I have published over forty peer-reviewed research articles on a wide range of reproductive health issues. In addition, I have been the principal investigator or co-investigator on approximately fifty-five research studies relating to early pregnancy, sexually transmitted infections, abortion, and contraception.

15. I serve on the editorial board of the journal *Contraception*, and I am a reviewer for the *American Journal of Obstetrics and Gynecology*. I have also served as a reviewer for the journal *Pharmacoepidemiology*.

Abortion and the Science of Medication Abortion

16. Abortion is one of the safest and most common outpatient procedures performed in the United States. Approximately one in four women in the United States will have an abortion by age forty-five, and most who do so either already have children or are planning to

raise a family when they are older, financially stable, and/or in a supportive relationship with a partner.[3]

17. Carrying a pregnancy to term carries much higher risks of both morbidity and mortality than does abortion. The mortality rate associated with pregnancy in the United States is approximately fourteen times higher than the risks associated with abortion, and the complication rates for abortion are similar to, or lower than, complications associated with other outpatient procedures.[4]

18. As indicated above, there are both procedural and non-procedural (i.e., medication) abortion methods available. Medication abortion for early abortions (eleven weeks or fewer from the first day of the woman's last menstrual period (LMP)) is a safe method of ending a pregnancy by taking two medications, mifepristone (also known as RU-486 or by its trade name in the U.S., Mifeprex®) and misoprostol, that together cause the woman to undergo a pregnancy termination within a predictable period of time. In order to understand why the Act is grossly inconsistent with good medical practice and evidence-based care, it is important to understand the nature of medication abortion and how it is provided.

19. I understand that Plaintiffs provide medication abortion using an evidence-based regimen outlined in the 2016 Food and Drug Administration ("FDA") label for Mifeprex, which involves use of both mifepristone and misoprostol for patients with pregnancies at ten or fewer

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[3] *See Induced Abortion in the United States, Guttmacher Institute* (Sep. 2019), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states; Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008* (May 2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014.

[4] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215, 216-17 (2012).

weeks LMP. [5] The dosage, timing, and route of administration of this regimen has been endorsed by ACOG.[6] As set forth in the 2016 label, the protocol for administration of medication abortion is as follows: on day one, the patient takes 200 mg of mifepristone orally; twenty-four to forty-eight hours later, the patient takes 800 mcg of misoprostol buccally (in the cheek pouch) at a location of her choosing. The success rate for medication abortion in the United States under this protocol is 97.4%. As emphasized by the FDA in the updated 2016 label, this protocol has been demonstrated by clinical trials to be safe and extremely effective through seventy days or ten weeks LMP, and there is likewise evidence for the safe, effective use of a mifepristone-misoprostol regimen through seventy-seven days or eleven weeks LMP.[7] To date, more than four million women have used this method in the United States.[8]

20. This is the same combination of medications I use to provide medication abortion in my own practice and in my teaching.

21. When used in a medication abortion, mifepristone works by binding to receptors in the uterus and elsewhere, temporarily blocking the activity of the hormone progesterone and causing the pregnancy tissue and lining of the uterus to break down and separate from the uterine

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[5] I understand that Plaintiffs also provide medication abortion for patients with pregnancies up to eleven weeks LMP using mifepristone and misoprostol. This is also an evidence-based use. *See* American College of Obstetricians & Gynecologists and Society of Family Planning, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1, 4 (2020) (hereinafter "ACOG/SFP Guidelines").

[6] ACOG, *Practice Bulletin Number 143: Medical Management of First-Trimester Abortion,* 123 Obstet. Gynecol. 676 (Mar. 2014).

[7] *MIFEPRIX (Mifepristone) Tablets Label*, FDA https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (2016) (detailing studies regarding the safe and effective use of Mifeprex through seventy days LMP); ACOG/SFP Guidelines, *supra* n.5.

[8] *Mifeprex Effectiveness & Advantages*, Danco Laboratories (last visited Sept. 11, 2019), https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/.

wall.[9] Mifepristone binds preferentially to progesterone receptors in the presence of progesterone because it has a higher affinity for the receptors, meaning that mifepristone binds more tightly to the receptors than progesterone does.[10] Mifepristone also triggers the release of endogenous prostaglandins (which can cause uterine contractions),[11] softens and opens the cervix,[12] and increases uterine contractility (capacity to contract).[13] Mifepristone is quickly absorbed, reaching peak concentrations in the blood about one to two hours after it is ingested.[14] Mifepristone is eliminated from the bloodstream slowly for the first seventy-two hours, then rapidly thereafter.[15]

22. In some percentage of pregnancies, particularly at the earliest stages, mifepristone alone will terminate the pregnancy. However, early research showed that mifepristone could not effectively be used alone as an abortion-inducing medication because it failed to work

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[9] Narendra N. Sarkar, *Mifepristone: Bioavailability, Pharmacokinetics, and Use-Effectiveness*, 101 Eur. J. of Obstetrics & Gynecology & Reprod. Biology 113, 115 (2002); Regine Sitruk-Ware & Irving Spitz, *Pharmacological Properties of Mifepristone: Toxicology and Safety in Animal and Human Studies*, 68 Contraception 409, 410-411 (2003); Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU486 (Mifepristone)*, 315(25) N. Eng. J. Med. 1565, 1568 (1986).

[10] Sitruk-Ware & Spitz, *supra* n.9, at 410; Oskari Heikinheimo et al., *The Pharmacokinetics of Mifepristone in Humans Reveal Insights Into Differential Mechanisms of Antiprogestin Action*, 68 Contraception 421, 425 Table 1 (2003); Christian Fiala & Kristina Gemzell-Danielsson, *Review of Medical Abortion using Mifepristone in Combination with a Prostaglandin Analogue*, 74 Contraception 66, 68 (2006).

[11] Couzinet et al., *supra* n.9, at 1568; Remi Peyron et al., *Early Termination of Pregnancy with Mifepristone (RU 486) and the Orally Active Prostaglandin Misoprostol*, 328 N. Eng. J. Med. 1509, 1509 (1993).

[12] Couzinet et al., *supra* n.9, at 1568; Fiala & Gemzell-Danielsson, *supra* n.10, at 76.

[13] Couzinet et al., *supra* n.9, at 1568; Peyron et al., *supra* n.11, at 1509; Fiala & Gemzell-Danielsson, *supra* n.10, at 68; Sitruk-Ware & Spitz, *supra* n.9, at 411-12.

[14] Heikinheimo et al., *supra* n.10, at 422; Sarkar, *supra* n.9, at 114; Fiala & Gemzell-Danielsson, *supra* n.10, at 68.

[15] Sarkar, *supra* n.9, at 115.

sufficiently well on its own.[16] Subsequent research showed that the combination of mifepristone and a prostaglandin (misoprostol) work synergistically to terminate an early pregnancy with high efficacy.[17] Misoprostol taken buccally between twenty-four to forty-eight hours (or even up to seventy-two hours) after taking mifepristone induces uterine contractions. Mifepristone is also understood to increase the efficacy of misoprostol by weakening the endometrial lining and increasing the strength and efficacy of these contractions,[18] thereby increasing the likelihood that together they will result in pregnancy termination and expulsion.

23. Because taking these two drugs is part of a single regimen, "medication abortion" is commonly used to refer not to either mifepristone or misoprostol on their own but rather to the combination of the two drugs. Indeed, this is how the FDA approved the use of mifepristone for medication abortion.

24. As stated above, early research showed that when mifepristone was used alone to effect abortion, a significant number of pregnancies continued, making the drug inadequate for pregnancy termination on its own. It is difficult to estimate with accuracy the percentage of medication abortion patients who would have ongoing pregnancies after taking mifepristone alone. There are several reasons for this: (1) there are very few studies showing the proportion of pregnancies in which mifepristone alone caused embryonic or fetal demise; (2) almost all of those focused on pregnancies earlier than forty-nine days LMP;[19] (3) nearly all of those studies

[16] *See, e.g.*, *infra* n.21.

[17] Fiala & Gemzell-Danielsson, *supra* n.10, at 66-67.

[18] Fiala & Gemzell-Danielsson, *supra* n.10, at 66; Couzinet et al., *supra* n.9, at 1568.

[19] *See, e.g.*, Laszlo Kovacs et al., *Termination of Very Early Pregnancy by RU 486—An Antiprogestational Compound*, 29(5) Contraception 399 (1984) (including only women with pregnancies of forty-two days LMP or fewer).

involved higher doses of mifepristone than are currently used by most clinicians;[20] (4) more recent studies describe the efficacy of mifepristone only when combined with misoprostol, and most researchers do not study or compute success after mifepristone alone; and (5) large, population-based datasets are not available to analyze, since very few women elect to discontinue this medication abortion regimen after ingesting the mifepristone. But there is some evidence to suggest that up to 46% of women would have continuing pregnancies after taking mifepristone alone.[21] Additionally, data from trials looking at the efficacy of the mifepristone/misoprostol combination suggest that the rate of continued pregnancy increases as gestational age increases.[22]

The Lack of Credible Scientific Research to Support the Possibility of "Reversing" Medication Abortion

25. I am aware of a proposal by two physicians based in California, Dr. George Delgado and Dr. Mary Davenport, that physicians administer progesterone to "reverse" the effects of mifepristone in women who started the medication abortion regimen but did not take the misoprostol. Delgado and Davenport have published two papers that they claim support their proposal regarding the use of progesterone. These two papers are attached as Exhibits B and C.

26. In my medical and scientific opinion, the administration of progesterone to reverse the effects of mifepristone is experimental and unsupported by reliable scientific

[20] *See, e.g.*, Iain T. Cameron et al., *Therapeutic Abortion in Early Pregnancy with Antiprogestogen RU486 Alone or in Combination with Prostaglandin Analogue (Gemeprost)*, 34(5) Contraception 459 (1986) (studying total mifepristone dosage of 600mg, which is three times the current standard dosage).

[21] Zheng Shu-rang, *RU 486 (Mifepristone): Clinical Trials in China*, 149 Acta Obstericia Gynecologica Scand. Suppl. 19, 21 (1989).

[22] Beverly Winikoff et al., *Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Control Trial*, 112(6) Obstetrics & Gynecology 1303, 1306 (2008).

evidence. ACOG and the Society of Family Planning ("SFP") recently issued a joint practice bulletin providing clinical management guidelines for obstetrician/gynecologists stating that "[t]here is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing."[23] The practice bulletin is attached as Exhibit D.

27. Thus, requiring physicians to tell patients that "it may be possible to reverse" the "intended effects" of a medication abortion utilizing mifepristone and refer them to the Department of Health website for "information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone" could easily mislead patients into wrongly assuming that there are reliable data to support this practice. Doing so on the bases of the Delgado and Davenport papers, which provide no reliable scientific support for this practice, is unethical, and dangerous to the health and well-being of patients. ACOG previously published a statement on its website to this effect, explaining that "[c]laims regarding abortion 'reversal' treatment are not based in science and do not meet clinical standards," and that requiring physicians to inform patients about so-called "reversal" and to make referrals for such treatments "compromise[s] patient care and safety." That statement is attached here as Exhibit E. I agree with ACOG's determinations completely.

28. The two papers written by Dr. Delgado and his colleagues do not come close to providing scientifically valid support for the theory of medication abortion "reversal."

Delgado's 2012 paper fails to demonstrate that progesterone is effective to "reverse" mifepristone

29. The first paper, published in 2012 in the *Annals of Pharmacotherapy*, describes seven patients who took mifepristone and were then administered progesterone, using various routes of administration (oral, vaginal, and intramuscular). Of these patients, four carried their

[23] ACOG/SFP Guidelines, *supra* n.5, at 3.

pregnancies to term, two experienced abortions, and one was lost to follow-up.[24] At the end of the case series, Delgado and Davenport propose a protocol of regular intramuscular injections of doses of progesterone (200 mg) administered throughout the first trimester of pregnancy to reverse the effects of mifepristone.

30. As an initial matter, it is unclear why the authors chose to publish in the *Annals of Pharmacotherapy*, which is not known as being a journal that obstetrician/gynecologists or women's health clinicians regularly consult, and therefore the authors are unlikely to reach their target audience. By its title, *Annals of Pharmacotherapy* appears to be geared towards authors and readers who are pharmacologists and pharmaceutical scientists, rather than clinicians, and it is certainly not geared toward specialists in women's health or reproduction.

31. I was also surprised to see that the authors included clinical recommendations at the end of their paper, which the authors describe as containing "case reports."[25] Generally, case reports or series are used to identify new possible adverse effects of a drug or to identify a potential novel finding that the author is proposing for future study. Case reports or series are not considered sufficient evidence to support the safety, efficacy, or utility of a new treatment, nor are they considered the basis for providing or recommending a new course of treatment. Larger data sets with more rigorous study methodologies that include a sample size calculation and a control group are generally required in order to recommend practice change.

32. Control groups allow researchers to assess whether the change in a study participant's outcome was due to the treatment or some other factor. In a rigorous clinical trial with a control group, participants are randomly and blindly assigned to either a test group or a

[24] George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 Annals of Pharmacotherapy e36 (Dec. 2012).

[25] *Id.*

control group. The test group receives the treatment being tested, while the control group generally receives a placebo or another treatment known to be effective. Randomly assigning participants to the test or control group avoids other variables affecting the outcome, and blinding (meaning that both the participants and researchers do not know to which group the participant has been assigned) is intended to minimize potential biases that could otherwise be introduced. Because case reports or series lack these critical features, they generally are not considered to be of sufficient quality to support a change in treatment.

33. Not only do appropriately-sized data sets not exist on the topic of the 2012 paper, but the authors of this paper disclose that they based their proposed treatment protocol on a different protocol proposed in the separate context of miscarriage prevention, "the protocol of Hilgers," which itself does not appear to have been endorsed by any major medical organization or derived from any peer reviewed studies.[26] Furthermore, while the authors of the 2012 paper based their proposed protocol on the proposed use of progesterone in the context of miscarriage prevention, the effectiveness of using progesterone to prevent miscarriage has been significantly undermined: a recent randomized trial published in the *New England Journal of Medicine* demonstrated that progesterone does not prevent miscarriage among women who experience bleeding in early pregnancy.[27]

34. There are serious problems with attempting to draw any inferences from the Delgado paper. The number of patients reported—seven—is so small that no responsible researcher or physician would generalize from the outcomes reported. There is also a scarcity of relevant facts reported for each woman (such as exact gestational age of the pregnancy and the

[26] *Id.*

[27] Arri Coomarasamy et al., *A Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy*, 380 N. Eng. J. Med. 1815 (2019).

amount of mifepristone administered). The seventh patient was reported as lost to follow-up, and the outcome of her pregnancy is not included.

35. Moreover, as explained above, some women would be expected to have ongoing pregnancies after taking mifepristone alone, and this percentage would probably be higher the later in pregnancy a patient took the mifepristone. In the paper, the four patients who had a continued pregnancy took mifepristone later in gestation (between seven and ten or eleven weeks),[28] when mifepristone alone is known to be less effective at ending the pregnancy. Therefore, it is impossible to draw any conclusion about whether the progesterone injections had any effect at all on the patients' pregnancies.

36. In addition, it appears that all of the patients discussed in the paper as "successes" had confirmed embryonic or fetal cardiac activity before beginning progesterone treatment.[29] This fact—that all of these patients had pregnancies that had already withstood the initial effects of the mifepristone—itself indicates that these pregnancies were predisposed to continue and not demise. In other words, there is a selection bias in the study's small sample.

37. The paper also describes a variety of drug regimens provided to the patients, including different routes of administration (intramuscular and oral) of the progesterone, intervals between doses, and durations of treatment.[30] Some patients even continued taking progesterone into the seventh month of pregnancy. The reasons for these variations are not explained, nor is it explained why they used a variety of different formulations and doses, but

[28] Delgado & Davenport, *supra* n.24.

[29] The authors report that, in one case (of a patient who went on to miscarry), there was no documentation of cardiac activity before treatment, but do not explain why treatment was provided.

[30] Delgado & Davenport, *supra* n.24.

then recommend one particular regimen at the end of the paper. The "success" they report with a variety of regimens raises the likelihood that these women would have had ongoing pregnancies with placebo treatments, as well.

38. In short, no responsible physician would suggest, based on this paper, that "reversal" of mifepristone is possible. As ACOG has explained in the statement attached as Exhibit D, Dr. Delgado's claims of "reversing" mifepristone "are unproven and unethical," and his study does not amount to valid "scientific evidence that progesterone" can be used for these purposes.

Delgado's 2018 paper fails to demonstrate that progesterone is effective to "reverse" mifepristone

39. The second Delgado paper, published in 2018 in *Issues in Law and Medicine*, is, if anything, more problematic.[31] First, the journal in which the paper was published is once again noteworthy. *Issues in Law and Medicine* is known primarily as a legal policy journal, not as a publication for peer-reviewed scientific research. The journal's website states that it "is devoted to providing technical and informational assistance to attorneys, health care professionals, educators and administrators on legal, medical, and ethical issues arising from health care decisions."[32] This journal is not one that is utilized by clinicians or scientists for clinically relevant or actionable data. The journal's website further states that the journal "is co-sponsored by the National Legal Center for the Medically Dependent & Disabled, Inc. and the Watson Bowes Research Institute."[33] The Watson Bowes Research Institute, in turn, is affiliated with the

[31] George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33(1) Issues in L. & Med. 21 (2018).

[32] About, Issues in Law and Medicine (last visited Aug. 25, 2020), https://publons.com/journal/16314/issues-in-law-and-medicine/

[33] *Id*.

American Association of Pro-Life Obstetricians and Gynecologists (an anti-abortion advocacy organization), according to the latter's tax forms.[34] It is a journal with a political, not scientific, agenda.

40. The paper, entitled "A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone," was published in 2018, but was subsequently withdrawn. Media reports indicate that the University of San Diego's Institutional Review Board ("IRB")[35] requested that the paper be withdrawn "because the wording regarding [Institutional Review Board] approval in the paper was ambiguous, leading many readers to incorrectly conclude that the University of San Diego's IRB had reviewed and approved the entire study," when it had in fact only approved a *retrospective* analysis (meaning, an analysis of data from past events) of pre-existing, patient de-identified data.[36]

41. When the paper was subsequently republished, the authors altered the description of their methods but not the results or discussion. Originally, the authors called the paper an

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[34] *See Form 990, Am. Ass'n of Pro-Life Obstetricians and Gynecologists* (2015), *available at* https://rewire.news/wp-content/uploads/2017/02/AAPLOG-990-2015.pdf.

[35] The professional norm and expectation is that research on human subjects should be approved by an IRB, which is a committee that performs an ethical review of proposed research. The purpose of IRBs is to protect human subjects of research. Some IRBs also review the design of a study to assess its potential to generate useful knowledge, and to ensure that the assessed potential benefits of the research outweigh the potential harms from a public health perspective. For these reasons, they are viewed as an important quality control mechanism; the government requires this step as a funding prerequisite, and reputable journals will not publish results obtained without IRB approval or exemption. I have conducted over 50 studies involving human subjects, and each one has been through the IRB-approval process. I can attest that this mechanism is not simply administrative but is vital to enabling the delicate balance between medical ethics and scientifically progressive research.

[36] *See*, *Study Claiming "Abortion Reversal" Is Safe and Effective Temporarily Withdrawn for Ethical Issues,* Retraction Watch (Jul. 17, 2018), https://retractionwatch.com/2018/07/17/study-claiming-abortion-reversal-is-safe-and-effective-temporarily-withdrawn-for-ethical-issues/ (alteration in original).

"observational case series," which is not actually an accepted or valid study design. The paper is also not a true "case series," because it was *prospective* in design—which is generally not the case with a case-series design. Similarly, the paper is not "observational" because instead of just observing the impact of a treatment on patients, the researchers actively enlisted participants to undergo an *experimental* intervention—here, the administration of progesterone after mifepristone. Worse still, the researchers administered the experimental intervention on patients without a control group—i.e., there was no group of similarly situated patients (meaning, patients who took mifepristone but not misoprostol or progesterone) to which the researchers could compare the patients who received progesterone to assess differences in birth outcomes. When the paper was republished, the authors described their methods differently, calling it a "retrospective analysis of clinical data," but did not alter their described results or discussion. It is unheard-of to withdraw a paper, rewrite its methods to describe an entirely different study design, and republish the remainder of the paper unchanged.[37]

42. No valid scientific conclusions can be drawn from the 2018 Delgado paper. It does not include a control group, and so no inference can be made about whether administration of progesterone has any effect (or the size of such effect, if any).[38] It would be inappropriate to draw any conclusions about causation from this paper.

43. Moreover, like the 2012 Delgado paper, the 2018 Delgado paper almost certainly overestimates the ongoing pregnancy rate among patients who received progesterone, making its

[37] Delgado et al., *supra* n.31.

[38] The best way to design a study in order to draw any inference about the impact of the exposure (here, progesterone), would be to take women receiving mifepristone, administer progesterone to those women who desire it, and then follow all women, regardless of exposure to progesterone, to their definitive pregnancy outcome. From such a study design, the authors would be able to compute the absolute risk and the relative risk or odds ratios of a continuing pregnancy with and without exposure to progesterone. Dr. Delgado's papers do none of this.

results unreliable. Specifically, women in the paper were administered progesterone only *after* ultrasound was used to confirm ongoing fetal cardiac activity after taking mifepristone (except in an unknown number of instances in which pre-administration ultrasound was not readily available). The fact that the data consisted primarily of women whose pregnancies had already withstood the effects of mifepristone means that the authors were reporting on pregnancies that were already predisposed to continue. The authors generously describe this as a "confounding variable," but the paper does not adequately account for its significance or attempt to statistically control for this as a confounding variable, as any valid scientific research study would do.[39]

44. Additionally, as with Dr. Delgado's 2012 paper, the heterogeneity of the delivery systems described in the 2018 paper further limits any interpretation of the results. The paper lists ten different progesterone regimens, which were not administered by study investigators following a research protocol, but by a dispersed group of clinicians.

45. The paper's ethics are likewise troubling. Because there is no specified regimen being assessed here, women were subjected to doses and routes of progesterone without any clinically actionable outcome gained. There is no sample size calculation provided, so it is entirely possible that more women were exposed than necessary to provide a statistically significant difference from the expected number of live births after mifepristone alone. Were women reimbursed for their time and trouble? Were these women coerced? As a clinician and as an investigator, this paper is deeply troubling on many levels.

46. As stated above, the 2018 Delgado paper does not use a control group; participants were not randomly and blindly assigned to either a control group or a treatment

[39] Delgado et al., *supra* n.31.

group. This makes it virtually impossible to infer from the paper whether treatment with progesterone played any role in participants' continued pregnancies.

47. The paper also lacks a scientifically valid use of what is known as a "historical control group." A study using a historical control is one in which there is no concurrent control group—meaning there is no group of participants who receive a placebo, no treatment, or a standard treatment concurrently while the experimental group receives the treatment being studied. Instead, the researchers select a population of patients who were studied previously, and the data from those previously studied patients make up the data for the historical control group. The outcomes from the treatment group are compared against the data for the patients whom the researchers chose as the historical control group. Because the researchers select which patients are included in the historical control group, these studies, by definition, do not have randomization and blinding. They are therefore much more susceptible to the introduction of bias. Such studies can be useful to prompt further study, but they are generally not sufficient by themselves to support a change in practice.

48. Moreover, if a historical control is to be used in a study, it is important that details about the population that is included in the historical control group be well documented and understood so that researchers can ensure that the control patients are as similar as possible to the patients who receive the treatment. The researchers should ensure that whether the participant received the treatment is the only variance between the participants selected for the historical control group and those selected for the treatment group. However, the 2018 Delgado paper did not follow this approach. Instead, the paper simply "selected a 25% embryo or fetus survival rate, if mifepristone alone is administered, as a control. . . ."[40] That is not a proper historical

[40]Delgado et al., *supra* n.31., at 6.

control. Additionally, as discussed below, the 25% number likely underestimates the true rate of continuing pregnancy in the historical population of patients who received mifepristone alone.

49. Finally, as discussed, a study using a historical control group is generally not sufficient to support a change in practice. To the extent any potential conclusions about the efficacy of the proposed treatment might be inferred from a study using a historical control group, it would only be where the researchers find a vastly larger difference in outcome between the historical control group and the treatment group than they would look for in a study using a concurrent control group. The 2018 Delgado paper does not consider this factor at all. In my opinion, even if the 2018 Delgado paper were a proper use of a historical control group (and as explained, it is not), any difference in outcome is not sufficiently significant to draw any conclusions from the paper.

Systematic review of research on mifepristone "reversal" establishes that there is insufficient evidence to support its effectiveness

50. Research and analyses published over the last few years confirm that both Delgado publications are inherently flawed and unsupported by the full body of scientific research on mifepristone and progesterone. A systematic review of the research on mifepristone "reversal," published in 2015 in the highly respected journal *Contraception*, demonstrated that evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.[41] This article is attached as Exhibit F. Similarly, an article published in 2018 in the *New England Journal of Medicine*, the most widely read, cited, and influential medical journal in the world, compared the data from the 2018 Delgado and Davenport paper to the only study of the rate of

[41] Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92(3) Contraception 206 (2015).

continuing pregnancy after the relevant dose of mifepristone (200 mg), and found that the confidence intervals around the point estimates overlap for women who do and do not use progesterone supplementation after using mifepristone. In essence, there is no evidence at all that progesterone administration after mifepristone use is effective at reversing, avoiding, or ceasing mifepristone's effects.[42] This article is attached as Exhibit G.

51. Delgado and Davenport published their own purported "systematic review" of the literature on mifepristone "reversal" in *Issues in Law & Medicine* in 2017, but like their other papers, it too is flawed.[43] Delgado and Davenport's review criticizes the review by Grossman et al. published in *Contraception* for including several studies "that did not assess abortion failures with ultrasound to verify if living embryos were present, or had other faulty criteria" despite the fact that Grossman et al. were in fact able to assess the number of continuing pregnancies in these studies. Meanwhile, Delgado and Davenport provide no rationale for excluding these studies from their review. Delgado and Davenport's review ultimately falls victim to several well-known errors in poorly conducted systematic reviews and meta analyses, including selective reporting, which occurs when the reporting of a subset of outcomes and analyses in the systematic review is based only on the results of the studies and does not take into account differences in the methods or populations included.[44] Finally, it appears that the purpose of this review was to compute the baseline rate of continuing pregnancy without progesterone

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[42] Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating without Evidence*, 379(16) N. Eng. J. Med. 1401 (2018).

[43] Mary L. Davenport et al., *Embryo Survival after Mifepristone: A Systematic Review of the Literature*, 32(1) Issues in L. & Med. 3 (2017).

[44] Matthew J. Page et al., *Bias Due to Selective Inclusion and Reporting of Outcomes and Analyses in Systematic Reviews of Randomised Trials of Healthcare Interventions*, 1(10) Cochrane Database Syst. Rev. (Oct. 2014).

intervention in the population to inform Delgado's then-upcoming 2018 paper. But their statistical analysis of the papers they reviewed is flawed because the 25% number they cite in the paper as a "control" likely *underestimates* the true rate of continuing pregnancy in the population, with the effect that they *overestimated* the effectiveness of progesterone treatment to "reverse" abortion in their 2018 paper.[45]

Delgado's papers do not provide evidence upon which to base a treatment regimen

52. For all these reasons, the two flawed Delgado papers do not provide evidence upon which to base a treatment regimen. At a very practical level, progesterone injections are painful and expensive, and as explained below, they carry safety risks. It is unethical to recommend a treatment that causes pain, potential economic hardship, and safety risks when there is insufficient evidence of benefit to patients.

53. Indeed, even Delgado and Davenport in their 2012 paper conclude that "*if* further [clinical] trials confirm the success without complications of this or similar protocols, it should become the standard of care" and that currently physicians "may not want" to provide this treatment and only some physicians may be "comfortable" doing so.[46] These statements appear to be an acknowledgement (although insufficient) by the authors that their proposal requires an actual scientific investigation to determine safety and efficacy before it could be considered as a treatment. The 2018 paper similarly acknowledges that only "randomized controlled trials" can "confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious

[45] *See* Delgado et al., *supra* n.31, at 24. To be appropriately conservative in preparation for the planned 2018 paper, the authors instead should have focused on the upper-bound 95% confidence interval around each study's point estimate of the rate of continuing pregnancy. *See* T.V. Sakpal, *Sample Size Estimation in Clinical Trial*, 1(2) Perspectives in Clinical Research 67 (Apr. 2010).

[46] Delgado & Davenport, *supra* n.24 (emphasis added).

and carries the least burden for the patient."[47] As described in the *New England Journal of Medicine* editorial regarding the now disproven use of progesterone to help reduce the risk of miscarriage, changes in clinical practice based upon observational studies alone (of which a case series is the least rigorous) have repeatedly been later proven to be misguided, and these findings need to be confirmed (or disproven) with more rigorous study designs.[48]

54. Further investigation would be especially necessary here because of the pharmacodynamics and pharmacokinetics of the competing medications. Given how high natural progesterone levels are in pregnancy already, it is unlikely that high doses of exogenous progesterone, sometimes beginning several days after the patient ingested the mifepristone and continuing throughout the first trimester of her pregnancy (or beyond), could reverse the effects of mifepristone. As explained above, mifepristone already outcompetes the body's natural progesterone (which is at very high levels in pregnancy, naturally), binds tightly to progesterone receptors within hours of being ingested, and acts quickly and most potently over a time-limited period of about seventy-two hours. For this reason, I would not expect that exogenous progesterone could have any effect once the mifepristone has started acting or that there would be any reason to further elevate a patient's (already high in pregnancy) progesterone levels long after the mifepristone has ceased blocking progesterone receptors, and one would need empiric evidence showing otherwise to credit an implausible theory. Further study would be required since, to date, sufficient data do not exist to make conclusive statements.

55. Further, as mentioned above in paragraph 33, recent research on the use of progesterone supplementation during pregnancy by Coomarasamy et al. calls into question its

[47] Delgado et al., *supra* n.31, at 29.

[48] *See* Green, *infra* n.50.

effectiveness in increasing the likelihood that a woman will carry a fetus to term. Specifically, a large, randomized, double-blind, placebo-controlled trial of progesterone use in over four thousand women with threatened miscarriages before twelve weeks of gestation found that the incidence of live births was the same in the group of women who received progesterone and the group that did not.[49] In addition, in an accompanying editorial in the *New England Journal of Medicine,* the following statement is made: "In retrospect, it is likely that the initial rationale for hormonal therapy—that is, the observed fall in pregnancy hormone levels before pregnancy loss—was, in fact, a consequence rather than a cause of pregnancy failure. The subsequent enthusiasm for hormonal therapy was driven by overestimation of the incidence of pregnancy loss in the absence of therapy and by reports of seeming success in uncontrolled case series."[50] This statement not only underscores the flaws with the concept of progesterone "rescue therapy" but also highlights the dangers of over-interpretation of data derived from case series, the methodology Delgado and associates claim to have used.[51] Clearly, if medical experts cannot draw strong scientific conclusions from a case series, Tennessee should not be legislating the practice of medicine based on the data they produce.[52]

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[49] Coomarasamy et al., *supra* n.27.

[50] Michael F. Green, Editorial, *Progesterone for Threatened Abortion*, 380(19) N. Eng. J. Med. 1867 (2019).

[51] While the Coomarasamy et al. study suggested some clinically significant benefit for the small group of patients in the sample that had three or more previous miscarriages (i.e. recurrent miscarriages), the study did not draw any conclusions about the potential benefit to these patients. Patients with recurrent miscarriages are commonly understood to have distinct and even unique medical etiology, as compared to other patients. *See, e.g.*, Mercy Y. Laurino, et al. *Genetic Evaluation and Counseling of Couples with Recurrent Miscarriage: Recommendations of the National Society of Genetic Counselors*, 14(3) J. of Genetic Counseling (Jun. 2005).

[52] Even if the hypothesis that sufficient quantities of exogenous progesterone can outcompete mifepristone was established, the message that it "may be possible to reverse" the intended effect of mifepristone is inaccurate and misleading. Mifepristone binds tightly to progesterone receptors. If it were shown that exogenous progesterone could outcompete mifepristone and bind

There are no reliable resources for medication abortion "reversal"

56. The Act requires the Tennessee Department of Health website to post information on resources that may be available to assist with medication abortion "reversal." Other than the two published Delgado papers, the only other source for information supporting medication abortion "reversal" about which I am aware is the Abortion Pill Reversal website and hotline that Drs. Delgado and Davenport founded, called abortionpillreversal.com.

57. The website states that "Abortion Pill Rescue" is a program of Heartbeat International,[53] a "network of pro-life pregnancy resource centers"[54] whose mission "is to make abortion unwanted today and unthinkable for future generations."[55] It appears that Delgado and Davenport are Medical and/or Research Advisors to Abortion Pill Rescue and there is a "network" of "professional healthcare providers" available to assist women who call their hotline.[56]

58. The website represents that there is a treatment that is "effective" in reversing abortion, which is a completely unproven claim. It states, "CAN THE ABORTION PILL BE REVERSED? The simple answer is yes! If done in time. There is an effective process called

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to the receptors, this would not be "reversing," "ceasing," or "avoiding" mifepristone or its effects. Rather, it would be overcoming the action of mifepristone. The term "reversal" in this context is thus a complete misnomer and is misleading and confusing to patients.

[53] *About Us*, Abortion Pill Reversal / Abortion Pill Rescue (2020), https://www.abortionpillreversal.com/about/our-team.

[54] *Frequently Asked Questions about Heartbeat International*, Heartbeat International (2020), https://www.heartbeatinternational.org/about-us/faqs#:~:text=is%20Heartbeat%20International%3F-,A.,to%20provide%20alternatives%20to%20abortion.

[55] *Our Passion*, Heartbeat International (2020), https://www.heartbeatinternational.org/about/our-passion.

[56] Abortion Pill Reversal, *supra* n.53.

abortion pill reversal that can reverse the effects of the abortion pill and allow you to continue your pregnancy, but time is of the essence."[57] This statement is false. It also states: "By giving extra progesterone, we hope to outnumber and outcompete the mifepristone in order to reverse the effects of mifepristone."[58] This conjecture has not been established and, based on the relative binding affinities and the other information described above, is unlikely to be true. The website lists the side-effects of mifepristone as a major section, which is not only irrelevant to their mission, but the side effects listed include additional false claims.[59] Finally, the website claims that "there have been many successful reversals," and that it "may not be too late" to reverse an abortion even after seventy-two hours,[60] which is highly misleading. It also goes against ACOG's recommendations. All told, this website conveys Abortion Pill Reversal's ideologically based agenda and is dangerous. It is replete with misinformation about mifepristone, and indicates the organization's intention to sow doubt in the patient's mind about the treatment protocol she and her physician have chosen. No physician practicing evidence-based medicine would refer a patient to this website.

Potential Safety Risks of Medication Abortion "Reversal"

Concerns about progesterone

59. Although progesterone is considered a low-risk medication, it does carry risks. Progesterone has been associated with maternal complications such as depression, cholestatic

[57] *Can the Abortion Pill be Reversed?* Abortion Pill Reversal / Abortion Pill Rescue (2020), https://www.abortionpillreversal.com/abortion-pill-reversal.

[58] *Reversal FAQ,* Abortion Pill Reversal / Abortion Pill Rescue (2020), https://www.abortionpillreversal.com/abortion-pill-reversal/faq.

[59] *How it Works*, Abortion Pill Reversal / Abortion Pill Rescue (2020), https://www.abortionpillreversal.com/how-it-works

[60] *Abortion Pill Reversal*, *supra* n.58.

jaundice, and hypertension. And while some data support the general safety of progesterone in pregnancy, there are also some studies that have raised concerns about a possible association with second-trimester miscarriage and stillbirth in pregnancies exposed to certain exogenous progesterone preparations.[61] Investigators also have reported associations with hypospadias, a defect in the male infant's genitalia, occurring in the male infants born to women who used progestins (synthetic or pharmacologic progesterones) during pregnancy.[62] While none of these data are conclusive, they are enough to raise concern in the absence of proven benefit. At a minimum, the safety of administering high-dose progesterone has not been adequately studied in this population or for this indication.

60. Even absent concerns about high-dose progesterone, I am also concerned about possible future complications to the pregnancy caused by the mifepristone alone, as well as a combination of mifepristone and progesterone. While mifepristone is not established to be teratogenic (meaning disruptive of embryonic/fetal development), neither mifepristone nor high doses of progesterone has been conclusively shown to be safe for fetal development, and the combined effect of the two has not been studied or even considered at all. It is entirely possible this regimen could cause harm to the fetus, including birth defects, and almost impossible that it would be acceptable per current federal standards—outlined in the Code of Federal Regulations Part 46, Protection of Human Subjects, Research Involving Pregnant Women or Fetuses[63]—

[61] Paul J. Meiss et al., *Prevention of Recurrent Preterm Delivery by 17 Alpha-Hydroxyprogesterone Caproate*, 348 N. Eng. J. Med. 2379, 2382 (2003).

[62] Suzan L. Carmichael et al., *Maternal Progestin Intake and Risk of Hypospadias*, 159(10) Archives of Pediatric & Adolescent Med. 957 (2005).

[63] 45 C.F.R. § 46.204.

without intensive data safety and monitoring board oversight. There is no mention of such oversight in the Delgado publications.

Potential safety risks of discontinuing the mifepristone-misoprostol combined regimen

61. As explained above, medication abortion is a regimen of two medications: mifepristone and misoprostol. Indeed, the FDA has approved the use of mifepristone for medication abortion in combination with misoprostol.

62. This two-drug regimen is both extremely effective and extremely safe. Studies have shown that major complications—e.g., heavy bleeding or serious infection—occur in approximately 0.3% of medication abortion patients.[64] Medication abortion is safer than Tylenol.

63. Recent research, however, shows that there are serious safety concerns for patients who begin the medication abortion regimen by taking mifepristone but do not complete the regimen by taking misoprostol. Researchers at the University of California, Davis Medical Center, led by Dr. Mitchell Creinin, conducted a study to test the "reversal" hypothesis in the Delgado papers. The purpose of the study was to evaluate continuing pregnancy rates, safety, and side effects of high-dose oral progesterone in patients who used mifepristone alone without misoprostol. Unlike the Delgado papers, the Creinin study was a randomized, double-blind, placebo-controlled trial; it had IRB approval; and it was published in a prestigious, peer-reviewed journal, *Obstetrics & Gynecology*.[65]

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[64] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125(1) Obstetrics & Gynecology 175 (Jan. 2015); Daniel Grossman and Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130(4) Obstetrics & Gynecology 778 (Oct. 2017).

[65] Mitchell D. Creinin et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135(1) Obstetrics & Gynecology 158 (Jan. 2020).

64. The researchers enrolled participants who were pregnant, wanted abortions, were eligible for medication abortion, and were willing to delay their abortion by approximately two weeks. Participants took 200 mg of mifepristone and were then randomly allocated into a progesterone group and a placebo group. Participants in the progesterone group were instructed to take 800 mg of progesterone daily for three days beginning twenty-four hours after mifepristone, then 400 mg of progesterone daily for the remainder of the time they were in the study. Participants in the placebo group received placebos. Participants who had ongoing pregnancy after approximately two weeks received procedural abortions.[66]

65. The researchers halted the study after enrolling only twelve participants, due to serious safety concerns with continuing the study. Three of the twelve participants had severe, brisk hemorrhaging and had to be taken by ambulance to an emergency room. Of those three patients, one had such severe bleeding that she had to receive a blood transfusion. These three patients came from both the progesterone population and the placebo population. This suggests that the patients' hemorrhaging resulted from not following the medication abortion two-drug regimen, i.e., from using mifepristone alone and not in combination with misoprostol.[67]

66. The study raises serious safety concerns about not completing the medication abortion two-drug combination regimen. ACOG and SFP have issued a practice bulletin cautioning that the "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[68] Yet this is exactly what Delgado's "reversal" treatment calls for. And Delgado's "reversal" hypothesis is based on his two flawed papers, neither of which reports any outcome

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[66] *Id.*

[67] *Id.*

[68] ACOG/SFP Guidelines, *supra* n.6, at 3.

for those patients who did not have continuing pregnancies after taking mifepristone but not misoprostol.

67. This study also confirms the dangers of performing unmonitored experiments such as following Delgado's "reversal" treatment. When a study is properly monitored, as the Creinin study was, the researchers can halt the study if safety concerns arise. It is especially inappropriate for Tennessee to enact the Act to encourage patients to participate in an experiment lacking the appropriate rigorous safety-monitoring protocols.

Delgado's Research is Unethical and Unprofessional

68. I also have serious concerns about what Dr. Delgado and his colleagues are doing from the perspective of scientific investigation. In my opinion, their activities amount to research on human subjects as it is commonly understood and as it is defined by the United States Department of Health and Human Services: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[69] I base this assessment on their own claims in their two published papers, as well as on media reports and statements, which indicate that these physicians are providing various experimental progesterone protocols to hundreds of women (with no indication of proper informed consent, ethical review, or data collection/publication), analyzing the results, and discussing these results publicly (and misleadingly) as supporting the efficacy and safety of their proposed experimental progesterone protocols.[70]

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[69] 28 C.F.R. § 46.102(d).

[70] Shannon Firth, *Reversing Abortion Pill: Can It Be Done?*, MedPage Today (Feb. 24, 2015), http://www.medpagetoday.com/OBGYN/GeneralOBGYN/50164 ("Of the 223 women who have received progesterone, 127 cases succeeded, according to a fact sheet Delgado shared."); Colette Wilson, *Interview: Reversing the Effects of RU-486*, Lifeline Newsletter (Life Legal Defense Foundation, Napa, CA) Vol. XXIV, No. 1 (Winter 2014), *available at*: http://lldf.org/interview-reversing-effects-ru486/ ("Dr. Delgado: We have established an exciting program called APR

69. Dr. Delgado's and his colleagues' approach also is contrary to ACOG Guidelines on Innovative Practice, which strongly warn against generalizing treatment practices before they have been subjected to rigorous study.[71] As these guidelines explain, there is a risk that, without this control, practices may become widely accepted even though they are ineffective. This proved to be the case, for example, with "[b]ed rest or home uterine activity monitoring for the prevention of prematurity," "[b]one marrow transplant for breast cancer," and "[d]iethylstilbestrol or paternal antigen sensitization for the prevention of recurrent miscarriage."[72] There is also a risk that unstudied treatments may carry "small but potentially important risks" that are not immediately apparent from an initial small sampling of experimental patients; past examples of such treatments include "[l]imb reductions associated with early chorionic villus sampling" and "[s]ex chromosome abnormalities associated with intracytoplasmic sperm injection used in assisted reproductive technology."[73]

70. For all the reasons above, in my opinion, the research that Dr. Delgado and his colleagues are conducting is highly unethical and unprofessional. Likewise, it would be unprofessional for a physician to recommend to a patient that she undergo an experimental protocol (outside of an IRB approved research protocol). As a physician, I would never recommend this treatment to a patient nor would I refer a patient for such care given the current state of the evidence. In the unlikely event that a patient came to me seeking not to continue the medication abortion regimen after she had ingested the mifepristone, I would initiate

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(Abortion Pill Reversal) . . . I have published a case series report in a peer-reviewed medical journal, Annals of Pharmacotherapy, and plan a second article when we have 200 deliveries.").

[71] ACOG Comm. on Ethics, *Committee Opinion No. 352: Innovative Practice: Ethical Guidelines*, 108 Obstetrics & Gynecology 1589 (2006).

[72] *Id*. at 1591.

[73] *Id*. at 1592.

comprehensive pregnancy options counseling and probe as to what had motivated the patient's change of heart; if I confirmed that she carried an ongoing pregnancy and wished to continue to term, I would then refer her for prenatal care.

Effect of the Act on the Patient-Provider Relationship

71. Even apart from the fact that the administration of progesterone to reverse, avoid, or cease the effects of mifepristone is not supported by medical evidence and that there are concerns that Dr. Delgado's research is not being conducted ethically, it is my opinion that requiring physicians to inform patients about the possibility of medication abortion reversal is in and of itself harmful to physicians and patients in a variety of ways.

72. To begin with, the vast majority of women receiving medication abortion are sure of their decision by the time they present for care at an abortion clinic,[74] so information about "reversal" would be irrelevant for those patients. Additionally, part of the value to the clinical encounter is pregnancy options counseling, when the provider reviews the plan of care with the patient *before* initiating any clinical intervention. Falsely claiming that an abortion could be reversible is dangerous to women, and dangerous to the practice of medicine. Women may erroneously believe it is advisable to start the abortion process before they are sure of their decision.

73. The Act thus disrupts and impedes the patient-provider relationship and contravenes the true purpose of the informed consent process: Namely, to give each patient medical information relevant to their healthcare decision-making in a way that is easy to absorb

[74] *See, e.g.*, Lauren J. Ralph et al., *Measuring Decisional Certainty Among Women Seeking Abortion*, 95(3) Contraception 269 (2016); Diana G. Foster et al., *Attitudes and Decision Making Among Women Seeking Abortions at One U.S. Clinic*, 44(2) Perspectives on Sexual & Reproductive Health 117 (2012).

and understand—i.e., that is clear, concise, and applicable to her circumstances and individual concerns.

74. Further, the Act requires the mandated information to be "conspicuously" posted in patient waiting rooms and consultation rooms used by patients receiving abortions, and does not limit this requirement to rooms used by patients receiving *medication* abortions. Thus, this mandated information would also be irrelevant, and even more confusing, for women who are not using mifepristone as a part of the standard medication abortion regimen, but instead are receiving drugs, such as misoprostol alone, as part of an induction or procedural abortion. No one even claims to have an effective reversal treatment in these circumstances, but that may not be clear to the patient given this confusing and irrelevant information. Moreover, a sign displaying the government's misleading message in boldfaced type, 3/4 inch (i.e. 54 point) font, as required by the Act, would be equivalent to the size of a poster. A message of this size and prominence is not typically present in a medical practice and would likely spark concern and confusion among patients. For patients seeking medication abortion with mifepristone, the notice may create confusion about whether the treatment protocol prescribed by their physician is effective, potentially eroding trust and undermining the doctor-patient relationship. The required statement on the sign and in the written discharge instructions that "[r]ecent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy" is also inaccurate and misleading. The statement implies that researchers have recently discovered that mifepristone is not as effective as previously believed, which is wholly untrue—as discussed, research dating back decades showed that mifepristone failed to work sufficiently well on its own as an abortion-inducing medication, and this is precisely why the standard medication

abortion regimen involves the use of mifepristone and misoprostol in combination.[75] Ultimately, the overall effect of the notice is coercive—instilling confusion, doubt, and distrust, all in service of coercing women away from the treatment they have chosen.

75. Furthermore, the Act's requirements are confusing and misleading for medication abortion patients. Under the Act, patients must hear from their physician that reversal "may be possible," and that the Tennessee Department of Health website offers information on and assistance with obtaining this treatment. Patients must again receive the same information, from their physician or their physician's agent, after they receive mifepristone, in written medical discharge instructions. In this situation, patients are likely to conclude that this treatment is established as safe and effective, which as explained above, is far from true. In effect, the Act forces physicians and their agents to repeatedly endorse experimental medical treatment, despite the fact that the physicians do not think this treatment is in their patients' best interests. In my opinion, these problems cannot be solved by physicians providing further explanation. If a physician tried to explain that what she had just been required to tell the patient was untrue, misleading, and/or not relevant at all to the patient, that would increase patient confusion and make it harder for the physician to ensure that the patient understood all the relevant facts she needed to make an informed decision about whether or not to proceed with an abortion in the first place. It could also lead a patient not to trust any of the information the physician gave her.

76. Additionally, the Act requires physicians to give patients conflicting information, which could cause further confusion and undermine the critical physician-patient relationship of trust. The Act essentially requires physicians to tell their patients that the misoprostol is an optional part of the medication abortion two-drug combination regimen—i.e., that they can take

[75] Zheng, *supra* n.21.

mifepristone and then decide not to take misoprostol. This is at odds with other information and counseling that the FDA mandates that physicians provide to medication abortion patients. The FDA has adopted a Risk Evaluation and Mitigation Strategy ("REMS") specific to mifepristone. The REMS for mifepristone is separate from the FDA label for mifepristone; while physicians can and do prescribe evidence-based off-label uses of a drug in general, medication abortion providers must follow the FDA's REMS for mifepristone. Indeed, mifepristone manufacturers are prohibited from supplying mifepristone to healthcare providers unless they are REMS-certified.

77. The mifepristone REMS restricts who can prescribe mifepristone and how it can be provided to patients, and also mandates that certain information be provided to patients.[76] Under the mifepristone REMS, to be eligible to provide mifepristone, healthcare providers must sign a Prescriber Agreement Form agreeing that they will follow the REMS guidelines for mifepristone. Those guidelines require the provider to review the REMS-mandated Patient Agreement Form with the patient, answer any questions, and obtain the patient's signature on the form. By signing the Patient Agreement Form, the patient agrees that they will take both mifepristone and misoprostol:

> **Patient Agreement:**
>
> 1. I have decided to take Mifeprex ***and misoprostol*** to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
>
> 2. I understand:
>
> a. I will take mifepristone on Day 1.

[76] *Risk Evaluation and Mitigation Strategy (REMS): Single Shared System for Mifepristone 200MG,* FDA (Apr. 2019), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_REMS_Full.pdf.

b. My provider will either give me or prescribe for me the ***misoprostol tablets which I will take 24 to 48 hours after I take Mifeprex***.

The provider must also sign the Patient Agreement Form, confirming that he or she has counseled the patient and answered all her questions.[77]

78. Informing medication abortion patients that they should take both mifepristone and misoprostol—as providers must do under REMS—conflicts with the "reversal" message that the Act compels physicians to tell their patients.

79. Finally, I am concerned that the Act's state-mandated advisory might distort the patient's decision-making and create a risk that she would begin the abortion procedure before she was fully prepared to do so. During the informed consent discussion with my abortion patients, I stress that they should not begin the procedure until they are resolved to terminate their pregnancy.

80. If a patient shows signs of ambivalence, I advise her to reflect further, and offer her professional resources if necessary. I do this for medication abortion patients as well as procedural abortion patients because no patient should undergo a procedure or take a medication she is unsure is indicated or appropriate. In addition, with medication abortion, patients need to be emotionally prepared for the real possibility that the mifepristone *will* terminate their pregnancy (as it does in a majority of pregnancies). Taking mifepristone is the start of the abortion process.

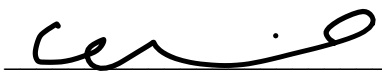
81. I believe, therefore, that introducing the misleading prospect that abortion "reversal" is possible when the patient is in the process of making their abortion decision

[77] *Patient Agreement Form,* FDA (Apr. 2019) (emphasis added), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2019_04_11_Patient_Agreement_Form.pdf.

undermines the physician's efforts to ensure that the patient does not begin pregnancy termination treatment unless they are certain about their decision to end the pregnancy. This is contrary to the most fundamental tenets of medicine.

82. For all of these reasons, the disclosures required by the Act about mifepristone "reversal" compel physicians to distort and damage the relationship of trust that they seek to build with their patients, and forces them to provide information to their patients that they do not agree with and that they rightfully think is false, misleading, irrelevant, and/or harmful to women seeking abortions. It violates the tenets of ethical and evidence-based medical care. Rather than promoting physician autonomy in the provision of healthcare and the health of women and families, it damages the physician-patient relationship, undercuts the physician's professional integrity, and harms women.

I declare under penalty of perjury that the foregoing is true and correct.
Dated this 31 day of August, 2020.



Courtney A. Schreiber, M.D., M.P.H.

EXHIBIT A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 07/26/2020

Courtney Anne Schreiber, MD, MPH

Address: Department of Obstetrics and Gynecology
3400 Spruce Street, 1000 Courtyard
Philadelphia, PA 19104 United States

If you are not a U.S. citizen or holder of a permanent visa, please indicate the type of visa you have:
none (U.S. citizen)

Education:

1993	B.A.	Columbia College, Columbia University, New York NY (Religion)
1995	OTH	University of Pennsylvania, Philadelphia, PA (Postbaccalaurate Premedical Program)
1999	M.D.	New York University School of Medicine, New York, NY
2005	M.P.H.	University of Pittsburgh, Graduate School of Public Health, Epidemiology Track, Pittsburgh, PA (Public Health)

Postgraduate Training and Fellowship Appointments:

1999-2003	Resident, Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Philadelphia, PA
2003-2005	Fellow, Contraceptive Research and Family Planning, University of Pittsburgh, Dept of Obstetrics, Gynecology and Reproductive Sciences, Pittsburgh, PA

Military Service:
[none]

Faculty Appointments:

2006-2014	Assistant Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2014-2020	Associate Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2020-present	Stuart and Emily Mudd Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

2005-Present	Attending in Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Department of Obstetrics and Gynecology, Philadelphia, PA

2008-2017	Founder and Director, Penn Family Planning and Pregnancy Loss Center
2009-present	Program Director, Fellowship in Family Planning, Hospital of the University of Pennsylvania
2017-present	Director, PEACE
2017-present	Division Chief, Family Planning, Department of Obstetrics and Gynecology, Penn Medicine

Other Appointments:

2018-present	Research Director, Building Interdisciplinary Research Careers in Women's Health K-12 Program, Perelman School of Medicine, University of Pennsylvania
2018-present	Senior Fellow, Leonard Davis Institute of Health Economics

Specialty Certification:

2007	American Board of Obstetrics and Gynecology

Licensure:

2003-Present	Pennsylvania Medical Licensure

Awards, Honors and Membership in Honorary Societies:

1996	Reproductive Health Fellowship, Medical Students for Choice, San Francisco, CA
1998	National Abortion Federation Early Achievement Award
1999	James E Constantine Award in Obstetrics and Gynecology, NYU School of Medicine
1999	Dr. Martin Gold Visionary Provider Award, Diana Foundation, NY, NY
2001	Resident Teaching Award, Hospital of the University of Pennsylvania
2004	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Donald F. Richardson Memorial Prize Paper Award Nominee, American College of Obstetricians and Gynecologists
2005	Philip F. Williams Prize Award, American College of OB/GYN
2005	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2010	Women's Way Unsung Heroine Award: Turning Talk into Action
2011	Emily B. Hartshorne Mudd Award for Contributions to the Field of Family Health
2011	The Penn Medicine "Penn Pearls" Award for Excellence in Teaching
2015	Penn Center for Innovation Accelerator Award Phase I
2016	Penn Center for Innovation Accelerator Award Phase II

2019	Clinical Research Forum Top 10 Clinical Research Achievement Award

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2017-present	Fellowship in Family Planning (Advisory Board (Chair, 2017-2019))

National:

1995-1999	Medical Students for Choice (Board of Directors)
1997-2002	American Medical Women's Association
1997-present	Physicians for Reproductive Choice and Health (Board of Directors 1997-1999)
1999-Present	American College of Obstetricians and Gynecologists (Physician Member, Committee on Health Care for Underserved Women (2012-13) Fellow (2002-present) Junior Fellow (1999-2008))
2001-2006	American Society for Reproductive Medicine
2003-2018	Association of Reproductive Health Professionals
2003-present	National Abortion Federation
2004-2012	American Public Health Association
2008-Present	Peer Health Exchange (Curriculum Advisory Board)
2012-present	Center for Disease Control Teen Pregnancy Prevention Project, Family Planning Council of Pennsylvania (Consultant)
2014	NIH (Study Section Reviewer: Female Contraceptive Development Program (U01))
2019-Present	American Board of Obstetrics and Gynecology, Complex Family Planning Committee (Inaugural Chair 2019)
2019-Present	The Accreditation Council for Graduate Medical Education, Complex Family Planning Task Force

Local:

2008-2016	Family Planning Council (Board Member of the Medical Committee)
2008-2016	Women's Medical Fund Medical Advisory Committee
2010-2016	American Civil Liberties Union of Pennsylvania, Clara Bell Duvall Reproductive

Freedom Project (Advisory Council Member)

2011-2017 Women's Way (Board Member. Vice Chair of the Board 2014-2016)

Editorial Positions:

2005-Present	Reviewer, Contraception
2007-Present	Reviewer, American Journal Obstetrics and Gynecology
2008-2010	Reviewer, Pharmacoepidemiology
2011-Present	Associate Editor, Contraception
2017-present	Section Editor, Contraception, UpToDate
2018-present	Section Editor, Ectopic Pregnancy, UpToDate
2018-present	Deputy Editor, Contraception

Academic and Institutional Committees:

2002-2003	House Officer Committee, Hospital of the University of Pennsylvania
2005-2010	Resident Curriculum Development Committee
2009-Present	Operating Room Committee
2010-2012	Grant Reviewer Penn CFAR Pilot Grants Program
2011-2014	Chair, Management of Early Pregnancy Failure Working Group
2012-2018	Center for AIDS Research Committee on Women and HIV
2013-2018	Core Member, Women's Health Scholar Certificate
2014-2015	Member, Department of Obstetrics and Gynecology Executive Committee
2014-present	Medical School Admissions Interview Committee, Perelman School of Medicine of the University of Pennsylvania.
2018-Present	Member, Review Committee for the Department of Biostatistics, Epidemiology, and Informatics
2018-present	Department of Obstetrics and Gynecology Executive Committee

Major Academic and Clinical Teaching Responsibilities:

2002-2003	Organizer, Ob/Gyn resident journal club, Hospital of the University of Pennsylvania
2002-Present	Lecturer, Ob/Gyn resident didactics and journal club
2005-2015	Lecture on Family Planning, Core Clinical Clerkship in Ob/Gyn (OG200), (8x/yr)
2005-2016	Faculty preceptor, Core Clinical Clerkship in Ob/Gyn (OG200), (1-2x/yr)
2006-2017	Lecturer "Contraception", Reproduction module (1 lecture/yr)
2006-2016	"Bridging the Gaps" Academic Mentor for one student each summer
2006-2017	Director, Family Planning Rotation for Ob/Gyn residents
2006-2017	Course Director, Family Planning and Abortion Care Elective (OG300), medical students
2006-2017	Small group discussion leader on abortion and contraception, Reproduction Module II (2 sessions/yr), medical students

2006-Present	Attending Physician, Family Planning, supervise and teach medical students, residents, and fellows
2006-2016	Attending physician, Resident Gynecology service (4 weeks/yr)
2006-Present	Research mentor for resident research projects
2006-2017	Lecture "Abortion," Reproduction Module II (1 lecture/yr), medical students
2006-2007	Mentor, Sabrina Sukhan, MD, Resident in Obstetrics and Gynecology "Is exposure to prenatal care associated with improved pregnancy outcomes and post-partum contraception continuation in a teenage population?"
2006	Hospital of The University of Pennsylvania Department of Obstetrics and Gynecology Grand Rounds: "The Characterization and Treatment of Early Pregnancy Failure"
2007	Division of Cardiology, University of Pennsylvania Medical Center, "Contraception in Women with Congenital Heart Disease",
2008-2010	Mentor, Monika Goyal, MD, Pediatric Emergency Fellow "Prevalence of Trichomonas vaginitis in a symptomatic adolescent ED population
2009-Present	Director, Family Planning Fellowship Program
2010-2012	Fellowship Mentor: Sara Pentlicky, MD
2010-2013	Mentor, Holly Langmuir, MD, Resident in Obstetrics and Gynecology "Immediate postpartum IUD placement: a decision analysis"
2010-2013	Mentor, Peter Vasquez, MD, Resident in Obstetrics and Gynecology "Factors that decrease morbidity among women undergoing second trimester uterine evacuation at an urban academic medical center"
2010-2013	Mentor, Ericka Gibson, MD, Resident in Obstetrics and Gynecology "Risk Factors for pregnancy during contraceptive clinical trials"
2010-2012	Mentor, Sara Pentlicky, MD, Fellow in Family Planning "Weight Loss in the postpartum: impact of different contraceptive methods"
2010-2013	Mentor, Corina Tennant, MD, Resident in Obstetrics and Gynecology "Uptake, acceptability, and continuation of the Implanon contraceptive implant immediately postpartum in an urban medical center"
2011-2013	Mentor, Lily Pemberton, MD, Resident in Obstetrics and Gynecology "establishment of an academic family planning outpatient facility increases uptake of LARC among inner-city women"
2011-2017	Public Health Perspectives in Family Planning Instructor and course co-director (offered through the MPH program)
2011-2012	Doris Duke Clinical Research Fellowship Mentor (Mentee - Kelly Quinley - Awarded Society of Academic Emergency Medicine Medical Student Excellence Award)
2011-2013	Fellowship Mentor: Stephanie Sober, MD
2011	Mentor, Valerie Colleselli, medical student, University of Innsbruck,

	Austria "Medical management of early pregnancy failure (EPF): a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice"
2012-2014	Fellowship Mentor, Susan Wilson, M.D.
2012-2015	Mentor, Andrea Roe, MD, Resident in Obstetrics and Gynecology "Cystic Fibrosis and Fertility"
2012-2015	Mentor, Joni Price, MD, Resident in Obstetrics and Gynecology "Risk of unplanned pregnancy by cycle day among contracepting women"
2012-2016	Clinician Trainings for the Family Planning Council's CDC Teen Pregnancy Prevention Project
2014-2015	Mentor, Pooja Mehta, MD, ACOG Industry-Funded Research Fellowship in Contraceptive Access within Low-Resource Populations
2014-2016	Mentor, Elizabeth Gurney, MD, Fellow in Family Planning "Six-month Retention Rates of Copper IUDs Placed Immediately Post-placentally"
2014-2016	Mentor, Alyssa Colwill, MD, Resident in Obstetrics and Gynecology "Immediate Post-placental IUD Expulsion - a Retrospective Cohort Study"
2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology, Pennsylvania Hospital, Philadelphia PA
2015-2017	Mentor, Elizabeth Greenstein, MD, Resident in Obstetrics and Gynecology "Doctor-Patient Communication at the Time of Miscarriage Management"
2015-2018	Mentor, Maryl Sackheim, MD, Resident in Obstetrics and Gynecology: "Rapid Repeat Pregnancy at Penn Medicine: Prevalence and Risk Factors"
2015-2017	Mentor, Alhambra Frarey, MD, Fellow in Family Planning "Referral and Delay in Abortion Care: a Cross-sectional Study"
2015	"Contraception for women with rheumatologic disease," Division of Rheumatology of Penn Medicine, Philadelphia Pa.
2016-2018	Mentor, Sarah Horvath, MD, Fellow in Family Planning "Quantifying Feto-Maternal Hemorrhage in the First Trimester of Pregnancy"
	Winner, Society of Family Planning Young Investigator Award, 2018
2016	"History of Contraception in the US," Master of Public Health Program, University of Pennsylvania, Philadelphia PA
2016	"Academic Medicine as an Instrument of Change," Master of Science of Health Policy, University of Pennsylvania, Philadelphia PA
2017	"The role of public health practice and research in reproductive health" Master of Public Health Program, University of

	Pennsylvania Perelman School of Medicine. Philadelphia, PA
2017-2019	Mentor, Divyah Nagendra, MD, Fellow in Family Planning "Pain Control for Uterine Evacuation: a Non-Inferiority Trial"
2017	"Academic Medicine as an Instrument of Change," University of Pennsylvania MSHP Program
2018	Pediatric Grand Rounds: Children's Hospital of Philadelphia, "Progress and Opportunities in Adolescent Reproductive Health"
2018-2020	Mentor, Jade Shorter, MD, Fellow in Family Planning "Disparities in Reproductive Health: The Patient Experience with Miscarriage Management"

Lectures by Invitation (Last 5 years):

Apr, 2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Jefferson Hospital, Philadelphia PA
Jul, 2015	"Immediate Postpartum Long Acting Reversible Contraception." Philadelphia Board of Health, Department of Health
Mar, 2016	"Increasing Access to Long-Acting Reversible Contraception for Philadelphia Women." Public Health and Preventive Medicine Section at the College of Physicians of Philadelphia, PA
Apr, 2016	Liletta: Challenges and Advantages of a New LNG IUD. Moderated a webinar for the Fellowship in Family Planning and Ryan Program Nationally
Apr, 2016	"Immediate Postpartum LARC: Evidence and Implementation." Department of Obstetrics & Gynecology Grand Rounds. WellSpan / York Hospital, York PA
Oct, 2016	"Unpacking Complex Contraception," University of British Columbia Interdisciplinary Grand Rounds, Vancouver, BC
Dec, 2016	"LARC for the medically complex patient," ACOG LARC Program, CME accredited webinar
Oct, 2017	"Climbing the career ladder and lifting others as you climb." Society for Family Planning Career Development Seminar, Atlanta, GA.
Nov, 2017	"Pregnancy of Unknown Location" Early Pregnancy Symposium. Philadelphia, PA
Nov, 2017	"Personalized Approaches to Early Pregnancy Loss Care" Early Pregnancy Symposium. Philadelphia, PA
Jan, 2018	"Patient-Centered Early Pregnancy Loss Care," UC San Diego Obstetrics and Gynecology Grand Rounds, San Diego, CA
Apr, 2018	"Hormonal Contraception and the Risk of Mood Symptoms," North American Society for Psychosocial Obstetrics and Gynecology, Philadelphia, PA.
Oct, 2018	"Advances in the Care of Patients with Early Pregnancy Loss," Magee-Women's Hospital Alumni Day, Pittsburgh, PA
Nov, 2018	"Healthy Child-Spacing, Healthy Families: Best Practices in Postpartum Contraception" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of

	ACOG, Santiago, Chile
Nov, 2018	"Miscarriage Management: Updates and Innovations" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of ACOG, Santiago, Chile
Nov, 2018	"Advances is Early Pregnancy Loss Care" Einstein Healthcare Network, Obstetrics and Gynecology Departmental Grand Rounds
Jan, 2019	"Advances in the Care of Patients with Early Pregnancy Loss," Obstetrics and Gynecology Grand Rounds, MedStar Washington Hospital Center and MedStar Georgetown University Hospital, Washington, D.C.
Mar, 2019	"Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss" Ob/Gyn Grand rounds, Beth Israel Deaconess Medical Center, Boston MA
Mar, 2019	"The Medical Management of Early Pregnancy Loss," Translational Science 2019 Conference, Washington, DC
Jul, 2019	"Abortion in the United States," Department of Obstetrics and Gynecology University of Helsinki, Helsinki, Finland.
Jul, 2019	"Biomarkers of Human Reproduction," Department of Obstetrics and Gynecology, Karolinska Institute, Stockholm, Sweden.
Jan, 2020	"Advances in the Care of Patients with Early Pregnancy Loss," Columbia University Medical Center Obstetrics and Gynecology Grand Rounds, New York, NY.

Organizing Roles in Scientific Meetings:

Apr, 2010	Chair, National Abortion Federation 2010 Postgraduate course: "Team Work and Patient Safety" Philadelphia, PA
2011	Co-Chair HIV and Women subgroup of the Penn Center For Aids Research Philadelphia, PA
Apr, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Chicago, IL
May, 2013	Co-Chair, Penn CFAR Women and HIV Symposium: "Biobehavioral approaches to HIV prevention and management in adolescent women" Perelman School of Medicine, Philadelphia PA
May, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Denver, CO
May, 2014	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting New Orleans, LA
Apr, 2015	Moderator, second year family planning fellows' research presentations on contraception San Francisco, California

Apr, 2017	Organizer and Panel Moderator, "Moving Forward: Protecting and Promoting Reproductive Health" University of Pennsylvania
May, 2019	Chairperson, Directors' Meeting, Fellowship in Family Planning Boston, Mass

Bibliography:

Research Publications, peer reviewed (print or other media):

1. Schreiber CA, Wan L, Sun Y, Krey L, Lee-Huang S: The antiviral agents MAP30 and GAP31 are not toxic to human spermatozoa and may be useful in preventing the sexual transmission of HIV-I. Fertil Steril 72:686-690, 1999.

2. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: Same day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation methods. Contraception 72(5):333-36, 2005.

3. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation. Contraception 71(5):333-336, 2005.

4. Schreiber CA, Creinin MD, Harwood BJ, Murthy AS: A pilot study of mifepristone and misoprostol administered at the same time for abortion from 50-63 days gestation. Contraception 71(6):447-50, 2005.

5. Schreiber CA, Creinin MD, Reeves MF, Harwood BJ: Mifepristone and misoprostol for the treatment of early pregnancy failure: a pilot clinical trial. Contraception 74:458-462, 2006.

6. Schreiber CA, Harwood BJ, Switzer GE, Creinin MD, Reeves MF, Ness RB: Training and attitudes about contraceptive management across primary care specialties: a survey of graduating residents. Contraception 73:618-622, 2006.

7. Schreiber CA, Meyn, L, Creinin MD, Barnhart KT, Hillier SL: The effects of long-term use of nonoxynol-9 on vaginal flora. Obstet Gynecol 107:1-9, 2006.

8. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA: Medical abortion at the same time (MAST) study trial group. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. Obstet Gynecol 109(4):885-894, 2007.

9. Schreiber CA, Sammel M, Barnhart KT, Hillier SL: A little bit pregnant: Modeling how the accurate detection of pregnancy can improve HIV prevention trials. Am J Epidemiol 169(4):515-521, 2009.

10. Schreiber CA, Ratcliffe SJ, Barnhart KT: A randomized controlled trial of the effect of advanced supply of emergency contraception in postpartum teens: a feasibility

study. Contraception 81(5):435-40, 2010.

11. Schreiber CA, Sober S, Ratcliffe S, Creinin MD: Ovulation resumption after medical abortion with mifepristone and misoprostol. Contraception 84(3):230-3, 2011.

12. Schreiber CA, Whittington S, Cen L, Maslankowski, L: Good Intentions: Risk factors for unintended pregnancies in the U.S. cohort of a microbicide trial. Contraception 83(1):74-81, 2011.

13. Su IH, Schreiber CA, Fay C, Parry S, Elovitz MA, Zhang J, Shaunik A, Barnhart K: Mucosal integrity and inflammatory markers in the female lower genital tract as potential screening tools for vaginal microbicides. Contraception 84(5):525-32, 2011.

14. Chen SP, Massaro-Giordano G, Pistilli M, Schreiber CA, Bunya V: Tear osmolarity and dry eye symptoms in women using oral contraception and contact lenses. Cornea 32(4):423-8, 2013.

15. Kinariwala M, Quinley K, Datner E, Schreiber CA: Manual vacuum aspiration in the emergency department for management of early pregnancy failure. Am J Emerg Med 31(1):244-7, 2013.

16. Pentlicky S, Rosen M, Coffey P, Kilbourne-Brook M, Shaunik A, Schreiber CA, Barnhart K: An exploratory, randomized, crossover MRI study of microbicide delivery with the SILCS diaphragm compared to a vaginal applicator. Contraception 87(2):187-92, 2013.

17. Swica Y, Chong E, Middleton T, Prine L, Gold M, Schreiber CA, Winikoff B: Acceptability of home use of mifepristone for medical abortion. Contraception 88(1):122-7, 2013.

18. Colleselli V, Schreiber CA, D'Costa E, Mangesius S, Ludwig W, Seeber BE: Medical management of early pregnancy failure (EPF):a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice. Arch Gynecol Obstet 289(6): 1341-45, Jun 2014.

19. Foster DG, Grossman D. Turok DK, Peipert JF, Prine L, Schreiber CA, Jackson A, Barar R, Schwarz EB: Interest in and experience with IUD self-removal. Contraception 90(1): 54-59, Jul 2014.

20. Wilson S, Tennant C, Sammel MD, Schreiber C: Immediate postpartum etonogestrel implant: a contraception option with long-term continuation. Contraception 90(3): 259-64, Sep 2014.

21. Quinley K, Ratcliffe S, Schreiber C: Psychological coping in the immediate post-abortion period. J Women's Health 23(1):44-50, 2014.

22. Schreiber CA, Traxler S: State of family planning. Clin Obstet Gynecol 58(2): 392-408, Jun 2015

23. Eisenberg DL, Schreiber CA, Turok DK, Teal SB, Westhoff CL, Creinin MD: Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. Contraception 92(1): 10-16, Jul 2015.

24. Quinley KE, Falk A, Kallan MJ, Datner EM, Carr BG, Schreiber CA: Validation of ICD-9 Codes for Stable Miscarriage in the Emergency Department. West J Emerg Med 16(4): 551-6, Jul 2015.

25. Schreiber CA, Ratcliffe SJ, Quinley KE, Miller C, Sammel MD: Serum biomarkers to predict successful misoprostol management of early pregnancy failure. Reprod Biol 15(2): 79-85, 2015.

26. Schreiber CA, Ratcliffe SJ, Sammel MD, Whittaker PG.: A self-assessment efficacy tool for spermicide contraceptive users. Am J Obstet Gynecol 214(2): 264.e1-7, Feb 2016.

27. Sober S, Shea J, Shaber A, Whittaker P, Schreiber C: Postpartum Adolescents' Contraceptive Counselling Preferences. Eur J Contracept Reprod Health Care 22(2): 83-87, April 2016.

28. Wilson SF, Degaiffier N, Ratcliffe SJ, Schreiber CA: Peer counselling for the promotion of long-acting, reversible contraception among teens: a randomised, controlled trial. Eur J Contracept Reprod Health Care 21(5): 380-7, Oct 2016.

29. Roe AH, Traxler SA, Hadjiliadis D, Sammel MD, Schreiber CA: Contraceptive choices and preferences in a cohort of women with cystic fibrosis. Respir Med 121: 1-3, Dec 2016.

30. Schreiber CA, Chavez V, Whittaker PG, Ratcliffe SJ, Easley E, Barg FK: Treatment Decisions at the Time of Miscarriage Diagnosis. Obstet Gynecol 128(6): 1347-1356, Dec 2016.

31. Frisse AC, Marrazzo JM, Tutlam NT, Schreiber CA, Teal SB, Turok DK, Peipert JF: Validity of Self-Reported History of Chlamydia trachomatis Infection. Am J Obstet Gynecol 216(4): e1-393, April 2017.

32. Akers AY, Steinway C, Sonalkar S, Perriera LK, Schreiber C, Harding J, Garcia-Espana JF: Reducing Pain During Intrauterine Device Insertion: A Randomized Controlled Trial in Adolescents and Young Women. Obstet Gynecol 130(4): 795-802, Oct 2017.

33. Sonalkar S, Gurney EP, McAllister A, Schreiber CA: A randomized pilot evaluation

of individual-level abortion stigma resulting from Pennsylvania mandated abortion counseling. Contraception 96(4): 227-232, Oct 2017.

34. Colwill AC, Schreiber CA, Sammel MD, Sonalkar S: Six-week retention after postplacental copper intrauterine device placement. Contraception 97(3): 215-218, Mar 2018.

35. Schreiber CA, Teal SB, Blumenthal PD, Keder LM, Olariu AI, Creinin MD: Bleeding patterns for the Liletta levonorgestrel 52 mg intrauterine system. Eur J Contracept Reprod Health Care 23(2): 116-120, Apr 2018.

36. Akers AY, Harding J, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S: Satisfaction with the Intrauterine Device Insertion Procedure Among Adolescent and Young Adult Women. Obstet Gynecol 131(6): 1130-1136, Jun 2018.

37. Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT: Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 378(23): 2161-70, Jun 2018 Notes: selected as a CME activity for the New England Journal of Medicine.

38. Gurney EP, Sonalkar S, Mcallister A, Sammel MD, Schreiber CA: Six-month expulsion of postplacental copper intrauterine devices placed after vaginal delivery. Am J Obstet Gynecol 219(2): 183.e1-183.e9, Aug 2018.

39. Whittaker PG, Schreiber CA, Sammel MD: Gestational hormone trajectories and early pregnancy failure: a reassessment. Reprod Biol Endocrinol 16(1): 95, Oct 2018.

40. Sonalkar S, Hunter T, Gurney EP, McAllister A, Schreiber CA: A Decision Analysis Model of 1-Year Effectiveness of Intended Postplacental Compared with Intended Delayed Postpartum Intrauterine Device Insertion. Obstet Gynecol 132(5):1211-122, Nov 2018.

41. Clement EG, Horvath S, McAllister A, Koelper NC, Sammel MD, Schreiber CA: The Language of First-Trimester Nonviable Pregnancy: Patient-Reported Preferences and Clarity. Obstet Gynecol 133(1):149-154, Jan 2019.

42. Frarey A, Gurney EP, Sober S, Whittaker PG, Schreiber CA: Postpartum contraceptive counseling for first-time adolescent mothers: a randomized controlled trial. Arch Gynecol Obstet 299(2):361-369, Feb 2019.

43. Frarey A, Schreiber C, McAllister A, Shaber A, Sonalkar S, Sammel MD, Long jA: Pathways to Abortion at a Tertiary Care Hospital: Examining Obesity and Delays. Perspect Sex Reprod Health 51(1):35-41, Mar 2019.

44. Sackeim MG, Gurney EP, Koelper N, Sammel MD, Schreiber CA: Effect of

contraceptive choice on rapid repeat pregnancy. Contraception 99(3):184-186, Mar 2019.

45. Chen BA, Blithe DL, Muraguri GR, Lance AA, Carr BR, Jensen JT, Kimble TD, Murthy AS, Schreiber CA, Thomas MA, Walsh TL, Westhoff C, Burke AE: Acceptability of the Woman's Condom in a phase III multicenter open-label study. Contraception 99(6): 357-362, Jun 2019.

46. O'Flynn O'Brien KL, Akers AY, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S: Intrauterine Device Insertion Procedure Duration in Adolescent and Young Adult Women. J Pediatr Adolesc Gynecol 32(3):312-315, Jun 2019.

47. Deshpande NA, Labora A, Sammel MD, Schreiber CA, Sonalkar S: Relationship between body mass index and operative time in women receiving immediate postpartum tubal ligation. Contraception 100(2): 106-110, Aug 2019.

48. Traxler SA, Chavez V, Hadjiliadis D, Shea JA, Mollen C, Schreiber CA: Fertility considerations and attitudes about family planning among women with cystic fibrosis. Contraception 100(3):228-233, Sep 2019.

49. Miller CA, Roe AH, McAllister A, Meisel ZF, Koelper N, Schreiber CA: Patient Experiences with Miscarriage Management in the Emergency and Ambulatory Settings. Obstet Gynecol 134(6):1285-1292, Dec 2019.

50. Nagendra D, Koelper, N, Loza-Avalos SE, Sonalkar S, Chen M, Atrio J, Schreiber CA*, Harvie HS* (co-senior authors): Cost-effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy. Secondary Analysis of a Randomized Clinical Trial. JAMA Network Open 3(3):e20159, Mar 2020.

51. Chen BA, Eisenberg DL, Schreiber CA, Turok DK, Olariu AI, Creinin MD: Bleeding changes after levonorgestrel 52mg intrauterine system insertion for contraception in women with self-reported heavy menstrual bleeding. Am J Obstet Gynecol 222(4S):S888.e1-S888.e6, Apr 2020.

52. Turok DK, Nelson AL, Dart C, Schreiber CA, Peters K, Schreifels MJ, Katz B: Efficacy, Safety, and Tolerability of a New Low-Dose Copper and Nitinol Intrauterine Device: Phase 2 Data to 36 Months. Obstet Gynecol 135(4):840-847, Apr 2020.

53. Anand P, McAllister A, Hunter T, Schreiber C, Koelper N, Sonalkar S: A Simulated Patient Study to Assess Referrals to Abortion Care by Student Health Centers in Pennsylvania. Contraception In press, Feb 2020.

54. Albright BB, Shorter JM, Mastroyannis SA, Ko EM, Schreiber CA, Sonalkar S: Gestational Trophoblastic Neoplasia After Human Chorionic Gonadotropin

Normalization Following Molar Pregnancy: A Systematic Review and Meta-analysis. Obstet Gynecol [Epub ahead of print] Dec 2019.

55. Roe AH, McAllister A, Sammel MD, Schreiber CA: Pregnancy intentions and contraceptive uptake after miscarriage. Contraception [Epub ahead of print] Mar 2020.

56. Sonalkar S, Koelper N, Creinin MD, Atrio JM, Sammel MD, McAllister A, Schreiber CA: Management of early pregnancy loss with mifepristone and misoprostol: clinical predictors of success from a randomized trial. Am J Obstet Gynecol [Epub ahead of print], Apr 2020.

57. Horvath S, Tsao P, Huang ZY, Zhao L, Du Y, Sammel MD, Luning Prak ET, Schreiber CA: The concentration of fetal red blood cells in first-trimester pregnant women undergoing uterine aspiration is below the calculated threshold for Rh sensitization. Contraception [Epub ahead of print], Mar 2020.

58. Hunter TA, Sonalkar S, Schreiber CA, Perriera LK, Sammel MD, Akers AY: Anticipated Pain During Intrauterine Device Insertion. J Pediatr Adolesc Gyneco [Epub ahead of print], Sep 2019.

Research Publications, peer-reviewed reviews:

1. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (Suppl):19-24, 2005.

2. Schreiber CA, Creinin MD: Mifepristone in abortion care. Semin Reprod Med 23(1):82-91, 2005.

3. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (RA suppl):10-12, 2006.

4. Barnhart KT, Schreiber CA: Return to fertility following discontinuation of oral contraceptives. Fertil Steril 91(3):659-63, 2009.

5. Schreiber CA, Barnhart KT: Contraceptive Concerns: Return to Fertility. The Female Patient 34(12), 2009.

6. Gibson E, Schreiber CA: Controversies in Family Planning: When uterine leiomyomas complicate uterine evacuation. Contraception 82(6):486-8, 2010.

7. Vasquez P, Schreiber CA: Controversies in Family Planning: The missing IUD. Contraception 82(2):126-8, 2010.

8. Perron-Burdick M, Schreiber C, Gupta P: Ophthalmic migraines and combined hormonal contraceptives. Contraception 84(5):442-4, 2011.

9. Quinn SM, Schreiber C: Controversies in Family Planning: IUD use in HIV-positive women. Contraception 83(2):99-101, 2011.

10. Sober SP, Schreiber CA: Controversies in family planning: are all oral contraceptive formulations created equal? Contraception 83(5):394-6, 2011.

11. Lathrop E, Schreiber C: Controversies in family planning: management of second-trimester pregnancy terminations complicated by placenta accreta. Contraception 85(1):5-8, 2012.

12. Pentlicky S, Harken T, Schreiber CA: Controversies in family planning: first trimester uterine evacuation for the anticoagulated patient. Contraception 85(5):434-36, 2012.

13. Owen C, Sober S, Schreiber CA: Controversies in family planning: desired pregnancy, IUD in situ and no strings visible. Contraception 88(3):330-3, 2013.

14. Patel PR, Schreiber CA: Controversies in family planning: contraceptive counseling in the solid organ transplant recipient. Contraception 138-142, 2013.

15. Wilson S, Tan G, Baylson M, Schreiber CA: Controversies in family planning: how to manage a fractured IUD. Contraception 599-603, 2013.

16. Sober S, Schreiber CA: Postpartum contraception. Clin Obstet Gynecol 57(4): 763-76, Dec 2014.

17. Dzuba IG, Grossman D, Schreiber CA: Off-label indications for mifepristone in gynecology and obstetrics. Contraception 92(3): 203-5, Sep 2015.

18. Roe A, Traxler SA, Schreiber CA: Contraception in Women with Cystic Fibrosis: A Systematic Review of the Literature. Contraception 93(1): 3-10, Jan 2016.

19. Horvath S, Schreiber CA: Unintended Pregnancy, Induced Abortion, and Mental Health. Curr Psychiatry Rep 19(11): 77, Sep 2017.

20. Shorter Jm, Atrio JM, Schreiber CA: Management of early pregnancy loss, with a focus on patient-centered care. Seminars in Perinatology Dec 2018.

Contributions to peer-reviewed research publications, participation cited but not by authorship:

[none]

Research Publications, non-peer reviewed:

[none]

Abstracts (Last 3 years):

1. Gurney E, Sonalkar S, McAllister A, McClusky J, Frarey A, Schreiber C: Expulsion of Immediate Postplacental Copper IUDs at Six Weeks: A Prospective Cohort Study. Poster presentation, ACOG Annual Clinical and Scientific Meeting, San Diego, CA. _ May 2017.

2. Sonalkar S, Gurney EP, McAllister A, Schreiber CA: Abortion Stigma Resulting from State Mandated Abortion Consent Language: A Randomized Controlled Trial. ACOG Annual Clinical and Scientific Meeting; San Diego, CA. _ May 2017.

3. Chen BA, Kimble TD, Ginde SY, Jensen JT, Schreiber CA, Creinin MD: Bleeding patterns do not differ between obese and non-obese women using a levonorgestrel 52-mg intrauterine system. Poster Presentation, North American Forum on Family Planning, Atlanta, GA. _ Oct 2017.

4. Clement EG, Horvath SK, Koelper N, Sammel MD, Schreiber CA: The language of pregnancy demise: patient-reported clarity and preferences. North American Forum on Family Planning, Atlanta, GA. _ Oct 2017.

5. Hunter T, Gurney EP, Schreiber C, McAllister A, Sonalkar S: Probability of Pregnancy after Intended Postplacental versus Interval Intrauterine Device Placement. ACOG Annual Clinical and Scientific Meeting; Austin, TX. _ Apr 2018.

6. Eisenberg D, Schreiber C, Carr B, Turok D, Chen B, Creinin M: Change in Bleeding Patterns After Liletta Insertion for Women with Subjective Baseline Heavy Menstrual Bleeding. Poster Presentation, Forum on Family Planning, New Orleans, LA. _ Oct 2018 Notes: Winner, Translational Poster Award.

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EXHIBIT B

Progesterone Use to Reverse the Effects of Mifepristone

George Delgado and Mary L Davenport

OBJECTIVE: To present a series of cases demonstrating successful reversal of mifepristone effects in women who chose to reverse the medical abortion process.

CASE REPORTS: Four of 6 women who took mifepristone were able to carry their pregnancies to term after receiving intramuscular progesterone 200 mg.

DISCUSSION: Mifepristone has been available in the US since 2000. By 2008, approximately 25% of abortions prior to 9 weeks were accomplished with mifepristone. Some women who take mifepristone wish to reverse the medical abortion process. Progesterone competes with mifepristone for the progesterone receptor and may reverse the effects of mifepristone. A PubMed literature search from 1996 to May 2012 did not reveal any trials or case studies evaluating the efficacy of progesterone use to reverse the effects of mifepristone.

CONCLUSIONS: Health care professionals should be aware of the possible use of progesterone to reverse mifepristone in women who have begun the medical abortion process by taking mifepristone and then change their minds.

KEY WORDS: medical abortion, mifepristone, progesterone.

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Mifepristone has been available in the US as an oral tablet since 2000. It is indicated by the Food and Drug Administration (FDA) for termination of pregnancy up to 49 days after the first day of the last menstrual period. Mifepristone is followed 2 days later by misoprostol to complete the abortion.[1]

The drug's development was hailed as a breakthrough in abortion technology and as an advance for women in facilitating control of their bodies and privacy. By 2008, medical abortion replaced surgical abortion in one-fourth of approximately 800,000 abortions performed annually prior to 9 weeks.[2]

We present a series of patients who took mifepristone to terminate their pregnancies and then sought assistance to block the mifepristone effects. The 2-day gap between the ingestion of mifepristone and misoprostol in the typical abortion regimen potentially affords an opportunity to intervene and reverse the effects of the mifepristone. Six physicians in the US trained in NaProTECHNOLOGY protocols at the Pope Paul VI Institute have given progesterone as an antidote to mifepristone, treating 7 patients. The rationale of the proposed treatment was that higher bioavailable levels of progesterone could competitively inhibit the mifepristone to prevent the induced abortion.

Pharmacology of Mifepristone and Progesterone

Mifepristone was first tested to take advantage of its anti-glucocorticoid properties. It binds with high affinity to glucocorticoid receptors, about 4 times as avidly as dexamethasone.[3] When its antiprogesterone properties were discovered it was considered useful for fertility control because of its potential to counteract the actions of progesterone, which is critical for sustaining pregnancy.[4] Additionally, it has been studied for the treatment of endometriosis, uterine fibroids, and Cushing syndrome.[5-7] Mifepristone's most significant application has been in induced abortion because, by binding to the progesterone receptor, placental failure ensues and the developing embryo loses its nutrition and oxygen supply.

Mifepristone is an orally active compound with a nearly 70% absorption rate, but its bioavailability is reduced to approximately 40% because of the first-pass effect.[8] It binds to the progesterone receptor twice as well as progesterone, in addition to binding to the serum transport protein α_1-acid glycoprotein.[9] Demethylation and hydroxylation are catalyzed by CYP3A4; 3 metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepris-

Author information provided at end of text.

tone and its metabolites can be measured up to 72 hours after an ingested dose.[10] The half-life of progesterone is longer, approximately 25-55.13 hours.[11-13]

Current Regimens of Medical Abortion

The original FDA-approved regimen of mifepristone and misoprostol paralleled the European protocol that had been used in the 1990s. It consisted of mifepristone 600 mg followed 2 days later by oral misoprostol 400 µg.[14] Later trials evaluated mifepristone 200 mg.[15-18] The FDA and the drug's distributor recommend the 600-mg dose; however, others state that the 200-mg dose has been used in most of 1 million abortions.[19] The success rate of medical abortion decreases with gestational age. In the FDA clinical trials the rate of incomplete abortion was 5% before 49 days and 7-8% at 50-63 days; the rate of an ongoing living embryo ranged from less than 1% before 49 days to 9% at 57-63 days.[14]

Results of Progesterone Therapy

We report on 6 women who were treated with progesterone in an attempt to reverse pregnancy termination after mifepristone ingestion. Four of these women eventually delivered healthy term newborns. A seventh patient was lost to follow-up. Of the 2 abortions, 1 occurred soon after an intramuscular injection of progesterone was administered (patient 6). Data on this patient are incomplete. The other patient (patient 5) received progesterone micronized 200 mg vaginally 7 hours after ingesting mifepristone and receiving progesterone 200 mg intramuscularly 18 hours after mifepristone. However, a live embryo was not documented at the abortion clinic or in the physician's office for this patient.

Case Reports

CASE 1

A 19-year-old woman, gravida (G) 1 para (P) 0, elected to have the mifepristone effects reversed at gestation age 8 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 30-40 hours following mifepristone ingestion. The progesterone regimen was given 2 consecutive days and then 2 doses every other day, and then twice a week until 9 weeks 5 days.

Progesterone 200 mg in oil intramuscularly was restarted at 11 weeks 2 days and given twice weekly; the dose was then decreased to 100 mg twice a week and stopped at 29 weeks 5 days.

A viable male was delivered at 37 weeks. No untoward effects of progesterone noted and no birth defects were noted. Neonatal complications included neonatal physiologic jaundice and circumcision wound infection.

CASE 2

A 25-year-old woman, G8 P7007, elected to have the mifepristone effects reversed at gestation age 11 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 72 hours following mifepristone ingestion.

Further progesterone treatment included an intramuscular injection of 200 mg in oil for 2 weeks, then progesterone micronized orally for 5 months. No untoward effects of progesterone were noted.

A viable infant was delivered, with no neonatal complications or birth defects noted.

CASE 3

A 19-year-old woman, G3 P1011, elected to have the mifepristone effects reversed at gestation age 7 weeks. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 36-48 hours following mifepristone ingestion.

Further progesterone treatment included an intramuscular injection of 200 mg in oil 2 more times the first week, then weekly for 5-6 weeks, then 200 mg in oil twice weekly for 2 weeks, then micronized progesterone orally for 5 months. No untoward effects of progesterone were noted.

A viable infant was delivered at 39 weeks 3 days, with no neonatal complications or birth defects noted.

CASE 4

A 20-year-old woman, G1 P0, elected to have the mifepristone effects reversed at gestational age 7 weeks 4 days. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil intramuscularly 46 hours following mifepristone ingestion. Further progesterone treatment included an intramuscular injection of 200 mg in oil twice weekly for 19 weeks. No untoward effects of progesterone were noted.

A viable female infant was delivered at 40 weeks 1 day, with no neonatal complications or birth defects noted.

CASE 5

A 21-year-old woman elected to have the mifepristone effects reversed; gestational age was unknown. Misoprostol had not been ingested. The initial progesterone dose was 200 mg in oil (time following mifepristone ingestion unknown). The abortion was completed soon after the progesterone injection.

CASE 6

A 19-year-old woman, G1 P0, elected to have the mifepristone effects reversed at gestational age 7 weeks. Misoprostol had not been ingested. The initial micronized

progesterone oral capsule dose was 200 mg administered intravaginally 7 hours following mifepristone ingestion. Further progesterone treatment included an intramuscular injection of 200 mg 18 hours after ingestion, which was repeated 2 days later. No untoward effects of progesterone were noted.

The abortion was completed 3 days after mifepristone ingestion.

Discussion

The experience of these patients suggests that medical abortion can be arrested by progesterone injection after mifepristone ingestion prior to misoprostol due to the competitive action of progesterone versus mifepristone. Possible confounding factors are the lack of embryocidal and feticidal efficacy of mifepristone with increasing gestational age and the absence of documentation of viable pregnancy before ingestion of mifepristone in some patients. We welcome further clinical trials utilizing this protocol or others, in order to have an evidence basis for the best protocol. We believe that if further trials confirm the success without complications of this or similar protocols, it should become the standard of care for obstetrician-gynecologists, family physicians, and emergency department physicians to attempt mifepristone reversal on patient request.

SUGGESTED PROTOCOL

A rational protocol for treating women who have ingested mifepristone and then wish to continue the pregnancy can be considered. We drew on our experience of successfully treating pregnant women with threatened spontaneous abortion or low serum progesterone levels with intramuscular progesterone using the protocol of Hilgers.[19,20] Progesterone has been studied extensively and appears to be safe during all trimesters of pregnancy.

Table 1. Progesterone Dosing and Ultrasound Time Table[a]

Day	Progesterone 200 mg Intramuscularly	Ultrasound to Confirm Viability
1	X	X
2	X	
3	X	
5	X	
7	X	X
9	X	
11	X	
13	X	X
16[a]	X	

[a]Continue twice per week until the end of the first trimester. At end of the first trimester, the dose should be tapered according to the protocol of Hilgers.[19,20]

Protocol

1. Progesterone 200 mg intramuscularly as soon as possible after ingestion of mifepristone.
2. Transvaginal or transabdominal ultrasound as soon as possible to confirm embryonic or fetal viability (Table 1). If less than 6.5 weeks after last menstrual period, monitor serial human chorionic gonadotropin (HCG) levels. However, HCG levels may not increase at the same rate as those of healthy controls.
3. Repeat progesterone 200 mg intramuscularly daily for 2 more days, then every other day until day 13 after the ingestion of mifepristone.
4. Treat with progesterone 200 mg intramuscularly twice weekly until the end of the first trimester and according to the protocol of Hilgers.[19,20] However, do not decrease the dose until the end of the first trimester.

A primary care physician or emergency medicine physician may not want to continue the protocol once it is initiated. Such physicians may want to be ready to refer the patient to a physician comfortable with progesterone supplementation during pregnancy.

George Delgado MD FAAFP, Voluntary Associate Clinical Professor, Department of Family and Preventive Medicine, School of Medicine, University of California, San Diego

Mary L Davenport MD FACOG, Medical Director, Magnificat Maternal Health Program, Nigeria; Private Practice, Obstetrics and Gynecology, El Sobrante, CA

Correspondence: Dr. Delgado, gdelgadomd@yahoo.com

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Conflict of interest: Authors reported none

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EXHIBIT C

A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone

George Delgado, M.D.,* Steven J. Condly, Ph.D.,** Mary Davenport, M.D., M.S.,*** Thidarat Tinnakornsrisuphap Ph.D.,**** Jonathan Mack, Ph.D., NP, RN***** Veronica Khauv, B.S., and Paul S. Zhou

ABSTRACT:

Background: Some women who take mifepristone, a progesterone receptor antagonist, in order to terminate their pregnancies, change their minds and desire to stop the medical abortion process. There are only two articles in the medical literature documenting the reversal of the effects of mifepristone.

Objective: We present and analyze a series of women who attempted to reverse the effects of mifepristone by taking supplemental progesterone to determine if the reversal of the effects mifepristone with progesterone is possible and safe. Additionally, we compare different progesterone regimens to determine relative efficacies.

Methods: This is a retrospective analysis of clinical data of 754 patients who decided to attempt to reverse the medical abortion process after taking mifepristone but before taking the second drug in the protocol, misoprostol. We followed the patients, who were given progesterone in an effort to reverse

*Steno Institute, San Deigo, California; gdelgadomd@yahoo.com.

**Department of Behavioral Sciences and Leadership, United States Military Academy, West Point, NY.

***Magnificat Maternal Health Program, Nigeria.

****Adjunct Clinical Associate Professor, Hahn School of Nursing and Health Science, University of San Diego.

*****Associate Clinical Professor, Hahn School of Nursing and Health Science, University of San Diego.

the effects of mifepristone, and conducted statistical analyses to determine the efficacies of different protocols compared to a control mifepristone embryo survival rate, derived from the literature.
***Results*: Intramuscular progesterone and high dose oral progesterone were the most effective with reversal rates of 64% ($P < 0.001$) and 68% ($P < 0.001$), respectively. There was no apparent increased risk of birth defects.**
***Conclusions*: The reversal of the effects of mifepristone using progesterone is safe and effective.**

Introduction

Medical induced abortion utilizing mifepristone has been available in the United States since 2000. In 2014, 31% of non-hospital induced abortions were medical induced abortions.[1] Some women decide to attempt to reverse the medical abortion process after taking mifepristone but before taking misoprostol, and inquire about the possibility of reversing the effects of mifepristone.[2]

The new FDA protocol, approved for medical abortion in 2016, involves the administration of mifepristone 200 mg orally as a single dose, which leads to embryonic or fetal demise, followed 24-48 hours later by misoprostol 800 mcg buccally as a single dose, which stimulates myometrial contractions. The protocol is approved up to 70 days after the first day of the last menstrual period.[3] Misoprostol is part of the protocol because mifepristone alone has an incomplete abortion rate of 20-40%, as determined by the end point of complete expulsion.[4]

Pharmacology

Mifepristone is a competitive antagonist of progesterone at the progesterone receptor (PR). It binds to the PR twice as avidly as progesterone.[5] Mifepristone is an orally active compound with a nearly 70% absorption rate, but its bioavailability is reduced to approximately 40% because of the first-pass effect.[6]

Demethylation and hydroxylation are catalyzed by CYP3A4; three metabolites retain biologic activity. The half-life of mifepristone is approximately 18-25 hours. Mifepristone and its metabolites can be measured up to 72 hours after an ingested dose.[5] The half-life of progesterone is longer, approximately 25-55 hours.[6,7]

Effects of Mifepristone

By blocking progesterone receptors, mifepristone leads to the separation of the decidua basalis from the trophoblast. This separation diminishes the oxygen and nutrients that can be delivered to the embryo or fetus by the maternal circulation and is the primary embryocidal and feticidal effect of mifepristone.[4,8,9]

In addition to this primary effect, mifepristone causes softening and dilatation of the cervix.[4] It also leads to myometrial contractions, increased myometrial sensitivity to prostaglandins[4,10] and the disinhibition of prostaglandin synthesis by the myometrium.[11]

Progesterone has been shown to have an autoregulatory effect on progesterone synthesis by the corpus luteum. Blocking progesterone receptors with mifepristone decreases progesterone secretion by the corpus luteum.[12]

Logic of Using Progesterone to Reverse Mifepristone Effects

Mifepristone is a competitive inhibitor of the progesterone receptor. It is well known that receptor agonism and antagonism are parts of a dynamic process that can be influenced by changing concentrations of the agonist or antagonist. Therefore, it makes biologic sense that increasing the progesterone levels in a pregnant woman by giving supplemental progesterone would favor the agonist progesterone effects and blunt the abortifacient effects of mifepristone.

An Animal Model

A Japanese rat study provides basic-science evidence of the ability of progesterone to negate the effects of mifepristone. In this experiment, one group of pregnant rats was given mifepristone while a second was given mifepristone and progesterone. In the group that only received mifepristone, only 33% of the pups survived. In the group that received mifepristone and progesterone, 100% of the pups survived. Furthermore, the first group had characteristic changes in the myometrium and ovaries; the group that received the combination had no such changes.[13]

Early Mifepristone Studies Reporting Continuing Pregnancy

When mifepristone was first studied as an abortifacient, misoprostol was not part of the protocol. During the 1980's, researchers determined that even though mifepristone was effective as an abortifacient, they believed it was necessary to add a prostaglandin analog to achieve a satisfactory complete uterine evacuation rate.[4] We must emphasize that the definition of incomplete abortion is incomplete emptying of the uterus.[14] Embryo or fetus survival is not implied.

The earliest studies also revealed that some embryos survived mifepristone. Baulieu, the principal developer of the drug, stated that at 4-7 weeks the percentages of efficacy of the regimen were approximately 70% for complete abortions, 20% for incomplete abortions and 10% for ongoing pregnancies (i.e., presumed embryo survival). For gestations 8-10 weeks, the comparable rates were 50% for complete abortions, 35% for incomplete abortions and 15% for embryo survival.[15]

In 2015, Grossman et al. published a review of the first case series of progesterone reversal of mifepristone, as well as 13 studies from the 1980's, addressing continuing pregnancies after mifepristone. The authors concluded that there was insufficient evidence to show that progesterone therapy improved survival over expectant management, based on the reported high ongoing pregnancy rates in some of these older studies.[16] However, closer scrutiny of the studies cited for high ongoing pregnancy rates reveals inadequate criteria for the diagnosis of continuing pregnancies. Many early researchers focused on an efficacy end point of complete uterine evacuation, and did not distinguish missed or incomplete abortions from continuing pregnancies (embryo or fetus

survival).[17] Only eight studies cited by Grossman had criteria sufficient to determine embryo survival and showed continuing pregnancy rates of 8-25%.[17]

A recent review found that 18 of the 30 articles investigating mifepristone monotherapy had adequate criteria to determine embryo survival.[17] After eliminating duplicate publications, 12 studies were identified which utilized follow-up ultrasound to distinguish between incomplete or missed abortion and embryo survival at the end of the study period. The mean percentage of embryos surviving mifepristone among all studies was 12.6%.[17] A single dose of 600 mg in five studies of early gestations 42-49 days in 493 subjects showed survivals of 9.4-17.1%.[17,18,19,20,21] Three studies of 58 women with gestations <49 days, using the current predominant 200-300 mg doses, noted embryo survival rates of 10-23.3%.[19,22,23,24] Four studies of 83 women included gestations up to 70 days, daily doses of 100-200 mg, and total doses 400-800 mg.; in three of these four studies, embryo survival was <25%.[25,26,27,28,29,30,31]

Methods

This is a retrospective analysis of clinical data of a group of pregnant women who took progesterone in an effort to reverse the effects of mifepristone. The study was reviewed and approved by an institutional review board. The lead author contributed clinical data from a variety of clinical settings across the United States and several other countries for comparison.

Subjects were pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. Subjects called an informational hotline linked to an informational website and staffed by nurses and a physician assistant. After receiving information about the reversal process, those who decided to proceed with reversal were referred to physicians and mid-level practitioners in their respective geographic areas for treatment. The women gave written informed consent for treatment to their respective treating medical professionals that included permission to track their data. Data were collected from the women themselves and from their treating healtcare professionals.

Data were collected for different variables including gestational age at the time of mifepristone ingestion, mode of delivery of progesterone given, amounts of progesterone received, birth defects and preterm delivery. Progesterone was given in a variety of regimens by the 325 different medical professionals who treated these women. The modes of delivery of progesterone were intramuscular injection of progesterone in oil, oral administration of micronized progesterone, vaginal use of oral micronized progesterone capsules, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel and progesterone vaginal suppositories.

We selected a 25% embryo or fetus survival rate, if mifepristone alone is administered, as a control because it is at the upper range of mifepristone survival rates and close to the 23% survival rate of the one early study that used a single 200 mg dose, the dose currently favored for medical abortions.[17] This study is designed to ascertain which progesterone treatments clinicians have offered to women seeking mifepristone

reversal that demonstrate efficacy beyond the 25% embryo survival rate, and compares the relative efficacies of different treatment protocols to the historic control.

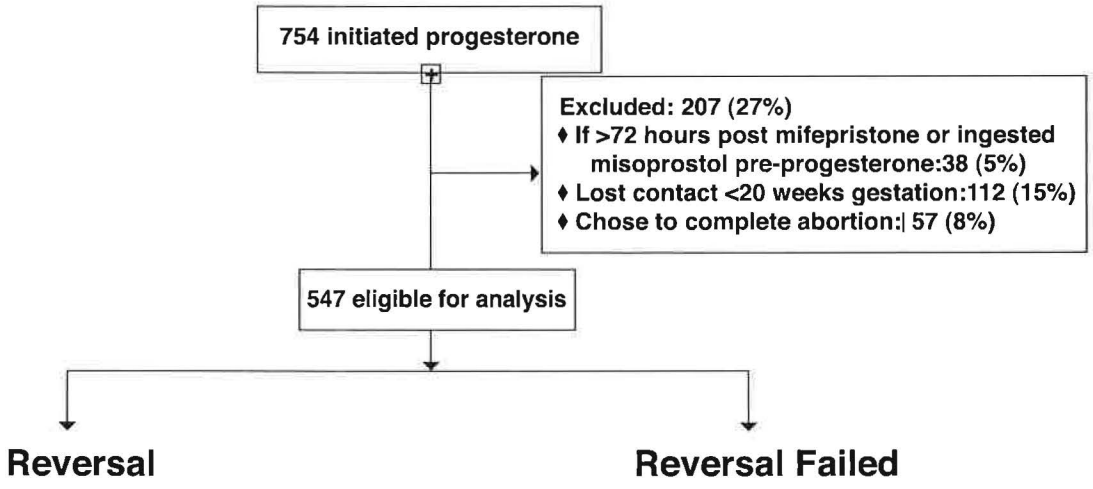
Results

From June 24, 2012 to June 21, 2016, 1,668 calls were received by the hotline from women who had taken mifepristone and were interested in reversal. Seven hundred fifty-four (45%) actually initiated progesterone therapy.

Subjects were included in the study if they were 72 hours or less post-mifepristone and had not taken misoprostol; 38 (5%) did not meet these criteria. Of the women who started progesterone therapy and met inclusion criteria, 116 (15.4%) were lost to follow-up at some point. Of those,112 (14.9%) were lost to follow-up prior to 20 weeks gestation and were excluded from the analysis. Four (0.5%) women remained pregnant with viable fetuses but were lost to follow-up after twenty weeks gestation and were included in the analysis as reversals.

Fifty-seven (7.6%) of the women, after starting progesterone therapy, changed their minds again and either took misoprostol to complete the medical abortion or procured surgical induced abortion. Of those 57, 39 (5.2%) chose to complete abortion medically with misoprostol, seven (0.9%) procured surgical abortions and 11 (1.5%) completed

Figure 1



abortion by unspecified means. These were not included in the analysis as they chose to no longer attempt reversal. See Figure 1.

Women who delivered babies after progesterone therapy or who were lost to follow-up after 20-weeks gestation were considered to have reversed their medical abortions, since any pregnancy loss after 20 weeks would be unlikely to be attributable to the early mifepristone exposure. The data analysis was accomplished using the Statistical Hypothesis Test on a population proportion.

After exclusions, there were 547 patients with analyzable outcomes who underwent progesterone therapy. There were 257 births (47%). Another four were pregnant with viable fetuses but were lost to follow-up after 20 weeks gestation (0.7%). The overall rate of reversal of mifepristone was 48%.

Two subgroups had the highest reversal rates. Those who received progesterone intramuscularly (IM) initially or exclusively had a 64% reversal rate. One subject in this group had an undocumented number of injections. The high-dose oral subgroup received oral progesterone, 400 mg twice a day for three days, followed by 400 mg once a day until the end of the first trimester and had a reversal rate of 68%, similar to the IM group. These survival rates compare favorably with published embryo and fetal survival rate of 25%, if no treatment is attempted,[17] the rate used as a control. See Table 1.

The gestational age at the time of ingestion was directly related to reversal success. See Table 2. This is not surprising since mifepristone embryocidal and feticidal rates fall with advancing gestational age.[33]

There was no correlation between maternal age and rate of reversal. In the subset of records noting time intervals, the time between mifepristone ingestion and the first progesterone dose was not statistically significant in relation to the success rate for reversals attempted within 72 hours of mifepristone injection.

Birth Defects

There were seven reported birth defects in the women who had reversals and follow-up after their deliveries for a rate of 7/257 (2.7%). See Table 3. This is equal to the birth defect rate in the general population of approximately 3%[34] and suggests that there is no increased risk of birth defects in babies born after mifepristone reversal.

Preterm Delivery

There were seven deliveries at <37weeks for a preterm delivery rate of 2.7%. The United States average is 10%.[35]

Multiple Gestations

There were nine sets of twins (4.3% of the pregnancies). There were no higher order multiples.

Discussion

Progesterone Safety

Progesterone is a naturally occurring hormone produced by the corpus luteum and by the placenta, and is essential for maintenance of the maternal fetal interface of pregnancy. It has been used safely in pregnancy for over 50 years.[36] The American Society of Reproductive Medicine states that no long-term risks have been identified when progesterone is used in pregnancy.[37] The FDA has given progesterone a category B rating in pregnancy, in contrast to synthetic progestins.[38]

Table 1: Reversals Compared to Reported Control of 25% Survival if No Treatment Undertaken

All Groups	547	261	286	48%	<0.001	0.44-0.52
High Dose Oral	31	21	10	68%	<0.001	0.51-0.84
Intramuscular, All groups	125	80	45	64%	<0.001	0.56-0.72
IM, 1 Injection	50	24	26	48%	<0.001	0.34-0.62
IM, 2-5 Injec.	36	21	15	58%	<0.001	0.42-0.74
IM, 6-8 Injec.	9	9	0	100%	<0.001	0.67-1
IM, 9-10 Injec.	10	9	1	90%	<0.001	0.77-1.0
IM, 11 or More Injec.	19	17	2	89%	<0.001	0.76-1.0
Oral, All Groups	119	64	55	54%	<0.001	0.45-0.63
Oral Caps Vaginally, All Doses	156	61	95	39%	<0.001	0.31-0.47
Vaginal Suppository	34	11	23	32%	0.161	0.17-0.48

A recent retrospective study of a Danish infertility cohort suggested a possible increased risk of acute lymphocytic leukemia and sympathetic neural tumors in children born to mothers who had taken progesterone during pregnancy and before pregnancy. The increased risk was greatest in women who had taken progesterone for three or more cycles.[39] However, the infertility population examined in the Danish study, exposed to

Table 2: Gestational Age Compared to Reversal Rate

5 weeks	76	19	57	25%	0.5	0.15-0.35
6 weeks	113	52	61	46%	<0.001	0.37-0.55
7 weeks	102	50	52	49%	<0.001	0.39-0.59
8 weeks	88	54	34	61%	<0.001	0.51-0.72
9 weeks	30	23	7	77%	<0.001	0.62-0.92

Table 3: Birth Defects

Port Wine Stain	1
Bilateral Absent Toe	1
Unilateral Two Absent Fingers	1
Choroid Plexus Cyst	1
Cystic Kidney	1
Unilateral Failed Hearing Test	1
Heart Murmur	1

many cycles of progesterone and other medications, differs significantly from our population of fertile women who had a single exposure to progesterone.

Mifepristone Teratogenicity

While previous human studies are not large in number, the available evidence suggests that mifepristone is not teratogenic.[4,40,41] The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin March 2014 states that there is no evidence that mifepristone is associated with teratogenicity.[42] Our data set, the largest of babies exposed to mifepristone in utero, also indicates that the birth defect risk in women who have reversed mifepristone abortions is no higher than the risk in the general population.

Study Limitations

This study is limited in that it is not a randomized placebo-controlled trial. However, a placebo-controlled trial in the population of women who regret their abortion and

want to save the pregnancy would be unethical. Furthermore, although the number of women lost to follow-up was small, it could have affected the results. In addition, some data collection was incomplete.

One potential confounding variable is the use of ultrasound to select for living embryos prior to the first progesterone dose. It is possible that those embryos who were alive at the time of sonogram may have survived without progesterone therapy. However, our study also included some women who started progesterone therapy prior to sonographic documentation that the embryo was alive. Undoubtably, this group included women who already had an embryonic demise prior to initiation of progesterone therapy. Inclusion of these women would falsely lower the success rate of progesterone therapy. The numbers of women who received or did not receive ultrasound exams prior to initiating therapy were not available to our researchers. If ultrasound is readily available, sound practice would dictate that embryonic or fetal viability should be confirmed, or at least suggested, before treatment is started in order to avoid giving women progesterone unnecessarily and to exclude ectopic pregnancy before starting progesterone therapy.

Conclusions

The use of progesterone to reverse the effects of the competitive progesterone receptor blocker, mifepristone, appears to be both safe and effective. Progesterone therapy makes biologic sense, has been previously published as effective in an animal model and is supported by this case series which demonstrates a statistically significant difference in survival between treatment groups and the historic control. Mifepristone is embryocidal and feticidal but not teratogenic; progesterone is not associated with birth defects.

Based on these new data, two reasonable protocols can be suggested for women who seek to reverse the effects of mifepristone:

1. Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester; and

2. Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

Recommendations for Future Research

We propose that further research employing randomized controlled trials comparing progesterone doses and routes of administration are needed to confirm which mode of delivery, dose and duration of progesterone therapy is most efficacious and carries the least burden for the patient.

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EXHIBIT D

ACOG
The American College of Obstetricians and Gynecologists

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Clinical Management Guidelines for Obstetrician–Gynecologists

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Medication Abortion Up to 70 Days of Gestation

Medication abortion, also referred to as medical abortion, is a safe and effective method of providing abortion. Medication abortion involves the use of medicines rather than uterine aspiration to induce an abortion. The U.S. Food and Drug Administration (FDA)-approved medication abortion regimen includes mifepristone and misoprostol. The purpose of this document is to provide updated evidence-based guidance on the provision of medication abortion up to 70 days (or 10 weeks) of gestation. Information about medication abortion after 70 days of gestation is provided in other ACOG publications (1).

Background

Epidemiology

An estimated one in four women in the United States will have an abortion in her lifetime. In 2017, an estimated 60% of abortions in the United States occurred at or before 10 weeks of gestation and medication abortion comprised 39% of all abortions (2). Between 2006 and 2015, there was a shift in the timing of abortion, with abortions taking place at earlier gestational ages; this is likely due, in part, to availability of medication abortion (3). From 2014 to 2017, the number of nonhospital facilities that provided medication abortion increased by 25% (2). A recent survey of American College of Obstetricians and Gynecologists (ACOG) Fellows and Junior Fellows found that 14% had provided medication abortion in the prior year (4).

Medication Abortion

The medication abortion regimen supported by major medical organizations nationally and internationally includes two medications, mifepristone and misoprostol (5, 6). If mifepristone is unavailable, then a misoprostol-only regimen is an acceptable alternative (5). Mifepristone is a selective progesterone receptor modulator that binds to the progesterone receptor with an affinity greater than progesterone itself but does not activate the receptor, thereby acting as an antiprogestin (7). Mifepristone's known actions on a uterus during pregnancy include decidual necrosis, cervical softening, and increased uterine contractility and prostaglandin sensitivity (8, 9). Misoprostol is a prostaglandin E1 analogue that causes cervical softening and uterine contractions. It is approved by the FDA for oral administration to prevent gastric ulcers in individuals who take anti-inflammatory drugs on a long-term basis, and it is included in the FDA-approved labeling of mifepristone for use in abortion (10).

The FDA currently restricts mifepristone access under the risk evaluation and mitigation strategy (REMS) program, which includes a requirement that the drug be "dispensed to patients only in certain health-care settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber" (10). However, the REMS

restrictions for mifepristone do not make the care safer, are not based on medical evidence or need, and create barriers to clinician and patient access to medication abortion (4, 11, 12). The American College of Obstetricians and Gynecologists advocates the removal of REMS restrictions for mifepristone (12).

Clinical Considerations and Recommendations

▶ ***How should patients be counseled about abortion methods?***

Only when patients have considered their options and decided to have an abortion does the discussion about the different methods become clinically relevant. Patients who choose abortion should be counseled about all methods available as well as the risks, advantages, disadvantages, and the different features of these options (5, 6). Most patients who initially are unsure about the method will have some preference after counseling (13). Generally, patients are satisfied with the method they choose (12, 14, 15). Patients who choose medication abortion tend to do so because of a desire to avoid a procedural intervention; a perception that medication abortion is safer, more natural, and private compared with uterine aspiration; or a combination of these reasons (16). Compared with uterine aspiration, medication abortion takes longer to complete and requires more active patient participation as the pregnancy expels outside of a clinical setting. The uterine aspiration procedure for a first-trimester abortion takes place most commonly in one visit, is slightly more effective, and allows for direct assessment of pregnancy tissue by the clinician.

▶ ***What information and counseling should be provided to patients who are considering medication abortion?***

Eligibility and Contraindications

Most patients at 70 days of gestation or less who desire abortion are eligible for a medication abortion. There are medical conditions for which a medication abortion may be preferable to uterine aspiration. Such examples include uterine fibroids that significantly distort the cervical canal or uterine cavity (17, 18), congenital uterine anomalies (19), or introital scarring related to infibulation (20). Patients with asthma are candidates for medication abortion because misoprostol does not cause bronchoconstriction and actually acts as a weak bronchodilator (21). Multiple gestation pregnancy is not a contraindication; patients with twin gestations can be treated with the same regimens as those with singleton gestations (22).

Medication abortion is not recommended for patients with any of the following: confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place (the IUD can be removed before medication abortion), current long-term systemic corticosteroid therapy, chronic adrenal failure, known coagulopathy or anticoagulant therapy, inherited porphyria, or intolerance or allergy to mifepristone or misoprostol (23). Patients with significant comorbidities may still have a medication abortion but may need more monitoring during the process depending on the stability of the conditions. The safety of medication abortion in patients with anemia is unknown because studies have excluded patients with anemia who have hemoglobin levels of less than 9.5 or 10 g/dL. Although the transfusion rates associated with medication abortion are low (less than 0.1%), they exceed those reported for uterine evacuation procedures in early pregnancy (0.01%) (24, 25). Patients may also not be good candidates for medication abortion if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion process, are not available for follow-up contact or evaluation, or cannot understand the instructions because of comprehension barriers.

What to Expect

Most patients who have a medication abortion will experience bleeding and cramping, which are necessary for the process to occur. Patient counseling should emphasize that bleeding likely will be much heavier than menses (and potentially with severe cramping).

Adverse effects can occur after mifepristone administration but are more typically experienced after misoprostol administration. Adverse effects commonly associated with misoprostol use include nausea (43–66%), vomiting (23–40%), diarrhea (23–35%), headache (13–40%), dizziness (28–39%), and thermoregulatory effects such as fever, warmth, hot flushes, or chills (32–69%) (26–29). The incidence of each adverse effect varies by regimen used, the dose and route of administration of the prostaglandin analogue, and the gestational age.

Patient counseling before medication abortion should include discussion of when patients should contact their clinician in the case of heavy bleeding (soaking more than two maxi pads per hour for 2 consecutive hours) and when to access urgent intervention (5, 6, 30). In rare cases, patients who undergo medication abortion may need to obtain an additional intervention, such as uterine aspiration. If the prescribing

clinician does not perform the intervention, it is medically appropriate to provide a referral. In patients who receive mifepristone and vaginal misoprostol, the need for intervention within the first 24 hours of treatment is rare, occurring in 0.2% of patients (31). The need for intervention is based on how the patient is feeling and whether the bleeding seems to be slowing. For patients with heavy bleeding, a baseline hemoglobin or hematocrit, if known, may also influence when to seek urgent care. Overall, less than 1% of patients will obtain an emergency intervention for excessive bleeding (13–15, 32), and the need for blood transfusion is rare (0.1% of patients or less) (24, 33). Should a rare medical emergency arise, patients should be advised to seek care at the closest emergency facility.

Teratogenicity and Ongoing Pregnancy

Before undergoing medication abortion, patients should be counseled regarding the teratogenicity of misoprostol in the event of an unsuccessful medication abortion. All patients with a continuing pregnancy after using mifepristone and misoprostol should be provided with all pregnancy options and a thorough discussion of the risks and benefits of each. Most individuals with a continuing pregnancy opt to complete the abortion, but patients should be supported in their choice of how to proceed. No evidence exists to date of a teratogenic effect of mifepristone (34). However, misoprostol can result in congenital anomalies, such as limb defects with or without Möbius' syndrome (ie, facial paralysis), when used during the first trimester (35–39). Because misoprostol is the common agent used with every medication abortion regimen, clinicians should counsel all patients regarding potential teratogenic effects.

In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly (40). There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing (41, 42). However, limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage (43).

▶ *What evaluation and ancillary testing is needed before a medication abortion?*

Before medication abortion is performed, the clinician should confirm pregnancy and estimate gestational age. For patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion. Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated (44). In situations where Rh testing and Rh D immunoglobulin administration are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care. Other laboratory evaluations are not routinely indicated but may be required by local and state laws (2). Preoperative assessment of hemoglobin or hematocrit is indicated only when anemia is suspected.

Most abortion care globally is provided without ultrasound examination. Although most U.S.-based studies have used ultrasonography to confirm gestational age and intrauterine location of the pregnancy, more recent evidence has shown that a patient's certain last menstrual period when within the prior 56 to 63 days is accurate (45–48). In one study, use of certain last menstrual period alone would have resulted in medication abortion being provided to only 26 of 3,041 (0.8%) patients with pregnancies beyond 70 days of gestation (45).

A potential concern when providing early abortion services is the possibility of an undiagnosed ectopic pregnancy. The overall ectopic pregnancy rate in the U.S. general population is low and declining and is approximately 6 per 1,000 pregnancies among insured patients and 14 per 1,000 among patients who receive Medicaid (49, 50). However, in studies of patients who seek abortion, ectopic pregnancy rates generally are lower. A U.S. study of uterine evacuation procedures performed at less than 6 weeks of gestation found the ectopic pregnancy rate to be 5.9 per 1,000 pregnancies (51) at a time when the national rate was three times higher (52). The largest published study of first-trimester medication abortion patients involved 16,369 patients with pregnancies of 49 days of gestation or less and yielded a calculated ectopic pregnancy rate of 1.3 per 1,000 pregnancies (53). Although ectopic pregnancy among individuals who seek early abortion is rare, patients with a medical history of ectopic pregnancy, medical risk factors (prior tubal surgery, pregnancy with progestin-only or IUD contraception use) or symptoms (ie, unilateral pain, vaginal bleeding) suggestive of ectopic pregnancy should have pretreatment clinical evaluation, which may include ultrasonography (5, 6).

Most patients with clinical indications for an ultrasound examination before medication abortion can be initially screened with transabdominal ultrasonography, reserving transvaginal ultrasonography for situations in which further clarification is required (54, 55).

If ultrasonography is medically indicated, transabdominal ultrasonography is sensitive for diagnosing the presence or absence of a gestational sac in patients who are not obese (54). A randomized trial that compared the use of transabdominal ultrasonography with transvaginal ultrasonography for eligibility assessment before medication abortion found that 80% of patients who received initial transabdominal ultrasonography did not require further testing to proceed with medication abortion, thus avoiding use of more invasive and resource-intensive screening with transvaginal ultrasonography (55).

Recommendations on whether Rh D immune globulin should be given to patients before medication abortion in early pregnancy are primarily based on expert opinion because available evidence is limited (6, 56). Rh D alloimmunization that is left undiagnosed and untreated can lead to significant perinatal morbidity and mortality in future pregnancies (57). And, guidelines from ACOG and various other major medical societies include recommendations for Rh D immune globulin prophylaxis for Rh D-negative patients undergoing medication abortion within the first 12 weeks of gestation (44, 58–60). For patients undergoing medication abortion before 10 weeks of gestation, some experts recommend against routine Rh testing and anti-D prophylaxis (6) or advise that forgoing Rh typing and Rh prophylaxis can be considered (61). Research regarding Rh alloimmunization during early pregnancy continues to evolve (62). However, based on currently available indirect evidence and the theoretical risk of Rh D alloimmunization in future pregnancies, ACOG recommends Rh D immune globulin prophylaxis for Rh D-negative patients undergoing medication abortion. In situations where Rh testing and anti-D prophylaxis are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can weigh the benefits and risks of their options and make an informed decision about their care.

▶ *What regimens are used for medication abortion, and how do they compare in effectiveness for treatment?*

Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are significantly more effective than misoprostol-only regimens. If a combined mifepristone–misoprostol regimen is not available, a misoprostol-only regimen is the recommended alternative (5, 63, 64). Mifepristone is approved by the U.S. FDA to be used with misoprostol for medication abortion through 70 days of gestation (23), but evidence also exists to support use with more advanced gestations (1, 5). The recommended medication abortion regimens are listed in Table 1. With all regimens, the mifepristone dose is the same: 200 mg taken orally. The misoprostol portion of the regimen is more variable in terms of dose, route, and timing. Oral use of misoprostol is not recommended because it may result in lower overall efficacy (65). In general, patients prefer a shorter interval between the two medications (66). These regimens have been extensively studied and are similarly safe and effective (5). Offering options provides patients with flexibility in the timing of abortion and the ability to avoid possible adverse effects related to the misoprostol route. Gastrointestinal adverse effects are less common when misoprostol is administered vaginally as compared with regimens that use oral, buccal, or sublingual misoprostol (65, 67). Buccal and sublingual administration cause similar adverse effects, with the sublingual route associated with a higher rate of chills (68).

Complete abortion rates with all regimens are highest at earlier gestational ages (Table 2). *Medication abortion failure* (defined as the need for uterine aspiration because of ongoing pregnancy or retained tissue) increases with advancing gestational age through 70 days of gestation (Table 2), although failure rates remain low even at this point. Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.

▶ *Who is qualified to provide medication abortion, and in what settings can medication abortion be provided?*

Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion. Clinicians who wish to provide medication abortion services should be trained to perform uterine evacuation procedures or should be able to refer to a clinician who has this training (5, 69).

In addition to physicians, advanced practice clinicians, such as nurse–midwives, physician assistants, and nurse practitioners, possess the clinical and counseling skills necessary to provide first-trimester medication abortion (70). Randomized trials in Mexico, Nepal, and Sweden have consistently found that patients randomized to receive medication abortion under the care of a nurse or nurse–midwife had a statistically equivalent risk of complete abortion compared with those under the care of a physician, without increased risk of adverse events (71–73). In some U.S. states, advance practice clinicians can provide medication abortion; however, many states require that a physician perform an abortion and prohibit provision of medication abortion by nonphysician clinicians (2).

Table 1. Medication Abortion Regimens Up to 70 Days of Gestation

Regimen	Mifepristone Dose	Misoprostol Dose	Interval Between Drugs
		Preferred	
Combination, FDA-approved*	200 mg (orally)	800 micrograms (buccally)	24–48 h
Combination, WHO recommended†	200 mg (orally)	800 micrograms (vaginally, sublingually, or buccally)	24–48 h
		Alternative	
Misoprostol only	N/A	800 micrograms (vaginally, sublingually, or buccally)	Repeat every 3 h for up to 3 doses‡

Abbreviations: h, hours; FDA, U.S. Food and Drug Administration; N/A, not applicable; WHO, World Health Organization.

*U.S. Food and Drug Administration. Mifeprex (mifepristone) information. Postmarket drug safety information for patients and providers. Silver Spring, MD: FDA; 2018. Available at: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm. Retrieved March 3, 2020.

†World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Retrieved March 3, 2020.

‡Although studies typically use no more than three doses for the initial treatment regimen, the World Health Organization guidelines do not specify a maximum number of misoprostol doses (Raymond EG, Harrison MS, Weaver MA. Efficacy of misoprostol alone for first-trimester medical abortion: a systematic review. Obstet Gynecol 2019;133:137-47 *and* World Health Organization. Medical management of abortion. Geneva: WHO; 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/278968/9789241550406-eng.pdf?ua=1. Retrieved March 3, 2020).

According to the requirements of the FDA REMS program, clinicians who want to prescribe mifepristone must complete a "prescriber agreement form" before ordering and dispensing mifepristone, and the clinician and patient need to sign a "patient agreement form" before the drug is dispensed (10).

The actual location of where a patient takes the medication abortion drugs has evolved over time. Although the FDA REMS program for mifepristone continues to require dispensing in the clinician's office, the U.S. labeling for mifepristone no longer indicates that the medication should be used only in the clinician's office (10). Patients can safely and effectively use mifepristone at home for medication abortion (74–77). A clinician can prescribe misoprostol and pain medications or can maintain an office supply and directly dispense to the patient. Patients can safely and effectively self-administer misoprostol at home for medication abortion (5, 78–80).

Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction, and telemedicine improves access to early abortion care, particularly in areas that lack a health care practitioner (81, 82). Telemedicine involves the use of video and information technology to provide a medical service at a distance. Medication abortion through telemedicine has been evaluated in observational studies and found to be equally effective as an in-person visit (33, 83–85). In an analysis of nearly 20,000 medication abortions, adverse events were rare (0.3% overall) and did not differ between those who choose telemedicine or in-person services (33, 84). Patients who choose telemedicine medication abortion are significantly more likely to say they would recommend the service to a friend compared with those who have an in-person visit (90% versus 83%) (83). Telemedicine also may help reduce the rate of delays to care because of barriers in access to abortion care in remote areas (82). After medication abortion through telemedicine was introduced in Iowa, a significant reduction in second-trimester abortion was reported, and patients in remote parts of the state were more likely to obtain a medication abortion (82). Despite this evidence, some states have passed legislation that bans the use of telemedicine to provide medication abortion (86).

▶ *Should prophylactic antibiotics be used in medication abortion?*

The routine use of prophylactic antibiotics is not recommended for medication abortion (6). Following concern about serious, rare, and deadly infection with clostridial bacteria in patients undergoing medication abortion, it has since become evident that no specific connection exists between clostridial organisms and medication abortion (87, 88). Uterine infection with medication abortion is uncommon, and published data do not support the routine use of prophylactic antibiotics in medication abortion. In a systematic review of 65 studies

Table 2. Outcome by Gestational Age After Mifepristone 200 mg and Misoprostol for Outpatient Medication Abortion

	Misoprostol Dose	Interval Between Mifepristone and Misoprostol (h)	Gestational Age			
			≤49 days	50–56 days	57–63 days	64–70 days
Complete abortion	800 micrograms buccally[*]	24–48	98.1%	96.8%	94.7%	92.7%
	800 micrograms vaginally[†‡§‖¶‡‡]	24–72	98.3–99.7%	95.3–98.6%	95.1–98.3%	94.9%
	800 micrograms vaginally[§]	6–8	97.1%	94.2%	95.2%	N/A
	800 micrograms vaginally[‖¶]	0–0.25	95.5–95.7%	93.7–94.3%	91.6–95.3%	N/A
	400 micrograms sublingually[#**]	24–48	95.4%	N/A	94.8%	91.9%
Ongoing pregnancy	800 micrograms buccally[*]	24–48	0.3%	0.8%	2.0%	3.1%
	800 micrograms vaginally[†‡§‖¶‡‡]	24–72	0–0.4%	0–1.2%	0–2.2%	3.4%
	800 micrograms vaginally[§]	6–8	0.4%	0	0.8%	N/A
	800 micrograms vaginally[‖¶]	0–0.25	1.4–2.3%	1.9–2.8%	1.6–5.0%	N/A
	400 micrograms sublingually[#**††]	24–48	N/A	N/A	1.8–3.5%	2.2%

Abbreviations: h, hours; N/A, not available.

*U.S. Food and Drug Administration. Mifeprex (mifepristone) information. Postmarket drug safety information for patients and providers. Silver Spring, MD: FDA; 2018. Available at: https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm. Retrieved March 3, 2020.

†Schaff EA, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg and vaginal misoprostol for abortion. Contraception 1999;59:1–6.

‡Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. Contraception 2001;64:81–5.

§Creinin MD, Fox MC, Teal S, Chen A, Schaff EA, Meyn LA. A randomized comparison of misoprostol 6 to 8 hours versus 24 hours after mifepristone for abortion. MOD Study Trial Group. Obstet Gynecol 2004;103:851–9.

‖Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. Medical Abortion at the Same Time (MAST) Study Trial Group. Obstet Gynecol 2007;109:885–94.

¶Lohr PA, Starling JE, Scott JG, Aiken AR. Simultaneous compared with interval medical abortion regimens where home use is restricted [published erratum appears in Obstet Gynecol 2018;132:219]. Obstet Gynecol 2018;131:635–41.

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**Bracken H, Dabash R, Tsertsvadze G, Posohova S, Shah M, Hajri S, et al. A two-pill sublingual misoprostol outpatient regimen following mifepristone for medical abortion through 70 days' LMP: a prospective comparative open-label trial. Contraception 2014;89:181–6.

††von Hertzen H, Huong NT, Piaggio G, Bayalag M, Cabezas E, Fang AH, et al. Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. WHO Research Group on Postovulatory Methods of Fertility Regulation. BJOG 2010;117:1186–96.

‡‡Hsia JK, Lohr PA, Taylor J, Creinin MD. Medical abortion with mifepristone and vaginal misoprostol between 64 and 70 days' gestation. Contraception 2019;100:178–81.

of heterogeneous design (prospective, retrospective, and randomized), the overall proportion of diagnosed or treated infection after medication abortion was 0.9% in more than 46,000 patients (89). In these studies, as in most studies of abortion by uterine evacuation, the diagnostic criteria for infection were variable, leading to possible overestimation of infection.

Although serious infections occur rarely in patients after medication abortion, clinicians need to be aware of the signs and symptoms. Tachycardia, severe abdominal pain, or general malaise with or without fever that occur more than 24 hours after misoprostol administration should increase suspicion of a serious infection (90). Clostridial toxic shock often resembles a flu-like illness, so clinicians should have a high level of suspicion for infection when symptoms consistent with flu are present (90). Patients with such infections typically have hemoconcentration and significant leukocytosis without fever and can rapidly progress to refractory hypotension and death (91).

▶ ***What is the recommended pain management approach for patients undergoing medication abortion?***

Nonsteroidal anti-inflammatory drugs are recommended for pain management in patients who undergo a medication abortion. Pain management during medication abortion is an important consideration because many patients report pain that requires analgesia. Studies of pain control and medication abortion have found that the duration of pain for most patients is no longer than 24 hours after misoprostol administration (92, 93). The most severe pain occurs approximately 2.5–4 hours after misoprostol use and lasts about 1 hour (94). One randomized trial found that ibuprofen taken when needed was more effective than acetaminophen to reduce pain associated with medication abortion (95). Another randomized trial found ibuprofen given prophylactically at the time of misoprostol administration did not significantly reduce pain associated with medication abortion compared with ibuprofen taken when needed (93). Nonsteroidal anti-inflammatory drugs do not appear to counteract misoprostol or affect the success of the medication abortion (96). Opioids have not been found to decrease the amount or duration of maximum pain associated with medication abortion up to 70 days of gestation (94). Other medications, like pregabalin, have been studied for pain control but have not been effective (97).

Patients should be sent home with appropriate instructions for analgesia with over-the-counter medications. If opioids are requested or desired, the Centers for Disease Control and Prevention (CDC) advises that "clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids" (98).

▶ ***What kind of assessment is recommended after medication abortion?***

Routine in-person follow-up is not necessary after uncomplicated medication abortion. Clinicians should offer patients the choice of self-assessment or clinical follow-up evaluation to assess medication abortion success. If medically indicated or preferred by the patient, follow-up evaluation can be performed by medical history, clinical examination, serum human chorionic gonadotropin (hCG) testing, or ultrasonography (5, 6, 99).

The type of follow-up visit after medication abortion has evolved over time. The mifepristone FDA label includes recommendations for follow up (23). However, some patients choose not to return for follow-up; this likely is due to the high success rates and because patients are able to self-assess abortion completion (100–102).

Remote Assessment and Self-Assessment

Follow-up can be performed by telephone at 1 week, with subsequent at-home urine pregnancy testing at 4 weeks after treatment, which avoids the need for the patient to go to a facility (103–106). Most studies have used a short series of questions that ask patients whether they have experienced bleeding and cramping (including how much and for how long) and whether they still feel pregnant or if they think the pregnancy has passed (104, 107). When the clinician and the patient think that expulsion has occurred based on symptomatology, they are correct 96–99% of the time (104, 108). Although urine pregnancy testing alone with standard high-sensitivity or low-sensitivity tests has not been shown to be a viable alternative to other forms of follow-up, newer semiquantitative or multilevel at-home urine hCG tests have shown promise in accurately identifying ongoing pregnancies after medication abortion (109–112).

Clinical Follow-Up

When a patient obtains in-person follow-up after medication abortion, transvaginal ultrasonography is commonly used, although it is not required (5). If an ultrasound examination is performed at follow-up after medication abortion, the sole purpose is to determine whether the gestational sac is present or absent. The measurement of endometrial thickness or other findings do not predict the need for subsequent uterine aspiration (113). In research trials, when a transvaginal ultrasound examination shows no evidence of a gestational sac

1 week after mifepristone use, only 1.6% of patients needed subsequent uterine evacuation (113).

Serum hCG testing before treatment and 1 week after treatment is another option for follow-up examination after medication abortion; however, data about use of this approach are lacking for gestations beyond 63 days. This strategy may be more effective than ultrasonography to confirm abortion completion in patients who were below the threshold for visualization of a gestational sac at the time of their medication abortion (114). Patients do not need to return to the same facility; they can obtain serum hCG testing at a convenient location (114, 115). The patient should then be informed of the result. A serum hCG level decrease of at least 80% over 6–7 days after initiating treatment with mifepristone and misoprostol indicates a successful abortion (114). In a randomized trial of in-clinic transvaginal ultrasound examination or serum hCG testing follow-up, 24.5% of patients were lost to follow-up, there were no significant differences reported in unplanned visits and interventions by 2 weeks (6.6% versus 8.2%, respectively) or in uterine evacuation rates by 4 weeks (4.4% and 1.4%, respectively) (116).

▶ *How is incomplete medication abortion or ongoing pregnancy managed?*

Guidelines for intervention vary for patients who have delayed expulsion, an incomplete medication abortion (ie, persistent gestational sac on ultrasonography without evidence of embryonic cardiac activity or retained tissue), or an ongoing pregnancy (ie, continuing development with embryonic cardiac activity).

Delayed Expulsion

After induced or spontaneous expulsion, the uterus will normally contain sonographically hyperechoic tissue or "thick" endometrial stripe that consists of blood, blood clots, and decidua. Rarely does this ultrasound finding in patients who have undergone medication abortion indicate a need for intervention. In the absence of excessive bleeding or pain by patient report, clinicians can monitor such patients based on symptoms.

Incomplete Medication Abortion

An incomplete medication abortion can be treated with a repeat dose of misoprostol, uterine aspiration, or expectant management, depending on the clinical circumstances and patient preference (23, 30, 117, 118). Studies indicate that even with a retained sac at 2 weeks after medication abortion, intervention is unnecessary, and that expulsion will typically occur in the ensuing weeks (30). However, some patients with incomplete expulsion will have bothersome symptoms, such as prolonged and irregular bleeding episodes. Patients with incomplete medication abortion 1 week after treatment can safely receive another dose of misoprostol (28, 118) or repeat misoprostol doses can be used for a persistent gestational sac (117). Patients who prefer not to wait or do not desire medical management can choose to have a uterine evacuation at any time.

Ongoing Pregnancy

Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference. In an analysis of data from two randomized trials with 14 cases of ongoing pregnancy, treatment with a repeat dose of misoprostol, 800 micrograms administered vaginally, resulted in expulsion of the products of pregnancy in five cases (36%); in an additional four cases (29%), gestational cardiac activity was no longer present at the next follow-up visit (118). If gestational cardiac activity persists at follow-up after a second dose of misoprostol, uterine aspiration should be performed.

▶ *What is the recommended timing of contraception initiation after medication abortion?*

Patients undergoing medication abortion who desire contraception should be counseled that

- almost all contraceptive methods, except IUDs and permanent contraception, can be safely initiated immediately on day 1 (mifepristone intake) of medication abortion.
- all contraceptive methods can be safely initiated after successful medication abortion.

Patients who select depot medroxyprogesterone acetate (DMPA) for contraception should be counseled that administration of DMPA on day 1 of the medication abortion regimen may increase the risk of ongoing pregnancy (119).

Providing desired contraception as soon as possible to patients undergoing medication abortion enables the greatest flexibility in care and decreases barriers to initiating contraception. The CDC and World Health Organization (WHO) support the initiation of almost all methods of contraception on day 1 of the medication abortion or on the same day as mifepristone administration (5, 6, 120). Permanent contraception procedures may be performed once abortion is confirmed complete.

Concern has been raised that the immediate use of hormonal contraception that contains progestins could theoretically interfere with medication abortion efficacy. Etonogestrel implant use does not affect medication abortion outcomes (121, 122). However, DMPA injection at the time of mifepristone administration may slightly increase the risk of an ongoing pregnancy

(119). In a randomized trial that evaluated the effects of DMPA injection timing on medication abortion outcomes, ongoing pregnancy was more common among those randomized to receive DMPA injection on the day of mifepristone administration compared with those who received DMPA at a follow-up visit (3.6% versus 0.9%; 90% CI, 2.7 [0.4–5.6]), although the proportion undergoing aspiration for any reason did not significantly vary (6.4% versus 5.3%; 90% CI, 1.1 [–2.8 to 4.9]) (119). Patients should be counseled about this small risk of ongoing pregnancy, which needs to be weighed against the risk of potentially not receiving their desired method of contraception.

Patients do not experience a higher rate of IUD expulsion with placement in the first week after medication abortion as compared with 3 to 6 weeks later (123, 124). However, IUD placement within 6 weeks after medication abortion is associated with a higher expulsion rate compared with IUD placement remote from pregnancy; the time frame after 6 weeks at which this rate decreases is unknown. Placement of a copper or levonorgestrel IUD close to the time of abortion results in improved uptake of a desired IUD compared with placement at an additional follow-up visit several weeks after the abortion (123–125), although overall use rates at 6 months may not differ (126). The IUD expulsion risk should be weighed against the potential for more patients to receive their desired IUD if it is placed sooner rather than later.

▶ *How should patients be counseled about the effect of medication abortion on future fertility and pregnancy outcomes?*

Patients can be counseled that medication abortion does not have an adverse effect on future fertility or future pregnancy outcomes (5, 6). Studies consistently demonstrate that medication abortion has no negative effect on future fertility or pregnancy outcomes. A study from China found that patients who had a prior mifepristone abortion had lower odds of preterm birth compared with those who had never been pregnant (adjusted OR, 0.77; 95% CI, 0.61–0.98), and the frequencies of low-birth-weight infants and mean lengths of pregnancy were similar in both groups (127). No significant differences were reported in risk of preterm delivery, frequency of low-birth-weight infants, or mean infant birth weight in the comparisons of patients who had previous mifepristone abortion and patients who had uterine evacuation. In a registry-based study from Scotland, no association was found between prior abortion and subsequent preterm birth during the period 2000−2008, when 68% of abortions were medication-induced (128).

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Combined mifepristone–misoprostol regimens are recommended as the preferred therapy for medication abortion because they are significantly more effective than misoprostol-only regimens. If a combined mifepristone–misoprostol regimen is not available, a misoprostol-only regimen is the recommended alternative.
- Clinicians should counsel patients that medication abortion failure rates, especially continuing pregnancy rates, increase as gestational age approaches 10 weeks.
- Any clinician with the skills to screen patients for eligibility for medication abortion and to provide appropriate follow-up can provide medication abortion.
- Patients can safely and effectively use mifepristone at home for medication abortion.
- Patients can safely and effectively self-administer misoprostol at home for medication abortion.
- Nonsteroidal anti-inflammatory drugs are recommended for pain management in patients who undergo a medication abortion.
- Routine in-person follow-up is not necessary after uncomplicated medication abortion. Clinicians should offer patients the choice of self-assessment or clinical follow-up evaluation to assess medication abortion success. If medically indicated or preferred by the patient, follow-up evaluation can be performed by medical history, clinical examination, serum human chorionic gonadotropin (hCG) testing, or ultrasonography.
- If an ultrasound examination is performed at follow-up after medication abortion, the sole purpose is to determine whether the gestational sac is present or absent. The measurement of endometrial thickness or other findings do not predict the need for subsequent uterine aspiration.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Medication abortion is not recommended for patients with any of the following: confirmed or suspected ectopic pregnancy, intrauterine device (IUD) in place (the IUD can be removed before medication abortion), current long-term systemic corticosteroid therapy, chronic adrenal failure,

known coagulopathy or anticoagulant therapy, inherited porphyria, or intolerance or allergy to mifepristone or misoprostol.

- Before undergoing medication abortion, patients should be counseled regarding the teratogenicity of misoprostol in the event of an unsuccessful medication abortion.
- Before medication abortion is performed, the clinician should confirm pregnancy and estimate gestational age. For patients with regular menstrual cycles, a certain last menstrual period within the prior 56 days, and no signs, symptoms, or risk factors for ectopic pregnancy, a clinical examination or ultrasound examination is not necessary before medication abortion.
- Most patients with clinical indications for an ultrasound examination before medication abortion can be initially screened with transabdominal ultrasonography, reserving transvaginal ultrasonography for situations in which further clarification is required.
- Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction.
- The routine use of prophylactic antibiotics is not recommended for medication abortion.
- An incomplete medication abortion can be treated with a repeat dose of misoprostol, uterine aspiration, or expectant management, depending on the clinical circumstances and patient preference.
- Ongoing pregnancy after medication abortion can be treated with a repeat dose of misoprostol or uterine aspiration, depending on the clinical circumstances and patient preference.
- Patients undergoing medication abortion who desire contraception should be counseled that
  - almost all contraceptive methods, except IUDs and permanent contraception, can be safely initiated immediately on day 1 (mifepristone intake) of medication abortion.
  - all contraceptive methods can be safely initiated after successful medication abortion.
- Patients who select depot medroxyprogesterone acetate (DMPA) for contraception should be counseled that administration of DMPA on day 1 of the medication abortion regimen may increase the risk of ongoing pregnancy.
- Patients can be counseled that medication abortion does not have an adverse effect on future fertility or future pregnancy outcomes.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Patients who choose abortion should be counseled about all methods available as well as the risks, advantages, disadvantages, and the different features of these options.
- Most patients at 70 days of gestation or less who desire abortion are eligible for a medication abortion.
- Patient counseling before medication abortion should include discussion of when patients should contact their clinician in the case of heavy bleeding (soaking more than two maxi pads per hour for 2 consecutive hours) and when to access urgent intervention.
- All patients with a continuing pregnancy after using mifepristone and misoprostol should be provided with all pregnancy options and a thorough discussion of the risks and benefits of each.
- In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly.
- Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated. In situations where Rh testing and Rh D immunoglobulin administration are not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care.
- Clinicians who wish to provide medication abortion services should be trained to perform uterine evacuation procedures or should be able to refer to a clinician who has this training.

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The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and February 2020. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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EXHIBIT E

August 2017

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Facts Are Important:
Medication Abortion "Reversal" Is Not Supported by Science

Facts are important, especially when discussing the health of women and the American public. Claims regarding abortion "reversal" treatment are not based on science and do not meet clinical standards. The American College of Obstetricians and Gynecologists (ACOG) ranks its recommendations on the strength of the evidence,[i] and does not support prescribing progesterone to stop a medical abortion.

Yet, politicians are pushing legislation to require physicians to recite a script that a medication abortion can be "reversed" with doses of progesterone, and to steer women to this care. Unfounded legislative mandates represent dangerous political interference and compromise patient care and safety.

What is Medication Abortion?

- Medication abortion is the use of medications, rather than surgery, to end a pregnancy. This safe and effective evidence-based regimen includes a combination of two drugs—mifepristone, taken first, and misoprostol, taken at a later point.
- Mifepristone stops the pregnancy growth by blocking the hormone progesterone; misoprostol makes the uterus contract to complete the abortion.
- Medication abortion is more effective when both drugs are used, because mifepristone alone will not always cause abortion. In fact, as many as half of women who take only mifepristone continue their pregnancies. [ii]
- Mifepristone is not known to cause birth defects.

So-called abortion "reversal" procedures are unproven and unethical.

- A 2012 case series reported on six women who took mifepristone and were then administered varying progesterone doses. Four continued their pregnancies.[iii] This is not scientific evidence that progesterone resulted in the continuation of those pregnancies.
- This study was not supervised by an institutional review board (IRB) or an ethical review committee, required to protect human research subjects, raising serious questions regarding the ethics and scientific validity of the results.
- Case series with no control groups are among the weakest forms of medical evidence.[iv]

Legislative mandates based on unproven, unethical research are dangerous to women's health.

Politicians should never mandate treatments or require that physicians tell patients inaccurate information.

Additional ACOG Resources:

- ACOG Practice Bulletin 143 *Medical Management of First-Trimester Abortion* (March 2014)

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EXHIBIT F

Contraception

Contraception 92 (2015) 206–211

Review article

Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review☆

Daniel Grossman[a,b,*], Kari White[c], Lisa Harris[d,e], Matthew Reeves[f,g], Paul D. Blumenthal[h], Beverly Winikoff[i], David A. Grimes[j]

[a]*Ibis Reproductive Health, Oakland, CA 94612, USA*
[b]*Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco, San Francisco, CA 94143, USA*
[c]*Department of Health Care Organization and Policy, School of Public Health, University of Alabama at Birmingham, Birmingham, AL 35233, USA*
[d]*Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, MI 48109, USA*
[e]*Department of Women's Studies, Program in Sexual Rights and Reproductive Justice, University of Michigan, Ann Arbor, MI 48109, USA*
[f]*National Abortion Federation, Washington, DC 20036, USA*
[g]*Johns Hopkins Bloomberg School of Public Health, Baltimore, MD 21205, USA*
[h]*Department of Obstetrics and Gynecology, Stanford University, Stanford, CA 94305, USA*
[i]*Gynuity Health Projects, New York, NY 10010, USA*
[j]*Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, Chapel Hill, NC 27516, USA*

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Abstract

Objective: We conducted a systematic review of the literature on the effectiveness of medical abortion "reversal" treatment. Since the usual care for women seeking to continue pregnancies after ingesting mifepristone is expectant management with fetal surveillance, we also performed a systematic review of continuing pregnancy after mifepristone alone.
Study design: We searched PubMed, CINAHL (*Cumulative Index to Nursing and Allied Health Literature*), Scopus and the Cochrane Library for articles published through March 2015 reporting the proportion of pregnancies continuing after treatment with either mifepristone alone or after an additional treatment following mifepristone aimed at reversing its effect.
Results: From 1115 articles retrieved, 1 study met inclusion criteria for abortion reversal, and 13 studies met criteria for continuing pregnancy after mifepristone alone. The one report of abortion reversal was a case series of 7 patients receiving varying doses of progesterone in oil intramuscularly or micronized progesterone orally or vaginally; 1 patient was lost to follow-up. The study was of poor quality and lacked clear information on patient selection. Four of six women continued the pregnancy to term [67%, 95% confidence interval (CI) 30–90%]. Assuming the lost patient aborted resulted in a continuing pregnancy proportion of 57% (95% CI 25–84%). The proportion of pregnancies continuing 1–2 weeks after mifepristone alone varied from 8% (95% CI 3–22%) to 46% (95% CI 37–56%). Continuing pregnancy was more common with lower mifepristone doses and advanced gestational age.
Conclusions: In the rare case that a woman changes her mind after starting medical abortion, evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.
Implications: Legislation requiring physicians to inform patients about abortion reversal transforms an unproven therapy into law and represents legislative interference in the patient–physician relationship.

Keywords: Medical abortion; Mifepristone; Reversal; Progesterone; Continuing pregnancy

1. Introduction

First-trimester medical abortion involves the use of mifepristone followed by misoprostol, generally up to a gestational age of 63 days from last menstrual period [1,2]. Many women prefer medical abortion to surgical abortion

☆ Conflicts of interest: none.

* Corresponding author. Ibis Reproductive Health, 1330 Broadway, Ste 1100, Oakland, CA 94612, USA. Tel.: +1-510-986-8941; fax: +1-510-986-8960.
E-mail address: DGrossman@ibisreproductivehealth.org (D. Grossman).

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0010-7824/

because they perceive it as less invasive and more private [3]. The proportion of all nonhospital abortions in the United States that were early medical abortions increased from 17% in 2008 to 23% in 2011 [4].

In early 2015, legislatures in Arizona and Arkansas passed laws requiring physicians providing abortion to inform women that if they choose to have a medical abortion and then decide not to complete the abortion, the effect of mifepristone may be reversed with specific treatment [5]. Treatment to reverse the effects of mifepristone is not considered an established practice by the American College of Obstetricians and Gynecologists (ACOG) [6] and was not described in a recent practice bulletin on first-trimester medical abortion issued by ACOG and the Society of Family Planning (SFP) [1].

The purpose of this study was to perform a systematic review of the literature on reversal of medical abortion that documented the proportion of pregnancies continuing after treatment. Since the usual care for women seeking to continue pregnancies after ingesting mifepristone is expectant management with fetal surveillance, we also performed a systematic review of continuing pregnancy after treatment with mifepristone alone.

2. Materials and methods

2.1. Systematic review of medical abortion reversal

In this review, we searched for reports of pharmacological methods (e.g., intramuscular injection of progesterone) to reverse the effects of mifepristone prior to administration of misoprostol (or any other prostaglandin) for first-trimester medical abortion. We anticipated few, if any, randomized controlled trials and therefore broadened our search to include cohort studies and case studies or case series; we excluded review articles, editorials and commentaries. The primary outcome was the proportion of women who carried their pregnancies to term after receiving treatment to reverse the effect of mifepristone.

We searched for studies published through March 31, 2015, using databases for PubMed, the CINAHL (*Cumulative Index to Nursing and Allied Health Literature*), Scopus and the Cochrane Library. We combined the following search terms as Medical Subject Headings (MeSH) and text words: induced abortion, steroidal abortifacient agents; mifepristone; Mifeprex; Mifegyne; RU-486; reverse; antidote; progesterone; progestin; first-trimester pregnancy (see Box).

After initial title and abstract screening, two reviewers (DG and KW) independently evaluated full-text articles to determine whether they met the inclusion criteria. For relevant studies, we recorded the number of women enrolled in the study (or included in the case series) and the number of continuing pregnancies. We then calculated the percentage of continuing pregnancies and 95% Wilson Score confidence intervals (CIs) for women receiving reversal therapy.

Box
List of PubMed search terms used in a systematic review of studies on the efficacy of medical abortion reversal

Search	
(1)	"Abortifacient Agents, Steroidal"[mesh] or "Mifepristone" [mesh] or mifepristone or mifegyne or mifeprex or "r 38486" or r38486 or r-38486 or "ru 38486" or "ru 486" or ru486 or ru-486 or ru38486 or "zk 98296" or zk98296 or zk-98296
(2)	"Abortion, Induced"[mesh] or abort* or terminat*
(3)	("Pregnancy"[mesh] or pregnan* and ("first trimester") or (week*)) or "Pregnancy Trimester, First"[mesh] or "early pregnancy"
(4)	revers* or antidote or "Progesterone"[mesh] or progesterone or "progestins"[mesh] or progestin*
	#1 AND #2 AND #3 AND #4 AND (("0001/01/01"[PDAT]: "2015/03/31"[PDAT]) AND "humans"[MeSH Terms])

2.2. Systematic review of continuing pregnancies following the use of mifepristone alone for first-trimester medical abortion

We reviewed cohort studies and randomized controlled trials that used mifepristone alone during the first trimester of pregnancy to induce abortion, which we identified through a search of the same four databases and using the same search strategy, excluding the reversal terms. We also searched the reference lists of relevant publications for additional studies. We excluded studies that only reported medical abortion failure after mifepristone alone and did not specify the number of continuing pregnancies. We calculated the proportion of pregnancies continuing at the time of the follow-up visit after treatment with mifepristone alone and 95% Wilson Score CIs. Because the mifepristone regimens were not uniform, metaanalysis could not be performed.

3. Results

3.1. Systematic review of medical abortion reversal

Of the 319 unduplicated titles identified in our search, one article met our inclusion criteria (Fig. 1). This article was a case series by Delgado and Davenport [7] of seven women who received progesterone treatment after taking mifepristone for medical abortion at 7–11 weeks gestation. The mifepristone dosage was not noted. One patient was lost to follow-up. Of the six patients with follow-up data, four continued the pregnancy and delivered at term with no apparent congenital malformations; two patients aborted the pregnancy within 3 days of taking mifepristone. The progesterone regimen varied from progesterone in oil 200 mg intramuscularly daily to twice per week, sometimes followed by oral micronized progesterone, to micronized

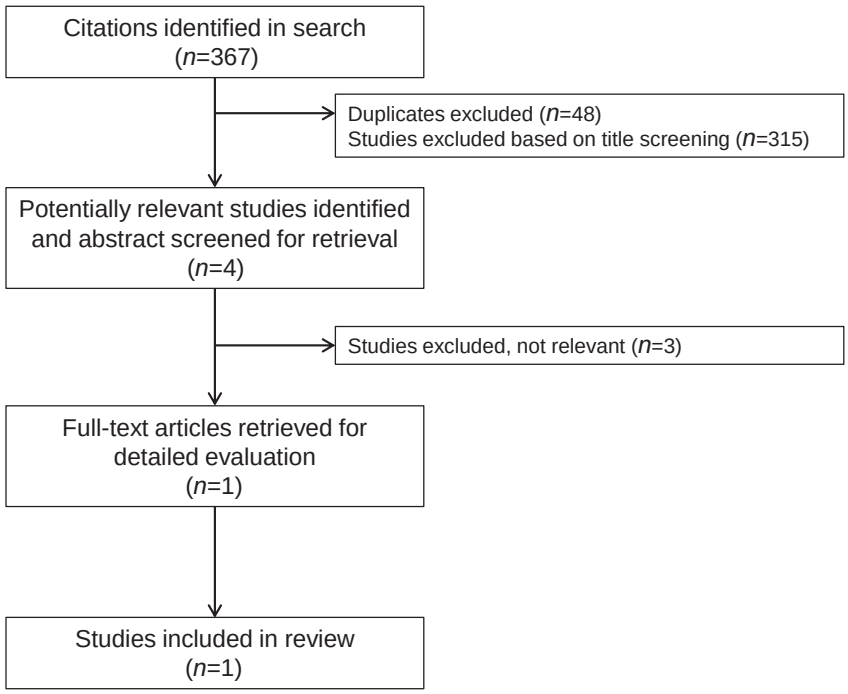

Fig. 1. Summary of study selection process for medical abortion reversal.

progesterone administered vaginally. Therapy was continued for up to 5 months. The publication provides limited details, but it appears that, in at least five cases, a living embryo was documented prior to initiating progesterone treatment. The authors did not report how many women presented seeking medical abortion reversal after taking mifepristone and were found to have already aborted and therefore excluded from treatment. The dates during which cases were collected are not specified, and it is unclear if all women treated were included in the case series. Based on the four continuing pregnancies and excluding the patient lost to follow-up, the proportion of pregnancies continuing after this therapy was 67% (95% CI 30–90%). If we assume that the patient lost to follow-up had an abortion, the continuing pregnancy proportion was 57% (95% CI 25–84%).

3.2. Systematic review of continuing pregnancies following the use of mifepristone alone for first-trimester medical abortion

Our search retrieved 1115 unduplicated articles, and 13 studies in 11 publications met our inclusion criteria (one publication was an English-language article that included two relevant studies performed in China, and one publication provided complete information on two relevant mifepristone dosages) (Fig. 2) [8–18]. Women were generally assessed 1–2 weeks after mifepristone and those with a continuing pregnancy at that time underwent surgical abortion. Table 1 shows for each study the mifepristone regimen used, the gestational age limit, when the follow-up visit occurred, the proportion of pregnancies that had a complete abortion after mifepristone alone and the proportion of pregnancies that were continuing at the follow-up visit. The continuing pregnancy proportions ranged from 8% to 46% with the different regimens.

4. Discussion

We found only one small case series that evaluated a treatment aimed at reversing the effects of mifepristone. The proportion of pregnancies that continued after this treatment was 57–67%, but the 95% CI of this estimate was wide, ranging from 25% to 90% [7]. The study was of poor quality with few details.

Due to the limited information in the article [7], one cannot directly compare the results of this single small series to the continuing pregnancy rate after mifepristone alone, which was as high as 46% in one of the clinical trials [15]. In the report by Delgado and Davenport [7], women presented 7–48 h after mifepristone ingestion, and, except for two cases, the patient had a live embryo at the time of treatment. In order to calculate the proportion of women with a continuing pregnancy seeking this treatment, which would be comparable to the proportion of continuing pregnancies after mifepristone alone, one must know how many women requested treatment and were found to already have an embryonic demise or incomplete abortion. It is reasonable to suppose that women who have an ongoing pregnancy 1–2 days after mifepristone are more likely to have pregnancies that continue to term with no further treatment. It is also possible that some of the continuing pregnancies noted 1–2

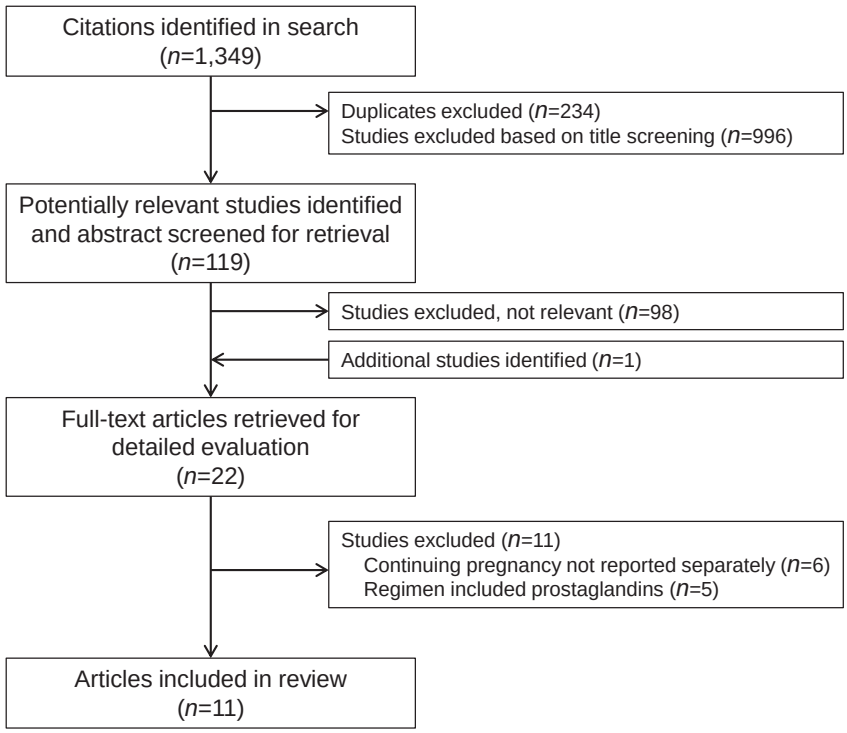

Fig. 2. Summary of study selection process for continuing pregnancy following administration of mifepristone alone for medical abortion.

weeks after treatment in the studies of mifepristone alone may have aborted if the period of follow-up were longer.

Although the dose of mifepristone was not noted in the report by Delgado and Davenport [7], women likely received 200 mg, which is the dosage recommended by ACOG and SFP and most often used by providers in the US [1,19]. Most of the studies of mifepristone alone used a higher dose, and the one study that compared 600 mg to 200 mg found a higher proportion of continuing pregnancies with 200 mg [18]. In addition, none of the studies of mifepristone alone included women pregnant beyond 56 days, while the report by Delgado and Davenport [7] included women up to 11 weeks gestation. In the first trimester, the risk of continuing pregnancy after medical abortion increases as gestational age advances [15,20].

Progesterone is used for other indications during pregnancy. Injections of 17a-hydroxyprogesterone caproate or administration of vaginal progesterone suppositories or

Table 1
Studies reporting the proportion of women with continuing pregnancies following administration of mifepristone alone for medical abortion

Study	Mifepristone oral dose	*N*	Gestational age limit	Follow-up visit (number of days after mifepristone)	Complete abortion	Continuing pregnancy at follow-up visit (%, 95% CI)
Birgerson 1988 [9]	10, 25 or 50 mg twice daily for 7 days	153	49 days	8–10 days	67%	27% (20–34%)
Cameron 1986 [8]	150 mg daily for 4 days	20	56 days	14 days	60%	25% (11–47%)
Carol 1989 [17]	600 mg (single dose)	50	39 days	NS	80%	12% (6–24%)
Grimes 1988 [10]	600 mg (single dose)	50	49 days	14 days	88%	10% (4–21%)
Kovacs 1984 [11]	25–100 mg twice daily for 4 days	36[a]	42 days	14 days	61%	8% (3–22%)
Maria 1988a [16]	600 mg (single dose)	149[a]	42 days	7 days	88%	9% (6–15%)
Maria 1988b [18]	600 mg (single dose)	174	49 days	7 days	84%	11% (8–17%)
Maria 1988b [18]	200 mg (single dose)	30	49 days	7 days	63%	23% (12–41%)
Somell 1990 [12]	600 mg (single dose)	70	42 days	7 days	80%	17% (10–28%)
Swahn 1989 [13]	25 mg twice daily for 4 days	14	49 days	14 days	57%	36% (16–61%)
Ylikorkala 1989 [14]	600 mg (single dose)	47[b]	43 days	14 days	70%	11% (5–23%)
Zheng 1989 [15]	600 mg (single dose)	204	42 days	7 days	65%	31% (25–38%)
Zheng 1989 [15]	600 mg (single dose)	95	49 days	7 days	53%	46% (37–56%)

NS, not specified.

[a] One additional participant was later found to have an ectopic and is excluded from the total here.

[b] Three additional participants had a missed abortion at time of treatment and are excluded from the total here.

gel may be used for prevention of preterm birth among women at high risk of early delivery, generally weekly from 16 weeks to 36 weeks gestation [21]. Progesterone supplementation is also used with assisted reproductive technologies that involve treatment with a gonadotropin-releasing hormone (GnRH) analog, agonist or antagonist, which may interrupt the normal functioning of the corpus luteum [22]. Progesterone in oil injections or vaginal suppositories or gel may be used for this purpose, but treatment is generally stopped after 9–12 weeks gestation, by which time the trophoblast is the primary source of progesterone. Progesterone is not associated with an increased risk of congenital anomalies, including genital abnormalities. Adverse events associated with progesterone injections include injection site swelling or irritation [23], as well as the potential of allergies to the yam, soy or peanut used in manufacturing or compounding the medication [21].

However, the evidence supporting the use of progesterone early in pregnancy after GnRH treatment or to prevent preterm birth is not directly applicable to the situation after mifepristone treatment. Mifepristone blocks the progesterone receptor with a higher affinity than progesterone itself [24]. Women treated with mifepristone for abortion have normal pregnancies with high progesterone levels, and it is not clear that adding more progesterone would counteract the effect of the receptor blockade. A recent randomized controlled trial found that insertion of an etonogestrel contraceptive implant, a very potent progestin, immediately after ingestion of mifepristone did not reduce the effectiveness of the medical abortion regimen compared to delayed insertion after abortion completion [25], confirming the findings of a previous pilot study [26]. In addition, the duration of treatment that women received in the report by Delgado and Davenport [7] was more consistent with preterm labor prevention (albeit with an unproven regimen). It also far exceeded the expected duration of action of mifepristone since the drug is undetectable in humans 10 days after ingestion of a 200-mg dose [27].

The evidence to date does not suggest an elevated risk of congenital malformations after mifepristone administration alone. A recent prospective study from France reported on 46 pregnancies exposed to mifepristone only [28]. Two major malformations occurred among 38 continuing pregnancies (5.3%), which, based on these small numbers, does not appear to be significantly elevated above the expected proportion of about 3%. While more prospective data are needed, information about the low risk of congenital malformations after mifepristone exposure should be given to women who decide to continue a pregnancy after taking the drug.

The clinical use and new state laws concerning abortion "reversal" raise serious ethical concerns. The limited data on mifepristone reversal grew out of the anecdotal experiences of physicians who performed experimental treatment on pregnant women, without usual research safeguards. Delgado and Davenport [7] do not report that their study had an ethics board or institutional review board (IRB) approval. Case reports involving retrospective analysis of three or fewer cases do not generally require IRB oversight, although institutions or journals may require IRB review to determine that the report is exempt. While Delgado and Davenport [7] published their findings as a "case report," their study is clearly "research" as defined in federal policy. Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [29]." The report clearly extends into the realm of research, whether measured by its prospective nature, the number of patients on which it reports, its attempt to assess a specific new treatment regimen or the suggestion that the data produced be used to guide treatment of other women. In recognition of the report's limitations, Delgado and Davenport [7] themselves called for further clinical trials before routine use of their protocol. The new laws in Arizona and Arkansas have now bypassed the research process, in effect making all women who undergo this treatment subjects in an uncontrolled, unmonitored experiment.

Providing evidence-based care is part of how physicians meet their beneficence-based obligations to patients, and therefore, it is a *moral* as well as a clinical mandate to base care on accepted scientific fact. The new laws compel physicians to say things that may contradict their clinical knowledge and judgment. Some physicians will not be able to do so in good conscience; they may feel that suggesting unproven treatment or suggesting that a woman can begin an abortion with uncertainty about her decision contradicts their duty to do no harm.

Women rarely change their minds after beginning a medical abortion. According to reports that physicians are required to submit to the drug's manufacturer, between 2000 and 2012, less than 0.004% of women taking mifepristone in the US later chose to continue the pregnancy (personal communication, Danco Laboratories). In such a case, a woman should be counseled that there is a reasonable chance (10–45%) that the pregnancy will continue. We found no credible evidence that using medication after ingestion of mifepristone is better than expectant management in assuring a continuing pregnancy; suggesting otherwise is scientifically untenable. Legislative interference in the patient–physician relationship is unwarranted and dangerous [30]. In the case of recent Arizona and Arkansas laws, this interference transforms an unproven therapy into law, bases law on methodologically flawed research and in effect turns unethical experimentation on pregnant women into legislative mandate. These features of mifepristone reversal represent an affront to responsible research conduct and to the ethical practice of medicine.

Acknowledgments

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EXHIBIT G

for all disclosures closer to strict scrutiny.

The Court's approach in *NIFLA*, as the dissent noted, "could radically change prior law, perhaps placing much securities law or consumer protection law at constitutional risk." Many health laws could be similarly threatened. Already a lower court has preliminarily enjoined Food and Drug Administration warning labels for cigars on the basis of *NIFLA*.[5] Whether that injunction holds, and whether other health laws will be struck down on First Amendment grounds, remains to be seen. What is clear is that the Court has created new uncertainty, and invited new litigation, regarding numerous health laws that were once assumed to be constitutional.

An audio interview with Prof. Parmet is available at NEJM.org

Disclosure forms provided by the authors are available at NEJM.org.

From Northeastern University School of Law, Boston (W.E.P.); the College of Public Health and the Moritz College of Law, Ohio State University, Columbus (M.L.B.); and California State University, East Bay, Hayward (J.A.S.).

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Abortion "Reversal" — Legislating without Evidence

Daniel Grossman, M.D., and Kari White, Ph.D., M.P.H.

Women up to 10 weeks pregnant who are having a medication abortion generally take one dose of mifepristone, which blocks the progesterone receptor, followed within 48 hours by a dose of misoprostol, a prostaglandin that causes cervical dilation and uterine contractions, leading to expulsion of the pregnancy tissue. Four states (Arkansas, Idaho, South Dakota, and Utah) require abortion providers to tell their patients about treatment that may reverse the effect of mifepristone if they change their mind after starting a medication abortion. So-called abortion reversal involves administering repeated doses of progesterone. Since 2017, other states have proposed similar bills and the California Board of Registered Nursing approved a course on medication-abortion reversal for continuing-education credit. This trend is troubling because of the lack of medical evidence demonstrating the safety and efficacy of the treatment; laws promoting it essentially encourage women to participate in an unmonitored research experiment.

When states began passing laws on abortion reversal, the only published report on this treatment was a case series involving seven patients. A systematic review we coauthored in 2015 found no evidence that pregnancy continuation was more likely after treatment with progesterone as compared with expectant management among women who had taken mifepristone.[1] Our review found that the proportion of continuing pregnancies after mifepristone alone varied from 8% to 46% in published studies.

Recently, Delgado et al. published a case series involving 754 patients who underwent reversal treatment in the United States and several unnamed countries.[2] After excluding 27% of patients for various reasons, they report that 47% had a live birth. The authors conclude that reversal treatment is effective, citing the higher proportion of continuing pregnancies in their study as compared with a historical control rate of 25% of women who had continuing pregnancies after taking mifepristone alone. This estimate comes from Maria et al., the only published report that examined rates of pregnancy continuation after a single 200-mg dose of mifepristone,[3] which is the dose most commonly used in current medication-abortion regimens. This study, which included 30 women who were up to 7 weeks pregnant, 25 of whom were no more than 6 weeks pregnant, found that 23% had continuing pregnancies 7 days later.

It is difficult to compare the results from Delgado et al. with data on mifepristone alone for several reasons. In the Delgado study, some providers performed ultrasonography in patients presenting for reversal and excluded those found to have embryonic death. These patients were removed from the denominator of the proportion of women with continuing pregnancies, which could have contributed to the higher success rate for reversal treatment — especially at gestational ages of more than 6 weeks, when cardiac activity is more apparent. In addition, the authors excluded patients who were lost to follow-up before 20 weeks, which probably exaggerated the treatment's reported success.

Percentage of Women with Continuing Pregnancies after Taking 200 mg Mifepristone with or without Progesterone.*				
Treatment	Total No. of Pregnancies	Continuing Pregnancies	Percentage of Continuing Pregnancies (95% CI)	P Value
Gestational age ≤6 wk				
Mifepristone followed by progesterone	189	71	38 (31–45)	0.119
Mifepristone alone	25	5	20 (9–39)	
Gestational age ≤7 wk				
Mifepristone followed by progesterone	291	121	42 (36–47)	0.076
Mifepristone alone	30	7	23 (21–41)	

* Data are from Delgado et al.[2] and Maria et al.[3] Maria et al. report a total of seven continuing pregnancies in the sample of 30 women who were 7 weeks pregnant or less. There were two abortion failures among the five women who were between 6 and 7 weeks pregnant, but whether these were continuing pregnancies is unclear. We therefore made the conservative assumption that five of the seven continuing pregnancies occurred among the 25 women who received mifepristone at 6 weeks' gestation or less and that the two failures that occurred among those who were between 6 and 7 weeks pregnant were both continuing pregnancies.

Gestational ages in Delgado et al. (up to 9 weeks) also differed from those in Maria et al. As Delgado et al. note, pregnancy continuation is more common with advanced gestation; therefore, it is important to compare groups of similar gestational age. We analyzed the effectiveness of reversal treatment by comparing rates of continuing pregnancy among women who were up to 6 or 7 weeks pregnant in the two studies.

Among women who were up to 6 weeks pregnant, 38% (95% confidence interval [CI], 31 to 45) of those who received reversal therapy had a continuing pregnancy.[2] This proportion was not significantly different from the 20% (95% CI, 9 to 39) of women who had a continuing pregnancy after taking mifepristone alone (P=0.119) (see table).[3] The rates of pregnancy continuation were also not significantly different when we included women who were up to 7 weeks pregnant, despite the fact that the reported success rate for reversal therapy was most likely an overestimate at 7 weeks because some patients were excluded from treatment after ultrasound screening for embryonic viability. Because there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation, we cannot evaluate the effectiveness of reversal treatment beyond this gestational age.

The safety data presented by Delgado et al. are minimal. No adverse events were reported among pregnant women, but it is unclear whether such data were routinely collected. The reported data on birth defects and preterm birth are generally reassuring; given the range of progesterone regimens used and the lack of reporting by regimen, however, it is difficult to draw conclusions about the treatment's safety. Data from a registry in France suggest that exposure to mifepristone alone does not increase the risk of birth defects.[4]

Equally unclear is the demand for reversal treatment. Since participants in the study by Delgado et al. were recruited from several unnamed countries over a period of 4 years, it is impossible to estimate what proportion of patients undergoing medication abortion is represented by this sample. According to data obtained from Danco Laboratories, the U.S. manufacturer of mifepristone, less than 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.[1] Other research indicates that decisional certainty among women having an abortion is high — and higher than it is among patients making other decisions about medical treatment.[5]

Still, efforts should be made at the time of preabortion counseling to identify women who may be conflicted and to provide additional support to help them make an informed decision. Allowing patients to take mifepristone at home, which has been permitted since the drug's label was updated in 2016, may reduce the already small number of women who change their mind by giving patients more control over where and when they take the medication. But for patients who do change their mind after taking mifepristone, what is the best course of action? If a woman changes her mind within an hour after taking the drug, vomiting should be induced. Beyond that time frame, we believe the pregnancy should be carefully followed.

One could argue that the demand for abortion reversal treatment is so low that additional research is not justified. But if

researchers do perform additional studies, it is critical that such studies be rigorously designed and conducted in an ethical manner. Clinical equipoise exists for this question, since there is no evidence that treatment is superior to doing nothing. In such cases, a randomized, placebo-controlled trial is the most appropriate study design. For now, any use of reversal treatment should be considered experimental and offered only in the context of clinical research supervised by an institutional review board (IRB). Delgado et al. obtained IRB approval for their retrospective data analysis, but it is not clear that approval was obtained in advance for their experimental treatment protocol. In fact, the study was retracted temporarily because of concerns raised about what the authors initially described as an IRB "waiver."

We believe that states' mandating that health care providers give patients information about an unproven and experimental therapy is a disturbing intrusion into the relationship between physicians and their patients. Additional states will undoubtedly consider such legislation, despite the lack of evidence for abortion reversal treatment. We should all be concerned when politicians recommend treatment options over the advice of medical professionals.

Disclosure forms provided by the authors are available at NEJM.org.

From Advancing New Standards in Reproductive Health, Bixby Center for Global Reproductive Health, and the Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco (D.G.); and the Department of Health Care Organization and Policy, School of Public Health, University of Alabama at Birmingham (K.W.).

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Extensively Drug-Resistant Typhoid — Are Conjugate Vaccines Arriving Just in Time?

Jason R. Andrews, M.D., Farah N. Qamar, F.C.P.S., Richelle C. Charles, M.D., and Edward T. Ryan, M.D.

In Hyderabad, Pakistan, an outbreak of extensively drug-resistant (XDR) *Salmonella enterica ssp. enterica* serovar Typhi, resistant to chloramphenicol, ampicillin, trimethoprim–sulfamethoxazole, fluoroquinolones, and third-generation cephalosporins, was recognized in November 2016 and has now spread to Karachi, home to more than 14 million people. More than 1000 cases have been confirmed by blood culture; since most typhoid cases are treated empirically, however, the true number of cases is probably many times greater. The outbreak is being caused by the H58 clade, a multidrug-resistant haplotype of *S.* Typhi that is common in Asia and areas of Africa. The H58 *S.* Typhi involved in the outbreak contains a chromosomally integrated antimicrobial-resistance cassette imparting resistance to chloramphenicol, ampicillin, and trimethoprim–sulfamethoxazole, and the XDR variant also contains an IncY plasmid that carries not only the fluoroquinolone-resistance gene *qnrS* but also the CTX-M-15 gene *bla* that mediates resistance to ceftriaxone.[1] *S.* Typhi already causes invasive disease in 12 million to 22 million people each year, many of whom live in South and Southeast Asia, and the emergence of an XDR variant in this densely populated area is extremely worrisome.[2]

Prior to the advent of antimicrobial therapy, case fatality rates for typhoid fever exceeded 20% in many areas, since untreated disease led to complications such as intestinal perforation. In 1948, the first effective antimicrobial therapy for typhoidal salmonella, chloramphenicol, ushered in a new era in the management of enteric fever (see timeline). Within 2 years, however, the first clinical isolate resistant to chloramphenicol was reported. But resistance was relatively uncommon, and chloramphenicol remained the mainstay of therapy for the next two decades. In the early 1970s, outbreaks of chloramphenicol-resistant typhoid with evidence of horizontal transfer of resistance genes were reported around the world. Ampicillin and trimethoprim–sulfamethoxazole emerged as alternative, albeit possibly inferior, therapies for chloramphenicol-resistant enteric fever. By the late 1980s, resistance to all three antibiotics (multidrug-resistant typhoid) was increasingly

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Planned Parenthood of Tennessee and North Mississippi, et al., Plaintiffs, v. Herbert H. SLATERY III, et al., Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

**DECLARATION OF STEVEN JOFFE, M.D., M.P.H.,
IN SUPPORT OF PLAINTIFFS' MOTION FOR
TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**

Steven Joffe, M.D., M.P.H., declares the following:

1. I submit this declaration in support of Plaintiffs' motion for temporary and/or preliminary injunctive relief to enjoin enforcement of Tenn. Code Ann. § 39-15-218 (effective October 1, 2020) ("the Act").

2. As set forth more fully below, I am a Professor of Medical Ethics at the University of Pennsylvania Perelman School of Medicine, where I serve as Interim Chair of the Department of Medical Ethics and Health Policy. I have spent two decades researching medical ethics issues that arise in the course of medical practice, including extensive research on the specific question of informed consent. Until last year, I also practiced children's cancer medicine and bone marrow transplantation at the Children's Hospital of Philadelphia.

3. Based on my expertise and two decades of research in medical ethics and informed consent, as well as my two decades of medical practice, it is my opinion that the Act, if implemented, would undermine informed consent for patients seeking medication abortion and

mislead patients concerning the safety and efficacy of medication abortion "reversal." In so doing, the Act forces physicians to violate fundamental tenets of medical ethics; puts patients at serious risk of making harmful errors in their decision-making; and steers patients toward experimental, unproven medical treatments, the safety and effectiveness of which have not been established.

Background

4. My curriculum vitae is attached hereto as Exhibit A.

5. I currently hold a number of positions at the University of Pennsylvania Perelman School of Medicine, including Interim Chair of the Department of Medical Ethics and Health Policy, Chief of the Division of Medical Ethics, Founders Professor of Medical Ethics and Health Policy, and Professor of Pediatrics. As a part of these appointments, I lead the activities of the Department of Medical Ethics and Health Policy, with supervisory responsibility for the Department's research and teaching. I also serve as Director of the Department's postdoctoral fellowship training programs in Medical Ethics, and am currently the Co-Director of the Cancer Control Program at the Abramson Cancer Center.

6. Prior to joining the University of Pennsylvania, I practiced pediatric hematology/oncology at Boston Children's Hospital and the Dana-Farber Cancer Institute, both affiliated with Harvard Medical School. I also completed four fellowships, including a medical ethics fellowship at Harvard Medical School and a professional ethics faculty fellowship at the Center for Ethics and Professions at Harvard University. Until last year, I practiced medicine at the Children's Hospital of Philadelphia, where I cared for children undergoing bone marrow transplants for cancer and other serious diseases.

7. I have authored and co-authored numerous peer-reviewed research articles and chapters in medical textbooks, including on issues of medical ethics and informed consent. In

addition, I regularly speak on informed consent and other ethical issues that arise in clinical research and practice to a variety of different audiences, including physicians, at national conferences, as well as at seminars at medical centers and universities.

8. In my previous role as a member for more than ten years of the Institutional Review Board at Dana-Farber Cancer Institute, an affiliate of Harvard Medical School, I have formally reviewed, approved, and monitored biomedical and behavioral research involving human subjects in order to protect the rights and welfare of research subjects.

9. I have also been a member of or chaired numerous institutional and national ethics committees. I am a member of the Pediatric Ethics Subcommittee of the Food and Drug Administration and the Bioethics Committee of the Children's Oncology Group. I also serve on a number of institutional and academic advisory committees, including two committees tasked with overseeing COVID19-related research and the Conflict of Interest Committee, at the Perelman School of Medicine. I also previously served on the Ethics Committee at the Children's Hospital of Philadelphia (2013-2019), the Ethics Advisory Committee of Boston Children's Hospital (2000-2013), and the Ethics Advisory Committee (2000-2013, co-chair 2001-2009) and the Institutional Review Board (1998-2012) at the Dana-Farber Cancer Institute.

10. In addition to my medical degree, I have a Master's of Public Health in epidemiology, which is the study of disease in human populations. Epidemiology focuses on the distribution and causes of disease in human populations, seeks to identify risk factors for disease, and conducts studies to determine optimal treatment approaches for clinical practice and for preventive medicine. Among other things, the discipline of epidemiology involves training in the design, conduct, and analysis of human research.

The Act

11. I have reviewed Tenn. Code. Ann. § 39-15-218 and understand that it imposes certain requirements on physicians (and their agents) performing abortions in Tennessee and on facilities in which "more than fifty (50) elective abortions" were performed during the previous calendar year.

12. Tennessee is not the first state to pass this type of requirement. I previously served as an expert in a case challenging a similar law passed by the Arizona legislature in 2015 and provided testimony in that case in support of the plaintiffs' motion for a preliminary injunction. In that case, the State ultimately agreed to a preliminary injunction and the case was subsequently dismissed after the Arizona legislature repealed the portions of the law concerning medication abortion "reversal" that the plaintiffs challenged.

13. I understand that, as it is commonly provided, the medication abortion protocol involves two medications: mifepristone first, followed by misoprostol twenty-four to forty-eight hours later. I further understand that, as detailed below, the claim that medication abortion can be "reversed," "avoided," or "ceased" once begun has been rejected as unsupported by the medical evidence by both the preeminent national professional organization of obstetricians and gynecologists ("OBGYNs") (the American College of Obstetricians and Gynecologists or "ACOG") as well as the primary association of family planning researchers (the Society of Family Planning or "SFP").

14. I further understand that the Act requires that, at least forty-eight hours prior to providing a medication abortion, the same physician who is to provide the mifepristone must inform the patient that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and that "information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the

department of health website." I further understand that the law requires any waiting room and patient consultation room used by patients obtaining abortions (whether medication or procedural abortions) to display a sign stating, in three-quarter inch font and boldfaced type: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately." I understand that such language must also be provided to medication abortion patients in writing alongside medical discharge instructions.[1]

15. I further understand that the Tennessee Department of Health is required, by December 30, 2020, to publish on its website information "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and must provide "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion."[2,3]

16. In order to understand why the Act seriously undermines informed consent for patients seeking abortions—and requires physicians to violate medical ethics in a number of other respects, including by forcing physicians to endorse an unproven and potentially unsafe medical intervention and mislead patients about the demonstrated efficacy or safety of that intervention—it is important to first understand the general principles of informed consent (for both proven medical treatments, like medication abortion, and unproven treatments, such as abortion

[1] Tenn. Code Ann. §§ 39-15-218(b), (c), (e), (f).
[2] Tenn. Code Ann. § 39-15-218(h).
[3] I understand that the Tennessee Department of Health has not yet published information about "reversing" medication abortion on its website.

"reversal"). I will thus first explain the basic principles of informed consent, and then apply those principles to the Act.

General Principles of Medical Ethics and Informed Consent

17. Medical ethics is a system of moral principles encompassing standards of professional conduct within the practice of medicine and medical research, developed primarily for the benefit of patients and research participants. The central tenets of medical ethics are: (1) respect for patients' autonomy as individuals, including the obligation to act on patients only with their informed consent; (2) acting in patients' best interests, as they define those interests ("beneficence"); (3) avoiding harm to patients ("non-maleficence"); and (4) promoting justice to patients and to society.[4] Ethical physician behavior recognizes that patients' rights and interests are paramount.

18. By adhering to principles of medical ethics, physicians build a relationship of trust with their patients. As the current COVID-19 crisis has made clear, it is crucial to public health and to the integrity of the medical profession that patients be able to trust that their physicians are providing them with accurate, evidence-based information. That trust is undermined if patients come to believe that their physicians are mere spokespersons for particular views that are not grounded in solid scientific evidence.

19. According to the standard conception of medical ethics, informed consent is fundamental to ethical practice. Patients have the right to control their own bodies and lives, which means that ultimately the decision about what medical treatment they get is theirs to make. Informed consent is the mechanism by which patients exercise their autonomy and choose whether to authorize medical interventions or courses of treatment

[4] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (6th ed. 2009).

20. Generally speaking, the goal of the informed consent process is to allow patients to make decisions—consistent with their wishes, values, and priorities—about their own medical treatment, and to ensure that these decisions are based on accurate information about the goals and nature of the treatment in question, the risks and benefits of that treatment, and the alternatives. Said differently, the goal of the process is to ensure that a patient does not undergo any treatment until they have made a fully informed decision, based on accurate information, that the treatment in question is right for them and that the treatment's benefits to them outweigh its risks.

21. Informed consent is also integral to maintaining a relationship of trust between patient and physician. According to the American Medical Association Code of Medical Ethics, "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy," and "[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."[5]

22. To make informed consent possible, a patient must be given accurate and relevant information about a particular procedure so that the patient can make the right decision for herself. Thus, the *goal* of informed consent is not simply to ensure that a physician provides certain specified information; rather, the provision of accurate and relevant information by a physician is the necessary prerequisite for the patient to make her own informed decisions about what treatment to obtain, if any.

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[5] AMA Code of Medical Ethics, *Opinion 2.1.1* (Nov. 14, 2016), https://www.ama-assn.org/delivering-care/ethics/informed-consent.

23. Under standard medical practice, physicians are expected to exercise appropriate medical judgment during the informed consent process regarding what information should be provided and how it should be provided, with the aim of helping the patient to make an informed decision that is right for her. This aim guides how the physician frames information to ensure that informed consent is facilitated and not impeded.

24. While the physician is ultimately responsible for ensuring that patients have obtained accurate and relevant information to make an informed decision, ethical practice does not require that the information be communicated directly by the treating physician, as other members of the healthcare team may also be expert at guiding a patient through the informed decision making process. Doctors work collaboratively within a team, and so long as the treating physician oversees the process and provides medical recommendations and information based on the patient's desires and values, as elicited through the informed consent process, informed consent information may ethically be provided by other members of the healthcare team.

25. In order to facilitate a patient's informed consent, one of the most fundamental obligations the physician has is to ensure patients are provided with truthful and accurate information.

26. It would be antithetical to the purpose of informed consent, and a violation of medical ethics, for a healthcare provider to knowingly give misleading and inaccurate information to a patient during the informed consent process. If a provider were to give a patient misleading or inaccurate information, the provider would be manipulating the patient's decision, thus depriving her of the ability to make an authentic decision based on her own values and preferences.

27. Put more simply, providing *in*accurate information increases the likelihood that a patient will make a decision that is not right for her, violating not only ethical principles of

autonomy but also of doing no harm (non-maleficence) and acting in the patient's best interests (beneficence).

28. Similarly, informed consent requires physicians to use their best medical judgment as to what information is material and relevant to a patient's decision making. Patients count on their healthcare providers to exercise medical judgment in presenting relevant information in a clear, straightforward fashion. Patients who do not have medical expertise need to be able to digest relevant information and use it to inform their decision. It is therefore important that healthcare providers not overwhelm or confuse patients with extraneous or irrelevant information.

29. Thus, given the physician's paramount duty to provide only truthful and material information to their patient, and to do so in a way that facilitates rather than impedes informed consent, a physician must be able to make reasonable professional judgments about the validity and materiality of information when deciding what to tell patients during the informed consent process.

Applications of These Principles to the Act

30. In my opinion, the Act forces physicians to violate these elemental principles of medical ethics and informed consent and fundamentally threatens the informed consent process by overriding the physician's medical judgment and compelling physicians to tell patients information that is not supported by credible, scientific evidence. It is also my opinion that the Act, by forcing physicians to provide inaccurate, misleading, and unsupported information to their patients, damages the trust central to the patient-provider relationship, which is fundamental to the ethical provision of medical care. Furthermore, it is my opinion that the Act requires physicians to violate medical ethics by forcing them to endorse and direct patients to treatments, the safety and efficacy of which have not been established.

31. Moreover, it is my opinion that the Act undermines informed consent, creating a grave risk that a patient may make errors in their decision-making that will prove harmful to them, by forcing physicians to communicate to patients, forty-eight hours prior to taking mifepristone, an inaccurate, misleading message that suggests that the patient need not be certain in her decision before proceeding with an abortion because the effects of mifepristone may be "reversed," "ceased," or "avoided."[6]

The Act Undermines the Informed Consent Process

32. In my opinion, the Act is harmful to patients because it forces physicians to communicate a message to their patients that suggests to them that they need not be firm in their decision to terminate the pregnancy before beginning their abortion. This is directly contrary to physicians' ethical obligations as part of the informed consent process. Because the goal of the informed consent process is to ensure that a patient does not undergo any course of treatment that the patient does not truly want, it would undermine the purpose of informed consent for a physician to communicate things (or be forced to communicate things) that encourage a patient to delay making a final decision about whether to undergo a course of treatment until after the treatment has begun.

33. This is particularly so when patients are seeking a treatment with a desired outcome that may have significant implications for their life, like abortion, and when there is no question that, once women start the procedure, in most—or even many—cases (contrary to what the Act seems to imply) their pregnancy will end. In such a situation, it is crucial during the informed consent process to emphasize that the patient should be certain in her decision before she begins

[6] Tenn. Code Ann. § 39-15-218(f).

the medication abortion process. The Act undermines this important message and therefore impedes the informed consent process.

34. Thus, in my opinion, the Act's required message could mislead women into beginning the abortion process before they have come to a firm decision, based on the inaccurate assumption that an option for reversal exists should they change their mind. The Act's requirements thus impede informed consent and violate the principles of beneficence (acting in the patient's best interest) and non-maleficence (doing no harm to the patient).

35. I understand that, in the sterilization context, the ACOG Ethics Committee has recommended that physicians emphasize to patients, prior to sterilization procedures, that the procedures are permanent. This makes sense from an informed consent perspective, even though it is generally accepted in medicine that some sterilization procedures, such as tubal ligations and vasectomies, may be effectively reversed for some people.[7] However, because such procedures may well not be effectively reversed for any given person, it is necessary for physicians to ensure that patients have come to a complete decision to undergo permanent sterilization prior to undergoing such a procedure, by emphasizing the likely permanence of the procedure during informed consent.

36. It would make no sense in such instances to also require a physician to state that sterilization procedures "may be reversible," even though that statement may be accurate for some people. Doing so would undermine the informed consent process and confuse a patient who is being simultaneously told that the procedure should be "considered permanent and not reversible."

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[7] The Mayo Clinic, *Tubal Ligation Reversal* (Mar. 4, 2020), https://www.mayoclinic.org/tests-procedures/tubal-ligation-reversal/about/pac-20395158.; The Mayo Clinic, Vasectomy Reversal (July 25, 2020), https://www.mayoclinic.org/tests-procedures/vasectomy-reversal/about/pac-20384537.

One would not want to encourage the possibility that a patient who is uncertain about his or her decision to undergo sterilization would nevertheless proceed because he or she has been told that it might be reversible.

37. This logic applies all the more in the medication abortion context, where there is no reliable evidence demonstrating that "reversal" is possible for *any* patients. It is crucial that the informed consent process emphasize that the patient must come to a full and final decision about her treatment before it begins. The informed consent process simply must not mislead her into believing she may delay final decision-making until after beginning the medication abortion process.

38. I am aware of no other area of medicine in which physicians are forced by law to tell their patients about unproven or experimental treatments of unknown safety and efficacy.

The Act Damages the Trust Between Patient and Healthcare Provider

39. As noted above, physicians have an ethical obligation to communicate truthful and honest information to their patients. This is so not only because patients have the right to receive accurate information about their care so that they may make informed decisions, but also because trust is crucial to the physician-patient relationship. A relationship of trust ensures that patients feel comfortable asking any questions they have and revealing personal information about themselves and their lives. This level of open communication is crucial to the provision of ethical medical care, and especially to informed consent, ensuring that the physician understands the patient's needs and values, and that the patient feels comfortable asking any questions they may have.

40. The Act undermines this trust by forcing physicians to communicate medical information that the physician knows is inaccurate, misleading and, as discussed in more detail below, not supported by scientific evidence. *See infra* ¶¶ 44–56.

41. Patients rely on their physicians to provide them with accurate information to support informed decision-making. When a physician presents information to a patient about the treatment options that are available and the expected outcomes, the patient expects that information to be grounded in evidence and in the physician's honest understanding, and to constitute information the physician believes is material to the patient's decision-making process. This makes sense—healthcare providers have the information that patients need in order to make informed decisions about medical treatment. Patients, most of whom lack medical training or expertise, must be able to rely on their chosen healthcare providers to give them clear, appropriate, relevant, and scientifically accurate information. For a physician to do otherwise would violate patient expectations and undermine patient trust.

42. The Act undermines this trust by forcing physicians to direct patients to unproven medical treatments that physicians do not believe are in the patient's best interest. Indeed, the Act forces physicians to communicate messages that physicians believe may actually *harm* patients, thereby undermining the informed consent process.

43. In my opinion, the problems presented by the Act cannot be avoided merely by the physician telling the patient that the government thinks the reversal option exists even though the physician personally disagrees. Merely raising the idea of "reversal" wrongly encourages the patient to consider a possibility for which there is no evidence. To simply disavow the Act's mandated communications also fails to restore respect for the patient's autonomy because it still requires her to hear, from a health care professional in whom she needs to be able to trust, a medical

message that is not based on scientific evidence. In addition, providing contradictory messages about medical information to a layperson is virtually certain to cause confusion and distract them from the essential information they need to make a decision. Provoking this kind of profound confusion is precisely what healthcare providers should avoid doing during the informed consent process.

The Act Requires Provision of Inaccurate Information

44. Recently, ACOG and SFP issued a joint practice bulletin/clinical guidelines for OBGYNs concerning medication abortion, which noted:

> In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly. There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing. However, limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage.[8]

45. In explaining that there is no evidence that progesterone treatment increases the likelihood that a pregnancy will continue after taking mifepristone, the ACOG/SFP guidelines refer to articles,[9] analyzing the claim made in two papers by Drs. George Delgado and Mary Davenport,[10] that administering progesterone to a patient can "reverse" the effects of mifepristone.

46. I have read both of the papers by Delgado and Davenport. That these two papers are the only publications in the medical literature of which I am aware that claim to demonstrate

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[8] ACOG Practice Bulletin Number 225, Vol. 136, No. 4 (October 2020).

[9] Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating without Evidence*, 379 New Eng., J. of Med.1491, (Oct. 18, 2018).; Daniel Grossman et al., *Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review*, 92 Contraception 206 (2015).

[10] George Delgado & Mary L. Davenport, *Progesterone use to reverse the effects of mifepristone*, 46 The Annals of Pharmacotherapy 36, (2012).; George Delgado et al., *A case series detailing the successful reversal of the effects of mifepristone using progesterone*, 33 Issues in L. & Med. 21, (2018).

that administering progesterone (or any other medical intervention) may "reverse," "cease," or "avoid" the effects of mifepristone taken as part of a medication abortion, and thus are the only apparent basis in the medical literature for the mandated information in the Act.

47. Based on this understanding, in my opinion (along with the determination of major medical associations like ACOG), there is no credible evidence to support the statements, as mandated by the Act, that a medication abortion can be "reversed," "ceased," or "avoided" by any medical intervention. Moreover, I believe that compelling physicians to communicate to their patients that abortion reversal may be possible will lead patients to falsely believe that there is an established treatment to achieve that result.

48. The Davenport and Delgado papers are self-described as "case series."[11] A case series is a report on the treatment or outcomes of a group of individual patients. Essentially, they are observational reports lacking rigorous scientific design.

49. Case studies do not constitute reliable evidence of the safety or effectiveness of an experimental or novel medical treatment. To the contrary, they constitute the lowest form of research evidence available[12] because they are "often biased by the author's experience or opinions and there is no control of confounding factors."[13] Case series are particularly vulnerable to selection bias, which means the results reported may not appropriately represent the wider population.

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[11] *Id.*

[12] Deborah J. Cook et al., *Rules of evidence and clinical recommendations on the use of antithrombotic agents*, 102 (4 Suppl.) Chest, 305S, (1992).

[13] Patricia B. Burns, Rod J. Rohrich & Kevin C. Chung, *The Levels of Evidence and their role in Evidence-Based Medicine,* 128 Plastic and Reconstructive Surgery 305, (July 2011).

50. Unlike randomized clinical trials, case studies do not include a control group. The control group provides a benchmark to help determine whether the medical intervention in question results in a different outcome than providing no medical intervention at all. If the intervention results in outcomes similar to the benchmark rate in the control group, then there is no evidence that the intervention is effective. The Delgado and Davenport series included no control group, meaning they did not collect data on patients who did *not* receive progesterone treatment after taking mifepristone.

51. The only other reliable means by which to determine the efficacy of a novel or experimental treatment is when the outcome of a situation without medical intervention is understood to a very high degree of certainty. For example, if there is a medical condition from which, historically, virtually all patients die without exception, then one may be able to measure the efficacy of a novel intervention against that benchmark.

52. Without a clear comparison group,[14] the Delgado and Davenport case studies lack a reliable benchmark against which to determine whether their proposed intervention—administration of progesterone—is effective. Without such a benchmark, there is simply no way to reliably determine whether so-called "reversal" treatment has any effect, particularly where the medical literature has documented significant rates of continuing pregnancy after taking

[14] Grossman and White note that there is only a single published report to examine the rates of continuing pregnancy after a 200-mg dose of mifepristone, "which is the dose most commonly used in current medication-abortion regimens," and that this report concerned only 30 women all of whose pregnancies were at or less than 7 weeks' gestation. *Abortion "Reversal"—Legislating without Evidence, supra* note 13. Grossman and White further note that "there are no published data on rates of pregnancy continuation after a 200-mg dose of mifepristone alone at more than 7 weeks' gestation" and thus, no benchmarks at all against which to measure the efficacy of "reversal" regimens at this stage of pregnancy. *Id.*

mifepristone alone.[15] Indeed, Delgado and Davenport admit that the ongoing pregnancies documented in their case study "may have survived without progesterone therapy."[16]

53. To answer the question of whether high-dose progesterone increases the chances that a pregnancy will continue after a woman receives mifepristone, one would have to design a prospective trial that specifies the research question to be asked or hypothesis to be tested, defines the eligibility criteria for women to participate, describes the treatment regimen to be administered as well as the comparison group, specifies the data (including outcome data) to be collected, and ensures rigorous quality control mechanisms for data collection. Ideally, one would design a randomized trial that gave half the women progesterone and half the women a placebo, then compare pregnancy continuation rates between these two groups. Such a design, and only such a design, would allow for a strong claim that administration of progesterone increases the chances of a continued pregnancy.

54. I am aware that the only controlled double-blind clinical trial of this sort designed to test the hypothesis that the effects of mifepristone can be "reversed" via progesterone was halted before its completion due to serious safety concerns.[17] Three of twelve patients who had begun participation in the trials (*i.e.*, who had taken mifepristone, had taken either progesterone or a placebo, and had not taken misoprostol within the timeframe prescribed in the usual course of a medication abortion) experienced severe hemorrhage requiring hospital transport.[18] One patient required a blood transfusion.[19]

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[15] *Abortion "Reversal"—Legislating without Evidence, supra* note 13; *A case series detailing the successful reversal of the effects of mifepristone using progesterone, supra* note 14.
[16] *Id.* at 29.
[17] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medication Abortion: A randomized controlled trial*, 135 Obstetrics &Gynecology 158, (January 2020).
[18] *Id.*
[19] *Id.*

55. This study was cited by the ACOG/SFP guidelines in support of their statement that "limited available evidence suggest that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[20]

56. Because I am not an OBGYN, I am not offering any opinion as to the biological possibility or plausibility of medication abortion "reversal" via progesterone, nor on its likely safety. Rather, it is my opinion that there is not reliable evidence from human clinical trials demonstrating that the effects of mifepristone taken as part of a medication abortion can be safely or effectively "reversed" (or "avoided" or "ceased") by administration of progesterone. It is further my opinion that it is therefore unethical for physicians or other medical professionals to be forced to inform patients seeking a medication abortion that "it may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken."

The Papers Claiming to Support the Efficacy of "Reversal" Treatments May Be Based on Unethical Research

57. The Delgado and Davenport papers raise ethical concerns about whether proper protocols were followed for conducting research on human subjects. In my opinion, the activities described in the 2012 and 2018 paper constitute research on human subjects as it is commonly understood and as it is defined by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in its *Belmont Report:* "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge."[9]

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[20] ACOG, *supra* note 12.

58. Media reports that I have read suggest that the 2012 Delgado and Davenport paper did not obtain Institutional Review Board ("IRB") approval.[21] Media reports similarly suggest that for the 2018 paper Delgado and Davenport obtained IRB approval to conduct only retroactive analysis—i.e., looking at data from treatment that had already occurred—but never obtained IRB approval to collect prospective data or provide experimental treatment for the purpose of conducting research on human subjects.[22]

59. The professional norm and expectation in the biomedical research community is that research on human subjects should be approved by an IRB. Generally, before approving research proposals, IRBs are necessary to determine that (1) risks to subjects will be minimized through sound research design and, whenever appropriate, the use of procedures already being performed on subjects for clinical purposes; (2) risks will be "reasonable in relation to" the anticipated benefits for the subjects and to the importance of any discoveries that are expected to result; (3) selection of subjects will be equitable, taking special consideration of research involving vulnerable populations, including pregnant women; (4) informed consent will be sought; (5)

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[21] Shannon Firth, *Reversing Abortion Pill: Can It Be Done?, MedPage Today* (Feb. 24, 2015), http://www.medpagetoday.com/0BGYN/General0BGYN/50164 ("In an email, Delgado said that... institutional review board is not required to follow cases").; Paul Sisson, *Doctor began abortion reversal movement,* The San Diego Union-Tribune (Apr. 11, 2015), http://www.utsandiego.com/news/2015/apr/11 /george-delgado-abortion-reversal/?#article-copy ("Delgado said his nonprofit organization . . . which runs the Abortion Pill Reversal Program—has not begun working with a review board . . . . ").

[22] Azeen, Ghorayshi, *A Study About the "Abortion Reversal" Procedure Was Just Withdrawn For Ethical Issues*, Buzzfeed News (July 17, 2018), https://www.buzzfeednews.com/article/azeenghorayshi/abortion-pill-reversal-study-withdrawn ("The University of San Diego asked for the paper to be withdrawn, spokesperson Pamela Payton told Buzzfeed News, because it had 'ambiguous' wording regarding the university's ethics board, 'leading many readers to incorrectly conclude that the [school] reviewed and approved the entire study," when "in reality . . . the ethics board only approved analyzing preexisting data, not collecting it."); *see also Abortion "Reversal"—Legislating without Evidence, supra* note 13; *A case series detailing the successful reversal of the effects of mifepristone using progesterone, supra* note 14, at 1492.

consent will be appropriately documented; (6) the research proposal provides for monitoring the collected data to ensure subject safety; and (7) the study will follow appropriate efforts to protect subjects' privacy and maintain the confidentiality of data.[23] Specifically, IRBs must review and approve research protocols, informed consent documents, recruitment materials and other core study documents before participants are enrolled in the research.

60. Without IRB approval, there are serious questions about the reliability of any data a physician purports to have collected regarding the efficacy and safety of a proposed treatment, as well as whether the research was conducted ethically.

61. I have participated as a researcher in clinical trials and research studies involving human subjects. Every trial or study in which I have participated has been through the IRB approval process prior to the initiation of the research. This is done not only because it is the professional norm (and for this reason every institution I have worked for has required this) and because it is ethical, but also because if the research demonstrates that a new course of treatment is safe and effective, we want the medical community to know that the research was done rigorously and that the results are valid—in other words, that the treatment is evidence-based—so that other physicians can offer to recommend the treatment to their patients with confidence. IRB approval is also important to assuring other physicians that the research results were obtained ethically.

62. Indeed, in their 2012 paper, Delgado and Davenport indicated that they, too, considered the progesterone "reversal" protocol to be experimental and in need of clinical trials to demonstrate its safety and efficacy ("We welcome further clinical trials utilizing this protocol or others. . . We believe that *if* further trials confirm the success without complications of this or

[23] *See* Code of Federal Regulations, 45 U.S.C. § 46.111.

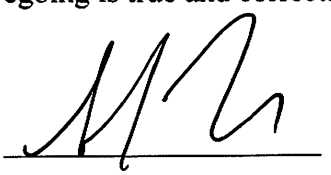
similar protocols, it should become the standard of care for obstetrician-gynecologists, family physicians, and emergency department physicians to attempt mifepristone reversal on patient request.")[24] (Emphasis added.) Thus their subsequent use of a range of unspecified progesterone "reversal" protocols in hundreds of women, outside of a formal IRB-approved protocol, is difficult to understand.

Conclusion

63. For all of these reasons, it is my opinion that the requirements of the Act are contrary to medical ethics and undermine informed consent, resulting in potential harm to patients, physicians, and the integrity of the medical profession. Rather than ensuring patients are firm in their decision to seek an abortion, the Act increases the chances that patients will begin medication abortions before they are sure that doing so is the right decision for them, under the mistaken belief that the abortion can be "reversed" once it has begun. Instead of providing patients with relevant information, the Act forces physicians to mislead patients and encourage them to undertake an entirely unproven treatment, the safety and effectiveness of which has not been reliably demonstrated.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 29, 2020



Steven Joffe, M.D., M.P.H.

[24] Delgado, *supra* note 10 (emphasis added).

EXHIBIT A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 08/07/2020

Steven Joffe, MD, MPH

If you are not a U.S. citizen or holder of a permanent visa, please indicate the type of visa you have:
none (U.S. citizen)

Education:

1988	A.B.	Harvard College (Fine Art)
1992	M.D.	University of California, San Francisco School of Medicine (Medicine)
1996	M.P.H.	University of California, Berkeley (Epidemiology)

Postgraduate Training and Fellowship Appointments:

1992-1993	Intern, Pediatrics, University of California, San Francisco
1993-1995	Resident, Pediatrics, University of California, San Francisco
1996-1997	Research Fellow, Department of Research, Kaiser Permanente Northern California
1997-2000	Clinical Fellow, Pediatric Hematology/Oncology, Children's Hospital Boston and Dana-Farber Cancer Institute
1998-2000	Research Fellow, Clinical Effectiveness, Children's Hospital Boston
1998-2000	Fellow, Medical Ethics, Harvard Medical School
2000-2001	Faculty Fellow, Professional Ethics, Center for Ethics and the Professions, Harvard University

Military Service:

[none]

Faculty Appointments:

2000-2004	Instructor of Pediatrics, Harvard Medical School
2004-2010	Assistant Professor of Pediatrics, Harvard Medical School
2010-2013	Associate Professor of Pediatrics, Harvard Medical School
2012-2013	Associate Professor of Global Health and Social Medicine (Secondary), Harvard Medical School
2013-2016	Associate Professor of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine
2013-2017	Associate Professor of Medical Ethics and Health Policy in Pediatrics, University of Pennsylvania School of Medicine (Secondary)
2016-2017	Emanuel and Robert Hart Associate Professor in Bioethics, University of Pennsylvania School of Medicine
2017-2018	Emanuel and Robert Hart Professor in Bioethics, University of Pennsylvania School of Medicine

2017-present	Professor of Medical Ethics and Health Policy in Pediatrics, University of Pennsylvania School of Medicine (Secondary)
2018-present	Founders Professor of Medical Ethics and Health Policy, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

1995-1997	Assistant Physician, Department of Pediatrics, University of California, San Francisco
1995-1997	Medical Staff, Department of Pediatrics, St. Luke's Hospital, San Francisco, CA
1995-1997	Pool Physician, Department of Pediatrics, Kaiser Permanente, Walnut Creek, CA
1998-2002	Medical Staff, Department of Pediatrics, Saints Memorial Medical Center, Boston, MA
1998-2010	Medical Staff, Department of Pediatrics, Newton-Wellesley Hospital, Newton, MA
2000-2013	Attending Physician, Department of Medicine Division of Hematology and Oncology, Children's Hospital Boston
2000-2013	Attending Physician, Department of Pediatric Oncology, Dana-Farber Cancer Institute
2000-2013	Medical Staff, Department of Pediatrics, Winchester Hospital, Winchester, MA
2001-2013	Hospital Ethicist, Dana-Farber Cancer Institute
2007-2013	Faculty Director, Survey and Data Management Core, Dana-Farber Cancer Institute
2011-2013	Director, Ethics Program in Clinical and Translational Research (EPiCTR), Harvard Catalyst (Associate Director, 2008-2011), Harvard Medical School
2013-present	Director, Penn Fellowship in Advanced Medical Ethics, Perelman School of Medicine
2013-2019	Attending Physician, Hematopoietic Stem Cell Transplantation, Children's Hospital of Philadelphia
2014-present	Chief, Division of Medical Ethics, Department of Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine
2017-present	Director, Postdoctoral T32 Training Program in the Ethical, Legal and Social Implications (ELSI) of Genetics and Genomics, University of Pennsylvania Perelman School of Medicine
2019-present	Interim Chair, Department of Medical Ethics and Health Policy, Perelman School of Medicine

Other Appointments:

2013-present	Member, Abramson Cancer Center
2016-present	Senior Fellow, Leonard Davis Institute
2017-present	Senior Fellow, Penn Center for Precision Medicine

2019-present	Co-Director, Cancer Control Program, Abramson Cancer Center

Specialty Certification:

1995	American Board of Pediatrics (1995-2019)
2000	American Board of Pediatrics, Hematology/Oncology Sub-Board (2000-2019)

Licensure:

1993-1997	California License Registration
1997-2013	Massachusetts License Registration
2013	Pennsylvania License Registration

Awards, Honors and Membership in Honorary Societies:

1983	National Merit Scholarship
1985-1988	John Harvard Scholar, Harvard College
1987	Phi Beta Kappa, Harvard College
1988	Regents Scholar, University of California, San Francisco
1992	Academic Excellence Award (Co-Valedictorian), University of California, San Francisco
1992	Alpha Omega Alpha, University of California, San Francisco
1995	Housestaff Teaching Award, Department of Pediatrics, University of California, San Francisco
2002	Award for Excellence in Human Research Protection, Health Improvement Institute
2008	Elected member, Society for Pediatric Research
2011	Excellence in Tutoring Award, Harvard Medical School
2012	Elected member, American Pediatric Society
2013	Fellow, The Hastings Center

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2019	External Review Committee, Biomedical Ethics Unit, McGill University School of Medicine, Montreal, Canada

National:

1992-2000	American Academy of Pediatrics
1999-Present	American Society of Clinical Oncology (Member, Subcommittee on Genetic Testing 2001-2003 Member, Ethics Committee 2002-2006 and 2017-9 Member, Data Governance Oversight Committee, CancerLinQ, 2014-2015)
2001-Present	American Society of Bioethics and Humanities
2003-Present	Children's Oncology Group, Bioethics Committee (Vice-Chair 2003-2008

	Chair 2008-2017)
2003-Present	Public Responsibility in Medicine and Research (PRIM&R) (Member, Annual Conference Planning Committee 2006-2009 Member, Education Committee 2007-2010)
2005-2011	Cancer and Leukemia Group B, Ethics Committee
2006-2007	National Institutes of Health, National Cancer Institute Central IRB Evaluation Review Panel
2007-Present	U.S. Food and Drug Administration, Pediatric Ethics Subcommittee, Advisory Committee
2008-Present	American Society for Blood and Marrow Transplantation
2008-2012	Genzyme Corporation (Data Monitoring Committee Member)
2008	National Institutes of Health, Center for Scientific Review, Ad hoc member, Special Emphasis Panel (ZRG1 HOP-J(90)S)
2009-2020	Center for International Blood and Marrow Transplantation Research, Health Policy Working Committee (Co-chair 2009-2014)
2009	National Cancer Institute/American Society of Clinical Oncology, Planning Committee, Science of Clinical Trial Accrual Symposium
2009	National Institutes of Health, Biobehavioral and Behavioral Processes IRG, Division of AIDS, Behavioral and Population Sciences, Center for Scientific Review, Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2009	National Institutes of Health, National Human Genome Research Institute (Ethical, Legal and Social Implications Program), Ad Hoc Member, Challenge Grant Review Panel Member (Stage 1)
2010-2013	U.S. Department of Health and Human Services, Secretary's Advisory Committee for Human Research Protections (SACHRP)
2011-2016	NHGRI Clinical Sequencing Exploratory Research (CSER) Consortium ELSI Group (Chair 2013-6)
2011	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics
2013-2016	National Institute of Allergy and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID) HIV Prevention Data and Safety Monitoring Board

	- Africa
2014-2020	Advisory and Executive Committees, Center for International Blood and Marrow Transplant Research (CIBMTR)
2014-2018	African HIV Data Safety and Monitoring Board, National Institute of Allergies and Infectious Diseases (NIAID), Division of AIDS (DAIDS)
2014-Present	American Society of Human Genetics
2015-Present	Board of Scientific Counselors, National Institutes of Health Clinical Center
2015-Present	Children's Oncology Group Pediatric MATCH Clinical Trial (Co-chair, Germline Subcommittee)
2015-2016	Committee on Federal Research Regulations and Reporting Requirements, National Academy of Sciences
2015	National Institutes of Health Clinical Center, Board of Scientific Counselors, Ad Hoc Member for Review of the Department of Bioethics
2017-Present	Genomics and Society Working Group, National Human Genome Research Institute, NIH (Chair, 2020-)
2018	Member, Advisory Committee to the NIH Director, Working Group on Ethical Considerations for Industry Partnership on Research
2018	National Institutes of Health Study Section ZHG1 HGR-P (M2) 1 for review of H3Africa ELSI proposals
2019-Present	American Society for Preventive Oncology
2019-Present	Disclosure Symposium Working Group on Relevancy, Association of American Medical Colleges
2019-Present	Helping End Addictions Long-Term Partnership Committee, National Institutes of Health
2019-Present	Multi-Regional Clinical Trials Center, Harvard University (Co-chair, "Promoting Global Clinical Research in Children, 2019-)
2020-Present	Cure Sickle Cell Initiative, National Heart Lung and Blood Institute (Member, External Scientific Panel, 2020-)
2020	National Human Genome Research Institute (Ad hoc member, GNOM-G 2 Study Section)

Local:

2008-2011	Department of Public Health, Commonwealth of Massachusetts, Altered Standards of Care Advisory Committee
2012-2013	Massachusetts General Hospital, Advisory Committee, Program in Cancer Outcomes Research Training (PCORT), Institute for Technology Assessment
2020	Member, Advisory Committee on Ethical Allocation Framework for Emerging Treatments of COVID-19, Pennsylvania Department of Health

Editorial Positions:

2005-2009	Editorial Board Member, Critical Reviews of Oncology and Hematology
2005-2013	Editorial Board Member, Journal of Clinical Oncology
2013-present	Peer reviewer, Genetics in Medicine
2014-present	Peer reviewer, Clinical Trials
2014-present	Peer reviewer, Pediatrics
2014-present	Peer reviewer, PLoS One
2014-present	Peer reviewer, Journal of Clinical Oncology
2014-present	Peer reviewer, PLoS Medicine
2014-present	Peer reviewer, Lancet
2014-present	Peer reviewer, Pediatric Blood and Cancer
2014-present	Peer reviewer, JAMA
2014-present	Peer reviewer, Hastings Center Review
2014-present	Peer reviewer, JAMA Pediatrics
2015-Present	Peer Reviewer, Generating Evidence & Methods to Improve Patient Outcomes
2015-present	Peer reviewer, American Journal of Bioethics-Empirical Bioethics
2015-Present	Peer Reviewer, JAMA Internal Medicine
2015-present	Peer reviewer, New England Journal of Medicine
2015-present	Peer reviewer, Journal of the National Cancer Institute
2015-present	Peer reviewer, BMC Medical Ethics
2016-Present	Peer Reviewer, Journal of Law and the Biosciences
2016-Present	Peer reviewer, Journal of Empirical Research on Human Research Ethics
2016-Present	Peer Reviewer, Journal of Pediatrics
2016-Present	Peer Reviewer, American Journal of Bioethics
2016	Peer reviewer, National Academy of Sciences/National Academy of Medicine
2016-Present	Peer Reviewer, Journal of Medical Ethics
2017-Present	Peer Reviewer, Journal of Oncology Practice
2019-Present	Editorial Board member, American Journal of Bioethics
2019-Present	Editorial Board Member, Ethics and Human Research

Academic and Institutional Committees:

1998-2012	Member, Institutional Review Board, Dana-Farber Cancer Institute
2000-2013	Member, Ethics Advisory Committee, Children's Hospital Boston
2000-2013	Member, Ethics Advisory Committee, Dana-Farber Cancer Institute (Co-chair 2001-2009)
2000-2009	Member, Board of Trustees Quality Assurance and Risk Management Committee, Dana-Farber Cancer Institute
2001-2004	Member, Research Integrity and Compliance Committee, Dana-Farber Cancer Institute
2001-2012	Member, Clinical Research Leadership Committee (formerly Clinical Research Policy and Operations Committee), Dana-Farber/Harvard Cancer Center
2002-2013	Member, Steering Committee, Division of Medical Ethics, Harvard Medical School
2003	Member, Organizational Ethics Task Force on the Refusal of Blood Products, Children's Hospital Boston
2003-2009	Partners HealthCare, Ethics Leaders Committee
2004-2013	Partners HealthCare, Embryonic Stem Cell Research Oversight (ESCRO) Committee
2005-2009	Member, Ethics Leaders, Harvard Medical School
2005-2006	Partners HealthCare, Tissue Banking Task Force
2008-2010	Member, Admissions Committee, Harvard Medical School
2009-2013	Member, Informed Cohort Oversight Board, Boston Children's Hospital
2011-2013	Expert Reader and Examiner, Committee on Awards and Honors, Harvard Medical School
2012-2013	Member, Research Conflict of Interest Management Committee, Dana-Farber Cancer Institute
2013-2015	Member, Internal Review Committee, Master of Science in Health Policy program, PSOM
2013-2019	Member, Ethics Committee, Children's Hospital of Philadelphia
2015-2016	Member, Committee on Teaching-Part 2, Perelman School of Medicine
2017-Present	Steering Committee member, Community Engagement and Research Core, University of Pennsylvania
2017	Member, Public Health Strategic Planning Subcommittee, Perelman School of Medicine
2017-present	Member, Committee on Appointments and Promotions (on leave 2019-21)
2017-2019	Member, Pediatric Patient-Reported Symptom Tracking in Oncology quality improvement project, Children's Hospital of Philadelphia
2018-2020	Member, Committee on Academic Freedom and Responsibility, Perelman School of Medicine
2018-Present	Member, Clinical Information Systems Genomics Oversight Committee, Penn Medicine

2018	Member, Internal Review Committee, Department of Biostatistics, Epidemiology, and Informatics
2019-Present	Member, Operating Committee, Abramson Cancer Research Career Enhancement and Related Activities Core
2020	Member, Internal Review Committee, Department of Genetics, PSOM
2020-Present	Member, Conflict of Interest Committee, Perelman School of Medicine
2020-Present	Member, COVID Clinical Trials Working Group
2020-Present	Member, COVID 19 Clinical and Translational Research Oversight Committee

Major Academic and Clinical Teaching Responsibilities:

2000-2003	Attending Physician, Pediatric Oncology, Jimmy Fund Clinic, Dana-Farber Cancer Institute (4 Fellows for 100 hours every year)
2000-2002	Attending Physician for Inpatient Oncology Service, Children's Hospital Boston (6 Fellows and 4 Residents for 200 hours every year)
2002-2013	Attending Physician for Hematopoietic Stem Cell Transplant Service, Children's Hospital Boston (6 Fellows and 2 Residents for 150 hours every year)
2003-2012	Attending Physician, Pediatric Stem Cell Transplant Outpatient Service, Dana-Farber Cancer Institute (3-4 Fellows for 200 hours every year)
2003	Informed Consent Presentation, Breast Cancer: Current Controversies and New Horizons, Harvard Medical School (CME)
2003-2011	Case-Based Ethical Dilemmas, Practical Aspects of Palliative Care, Harvard Medical School (CME Single Presentation every year)
2008-2012	Medical Ethics and Professionalism Course for first-year medical students (one 2 hour session per week for 14 weeks)
2008	"Therapeutic Innovation or Research" - Seminar, June 2008, Harvard School of Public Health
2008	"Ethics of research with human subjects" - Seminar, June 2008, Harvard Medical School
2008	"Informed consent to treatment and research" - Seminar, October 2008, Division of Medical Ethics, Harvard Medical School
2009	"The ethical conundrum of incidental findings in clinical & translational research" - Lecture, June 2009, Harvard Catalyst Colloquium Series
2009	"Informed consent to treatment and research" - Seminar, September 2009, Division of Medical Ethics, Harvard Medical School
2009	"Conflict of Interest in Biomedical Research" - Seminar, October 2009, Longitudinal Clinical Research Seminar/Bioethics Module, ME 731.0a, Scholars in Clinical Science Program, Harvard Medical School
2009	"Ethics and professional integrity in clinical and translational

	research" - Seminar, October 2009, Clinical Investigator Training Program, Harvard Medical School
2009	"At the point of the spear: ethical and scientific challenges in translational trials" - Lecturer, November 2009, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"Cancer patients' attitudes towards stored tissue research: outcomes and value of a factorial survey" - Lecture, January 2010, Harvard Pediatric Health Services Research Fellowship Program
2010	"Ethics in clinical research" - March 2010, Department of Medicine Residency Program, Children's Hospital Boston
2010	"What makes clinical research ethical?" - March 2010, Introduction to Clinical Investigation Course, Harvard Catalyst
2010	"The scientist as a responsible member of society" - June 2010, Responsible Conduct of Research Course, Dana-Farber Cancer Institute
2010	"Innovative treatment - research" - June 2010, Harvard Medical School Bioethics Course
2010	"Ethical issues in medical research" - Lecture, July 2010, CURE Summer Program, Dana-Farber Cancer Institute
2010	"Ethics in medical research" - Lecture, July 2010, Harvard Catalyst Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Medical School
2010	"Informed consent, subject selection and recruitment" - Lecture, September 2010, Scholars in Clinical Science Program, Harvard Medical School
2010	"Ethics and integrity in clinical research" - Lecture, September 2010, Introduction to Clinical Research Course, Children's Hospital Boston
2010	"Conflicts of interest" - Lecture, October 2010, Scholars in Clinical Science, Harvard Medical School
2010	"Case-based ethical dilemmas" - Lecture, October 2010, Practical Aspects of Palliative Care Course, Harvard Medical School
2010	"Informed consent to treatment and research" - Lecture, October 2010, Harvard Medical School Ethics Fellowship, Harvard Medical School
2010	"Attitudes of cancer patients and parents toward biobanking for future research" - Lecture, November 2010, Brigham and Women's Center for Bioethics, Research in Progress Seminar
2011	"Ethical conduct of research: Issues in consent" - Lecture, January 2011, Harvard Medical School Fellowship Programs in General Medicine and Primary Care, Pediatric Health Services Research, and Complementary and Alternative Medicine, Serving the Underserved: The Responsible Conduct of Research for the Underserved
2011	"Evaluating the ethics of clinical research" - Lecture, March 2011, Introduction to Clinical Investigation Course, Harvard Catalyst
2011	"Informed consent to research" - Lecture, April 2011, Training

	Session for Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
2011	"Ethics in medical research" - Lecture, August 2011, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst
2011	"Human subjects protection in survey research" - Seminar, September 2011, UMass Boston/Dana-Farber Harvard Cancer Center Survey and Statistical Methods Core Seminar Series
2011	"Ethics in integrity in clinical research" - Lecture, September 2011, Introduction to Clinical Research Course, Children's Hospital Boston
2011	"Case-based dilemmas: Ethical challenges in end-of-life care" - Lecture, September 2011, Practical Aspects of Palliative Care Course, Harvard Medical School
2011	"Informed consent, subject selection and recruitment" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Conflicts of interest" - Lecture, September 2011, Scholars in Clinical Science Program, Harvard Medical School
2011	"Informed consent to treatment and research" - Lecture, October 2011, Ethics Fellowship, Harvard Medical School
2011	"Ethics in clinic research" - Lecture, October 2011, Clinical Investigator Seminar, Dana-Farber Cancer Institute
2012	"Children's capacity to participate in research decisions" - Lecture, January 2012, Department of Medicine Grand Rounds, Children's Hospital Boston
2012	"Ethics & professional integrity in clinical and translational research" - Lecture, January 2012, Clinical Investigator Training Program, Harvard Medical School
2012	"The scientist as a responsible member of society" - Lecture, March 2012, Responsible Conduct of Research Course, Dana-Farber Cancer Institute
2012	"Responsible conduct of research" - Lecture, May 2012, Pediatric Health Services Research Fellowship, Children's Hospital Boston
2012	"Ethics in medical research" - Lecture, July 2012, Visiting Research Internship Program and Summer Clinical and Translational Research Program, Harvard Catalyst/HMS
2012	"Informed consent, subject selection and recruitment" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Ethics and integrity in clinical research" - Lecture, September 2012, Introduction to Clinical Research Course, Children's Hospital Boston
2012	"Conflict of interest" - Lecture, September 2012, Scholars in Clinical Science Program, Harvard Catalyst/HMS
2012	"Informed consent to treatment and research" - Lecture, October

	2012, Ethics Fellowship, Harvard Medical School
2013	"Evaluating the Ethics of Clinical & Translational Research" - Lecture, October 2013, Pediatric Translational Research Workshop for Basic Scientists, Children's Hospital of Philadelphia
2013	"Ethics in Biomedical Research," Guest Lecture, Health Policy and Research Methods I
2013	Course Director, BIOE701, "Bioethics Proseminar"
2013-Present	BIOE701/702, "Bioethics Proseminar," Course Director and Instructor. Two-semester course for postdoctoral fellows given annually.
2014	"Evaluating Informed Consent for Clinical Research" - Lecture, EPI690, University of Pennsylvania
2014	"Mandate or Millstone? The Ethical Challenge of Genomic Incidental Findings," Ellen Hyman-Browne Memorial Lecture, October 2014, Children's Hospital of Philadelphia
2014	"Evaluating the Ethics of Clinical Research" - How to Be An Academic Radiologist, Department of Radiology, University of Pennsylvania Perelman School of Medicine
2014	"Ebola virus disease" - GlobalMed, November 2014, University of Pennsylvania
2014	"Ethics in Biomedical Research" - Guest lecture, Health Services and Policy Research Methods I, December 2014, University of Pennsylvania
2014-2016	Faculty mentor to Elliott Weiss, MD, Postdoctoral Fellow in Bioethics and Neonatology Fellow
2014-2016	Faculty mentor to Erin Aakhus, MD, Fellow in Hematology/Oncology
2014	Capstone project mentor to Divya Yerramilli, MD/MBE student
2014	"Can we use children in research for the benefit of others?" Bioethics Boot Camp lecture & discussion, Department of Medical Ethics and Health Policy, PSOM
2015	"Pediatric Ethics" - Lecture, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"History of Research Ethics" and "Pediatric Ethics" - Leader, Small group discussions, MOD610 Introduction to Medical Ethics, February 2015, University of Pennsylvania
2015	"Ethics in pediatric hematopoietic stem cell transplant," Pediatric HSCT Education Series, Children's Hospital of Philadelphia
2015	"Involving Children in Decisions about Research"- Pediatric Grand Rounds, Children's Hospital of Philadelphia, April 2015
2015	"Ethics in Biomedical Research," Guest lecture, Health Services and Policy Research Methods I
2016	"Responsibilities of Principal Investigators in Multicenter Clinical Trials," 1.5 hour lecture to Dept Colloquium, History & Sociology of Science

2016	Small group facilitator, FR601, "Bioethics and Professionalism"
2016	"Adaptive clinical trial designs: an ethical perspective," Current Issues Regarding the Use of Adaptive Designs in Clinical Trials conference, Center for Clinical Epidemiology and Biostatistics
2016	"Can we use children in research for the benefit of others?" Bioethics Boot Camp, Department of Medical Ethics and Health Policy, PSOM
2016	External Reviewer, proposed Master of Science in Methods in Medical Ethics Degree Program, University of Oxford
2016-2018	Faculty mentor to Bege Dauda, PhD, Postdoctoral Fellow in Advanced Biomedical Ethics
2016	"Ethics in Biomedical Research," HPR603 lecture
2016	BIOE556, "Empirical Approaches to Medical Ethics and Health Policy," Instructor and Course Director
2016-2017	Faculty mentor to Justin Clapp, PhD, Postdoctoral Fellow, Anesthesia
2016	BIOE 560, "Pediatric Ethics." Co-instructor and co-course director.
2017	Ob/Gyn Grand Rounds, "Ethical and Policy Challenges in Research with Biospecimens," Lecturer
2017	Population Science Seminar, Responsibilities of Principal Investigators in Multicenter Clinical Trials, Abramson Cancer Center. January 26
2017	"Ethics in pediatric hematopoietic stem cell transplantation," lecture, pediatric HSCT program, CHOP
2017	Bioethics Bootcamp lecture: Can we use children in research for the benefit of others?
2017-Present	Faculty mentor to Kaitlyn Leahey, Student, Master of Science in Medical Ethics
2017	Faculty mentor to Katherine Saylor, PhD Student, University of North Carolina at Chapel Hill (Visiting student, UPenn, summer 2017)
2017	Faculty Mentor to Saad Shamshair, MD student, University of Maryland; Visiting student, UPenn, Summer 2017
2017	"Ethics in Biomedical Research," HPR603 lecture
2018	"Attitudes towards return of results among participants in the Jackson and Framingham Heart Studies," Basser Center for BRCA
2018	"Responsibilities of principal investigators in multicenter clinical trials," Leonard Davis Institute/Division of General Medicine Seminar
2018	Journal Club, Department of Genetics
2018	"Ethics in Pediatric Stem Cell Transplantation," lecture in Advances in Cellular Immunotherapy and Stem Cell Transplantation Symposium, Children's Hospital of Philadelphia
2018	Lecturer, "Ethics in pediatric hematopoietic cell transplantation," pediatric hematopoietic stem cell program, CHOP
2018	"Ethics In Biomedical Research," lecture, Health Services and

	Policy Methods I
2018	BIOE 560, "Pediatric Ethics." Co-instructor and co-course director.
2018-2019	Faculty capstone mentor to Timothy Lucas, MD, Master of Healthcare Innovation student
2019	BIOE 603, "Clinical Ethics." Course co-instructor and co-director.
2019	FR601, Bioethics and Professionalism, Small Group Facilitator
2019	"Ethics and Innovative Trial Design," Lecture, Research Ethics & Policy Series, PSOM
2019	"Ethics in Medicine," Future Women in Health Club, College of Liberal & Professional Studies, University of Pennsylvania
2019	Capstone adviser to Master of Bioethics candidate Donna Snyder, MD
2019	Instructor, HCIN-612, Ethics of Health Care Innovation Research (Online Master of Health Care Innovation Research)
2019	"Ethics In Biomedical Research," lecture, Health Services and Policy Methods I

Lectures by Invitation (Last 5 years):

Jan, 2015	"Nonfinancial Incentives to Research Participants" - Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics, Harvard Law School, presented at Brocher Institute, Hermance, Switzerland
Feb, 2015	"Involving Children in Important Medical Decisions" - Pediatric Ethics Grand Rounds, Visiting Scholar, Department of Pediatrics and Center for Bioethics, UNC Chapel Hill School of Medicine
Mar, 2015	"The Patient-Doctor Relationship" - Department of Bioethics, National Institutes of Health Clinical Center
May, 2015	"Empirical Methods in Bioethics Education" - Presidential Commission for the Study of Bioethical Issues, Perelman School of Medicine, University of Pennsylvania
May, 2015	"Enrolling Patients with Cancer in Early-Phase Clinical Trials: The Ethical Perspective" - ASCO Annual Meeting, Chicago, IL
Sep, 2015	"Integrating sequencing into cancer care: perspectives of patients and oncologists" - Individualized Medicine Conference, Mayo Clinic, Rochester, MN
Sep, 2015	"Patient-Centered Research: From Consent to Outcomes," National Human Genome Research Institute, Bethesda, MD
Oct, 2015	"Navigating the Boundary between Research and Care in Translational Genomics," American Society of Bioethics and Humanities Annual Meeting, Houston, TX
Oct, 2015	"Conflicts of Interest," National Institutes of Health Clinical Center, Bethesda, MD
Oct, 2015	"The Patient-Doctor Relationship," Department of Bioethics, National Institutes of Health Clinical Center, Bethesda, MD
Nov, 2015	"Could this happen to you? Lessons learned from the University of Minnesota." Closing General Session, Public Responsibility in

	Medicine & Research Annual Meeting, Boston, MA
Dec, 2015	"Returning Diagnostic, Uncertain and Incidental Genomic Results: Bioethical Considerations," Scientific Spotlight, American Society of Hematology Annual Meeting, Orlando, FL
Dec, 2015	"Research with Vulnerable Populations: The Dilemma of Risk," University of Minnesota, Minneapolis, MN
Feb, 2016	"Integrating sequencing into cancer care: perspectives of patients and oncologists," David Barap Brin Memorial Lecture, Johns Hopkins University School of Medicine, Baltimore, MD
Feb, 2016	"Navigating incapacity when caring for patients with cancer," Oncology Grand Rounds, Johns Hopkins University School of Medicine, Baltimore, MD
Apr, 2016	"Ethical challenges of monitoring clinical trials," Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa.
Apr, 2016	"Experimenting in extremis: research ethics during the Ebola epidemic" - Bioethics Grand Rounds, Cleveland Clinic, Cleveland, OH
Jun, 2016	"Ethical challenges in precision pediatric oncology," Coalition Against Childhood Cancer Annual Meeting, Philadelphia, PA
Jul, 2016	"A Learning Healthcare System for Precision Cancer Medicine," American Association for Cancer Research Think Tank on Genomics in Clinical Medicine, Washington, DC
Sep, 2016	"Involving Children in _Decisions about Research," Behavioral Science Committee, Children's Oncology Group, Atlanta, GA
Oct, 2016	"Quality, Evaluation, and Research: Balancing Human Protection and Knowledge Generation," Advisory Panel on Research, Association of American Medical Colleges, Washington, DC
Oct, 2016	"Opportunities and Challenges in Precision Pediatric Oncology", Cynthia Jean Stolman Memorial Lecture in Medical Ethics, Rutgers New Jersey Medical School
Nov, 2016	"Conflicts of Interest"- Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center
Nov, 2016	"The Patient-Doctor Relationship" - Department of Bioethics, National Institutes of Health
Nov, 2016	"Is it time for Belmont 2.0?," PRIM&R Advancing Ethical Research Conference, Anaheim,CA
Nov, 2016	"Patients' and Physicians' Willingness to Participate in Pragmatic Clinical Trials," PRIM&R Advancing Ethical Research Conference, Anaheim, CA
Dec, 2016	"Seamless Cancer Drug Development: Patient Protections & Ethical Considerations," The Drug Development Paradigm in Oncology, National Cancer Policy Forum, Washington, DC
Feb, 2017	"Children's Capacity to_Make Research Decisions," Institutional Review Board Retreat, UNC-Chapel Hill,

	Chapel Hill, NC
Apr, 2017	"Responsibilities of Principal Investigators in Multicenter Clinical Trials," Ruth C. Brufsky Memorial Lecture in Medical Ethics, Dana-Farber Cancer Institute, Boston, MA
May, 2017	"Access vs. Evaluation: An Enduring Dilemma in Therapeutic Development," Keynote Speaker, Center for Clinical and Translational Research Science Day, Seattle Children's Hospital, Seattle, WA
Jun, 2017	"Attitudes towards return of results among participants in the Jackson and Framingham Heart Studies," 4th ELSI World Congress, Farmington, CT
Jun, 2017	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology", Department of Pediatrics & Communicable Diseases, University of Michigan School of Medicine
Jul, 2017	"Financial Barriers to Trial Participation: Ethical Considerations," American Society of Clinical Oncology, Alexandria, VA
Oct, 2017	"Conflicts of Interest" Ethical and Regulatory Aspects of Clinical Research, National Institutes of Health Clinical Center, Bethesda, MD
Nov, 2017	"Justification, Authority, and Accountability in IRB-Investigator Correspondence," Public Responsibility in Medicine & Research (PRIM&R) annual meeting, San Antonio, TX
Nov, 2017	"The Role of Research Ethics Consultations in IRB-reviewed Research: Opportunities and Challenges" (plenary panel moderator), Public Responsibility in Medicine & Research (PRIM&R) annual meeting, San Antonio, TX
Mar, 2018	"Navigating Difficult Decisions in Pediatric Oncology," Pediatric Grand Rounds, Memorial Sloan-Kettering Cancer Center, New York, NY
Mar, 2018	"The Patient-Doctor Relationship," Department of Bioethics, National Institutes of Health Clinical Center
Apr, 2018	"Ethical issues surrounding cancer treatment," National Breast Cancer Coalition Annual Meeting, Arlington, VA
May, 2018	"Achieving the multiple aims of informed consent to research," Harvard Medical School Catalyst Research Community Forum, Keynote Address, Boston, MA
Sep, 2018	"Bedside to Bench or Bench to Bedside: The Ethics of the Investigator-Participant Relationship," National Institutes of Health, Bethesda, MD
Nov, 2018	"Ethics and Consent in the Age of Precision Medicine - Forging a Path Forward," Pediatric Oncology Group of Ontario, Toronto, Ontario, Canada
Nov, 2018	"Ethical Challenges of Cancer Predisposition Testing in Pediatrics," International Society of Paediatric Oncology (SIOP) Annual Meeting, Kyoto, Japan
Nov, 2018	"The Right to Try: The Ethics of Experimental Drugs," Temple Beth

	Sholom, Cherry Hill, NJ
Feb, 2019	"Precision Pediatric Oncology: an Ethical Perspective," Center for Research on Ethical/Legal/Social Implications of Psychiatric, Neurologic & Behavioral Genetics, Columbia University School of Physicians and Surgeons, New York, NY
Feb, 2019	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology," Center for Medical Ethics & Health Policy, Baylor College of Medicine, Houston, TX
Apr, 2019	"Prospect of Direct Benefit and Challenges Incorporating the Concept into Clinical Trials," Duke Margolis Center/US Food & Drug Administration joint workshop on Prospect of Direct Benefit in Pediatric Clinical Trials, Washington, DC
Apr, 2019	"Building a Learning Health Care Culture: Lessons from Pediatric Oncology," Chidren's Research Institute, University of North Carolina Chapel Hill School of Medicine, Chapel Hill, NC
Apr, 2019	"Ethical Obligations Towards Research Subjects: Bedside to Bench or Bench to Bedside," Inaugural Parr Center for Ethics/Center for Bioethics Joint Lecture, University of North Carolina Chapel Hill, Chapel Hill, NC
Sep, 2019	"Ethical Aspects of Germline Reporting in Pediatric Trials," American Society of Pediatric Hematology and Oncology/Children's Oncology Group Joint Symposium, Atlanta, GA
Sep, 2019	"Bedside to Bench or Bench to Bedside: The Ethics of the Investigator-Participant Relationship," National Institute of Health Clinical Center, Bethesda, MD
Oct, 2019	"Navigating between FDA's expanded access programs & the federal Right-to-Try Act: a clinician's view," American Society of Bioethics & Humanities Annual Meeting, Pittsburgh, PA
Nov, 2019	"Building a learning health care culture: lessons from pediatric oncology," Christine Harrison Pediatric Grand Rounds, Hospital for Sick Children, Toronto, Ontario, Canada
Nov, 2019	"Navigating the research/quality improvement divide: a qualitative study of learning healthcare systems," Public Responsibility in Medicine & Research Annual Meeting, Boston, MA
Nov, 2019	"Bioethics Turns 50-Reflections from The Hastings Center," Plenary Panel Presentation, Public Responsibility in Medicine & Research Annual Meeting, Boston, MA
Nov, 2019	"Ethics of Gene Editing for Sickle Cell Disease," Keynote Lecture, NHGRI Cure Sickle Cell Now Annual Forum, Bethesda, MD
Dec, 2019	"Ethics, genomics, and precision medicine," Institute for Global Public Policy, Fudan University, Shanghai, China
Dec, 2019	"Ethics of biomedical innovation and research," Peking Union Medical College, Beijing, China
Mar, 2020	"Emerging Therapies in a New Era of Care," Franklin Insitute Public Lectures Series, Philadelphia, PA

Organizing Roles in Scientific Meetings:

Nov, 2008	Plenary Panel Moderator, "What is Exploitation in Research?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Orlando, Florida
Nov, 2009	Plenary Panel Moderator, "Ethics in Research: Who's minding the store?", Public Responsibility in Medicine and Research (PRIM&R) Annual Meeting Nashville, Tennessee
Oct, 2014	Moderator, "Compensation for Research Related Injuries: Interdisciplinary Perspectives", American Society of Bioethics & Humanities San Diego, CA
Nov, 2014	Organizer, "Write Winning Grant Proposals," Perelman School of Medicine at the University of Pennsylvania and Grant Writers' Seminars and Workshops University of Pennsylvania, Philadelphia PA
Dec, 2014	Session moderator/organizer, "Inside the Black Box: Empirical Research on IRBs," Public Responsibility in Medicine & Research (PRIM&R) Annual Meeting Baltimore, MD
Mar, 2015	Workshop Leader, "Children as Stem Cell Donors in Research" National Institutes of Health
Nov, 2015	Moderator, "Innovations in Subject Perspectives: Risks, Benefits, and Incidental Findings" Scientific Session, Public Responsibility in Medicine & Research Annual Meeting Boston, MA
Apr, 2019	Member, Organizing Committee, Duke Margolis Center/US Food & Drug Administration joint workshop, "Prospect of Direct Benefit in Pediatric Clinical Trials" Washington, DC
Jun, 2020	Member, Organizing Committee, World Congress of Bioethics Philadelphia, PA
Jun, 2020	Member, Organizing Committee, National Human Genome Research Institute ELSI Congress New York, NY

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Research Publications, peer reviewed (print or other media):

1. Escobar GJ, Joffe S, Gardner MN, Armstrong MA, Folck BF, Carpenter DM: Rehospitalization in the First Two Weeks After Discharge from the Neonatal Intensive Care Unit. Pediatrics 104(1): e2, 1999.

2. Joffe S, Escobar GJ, Black SB, Armstrong MA, Lieu TA: Rehospitalization for Respiratory Syncytial Virus Among Premature Infants. Pediatrics 104(4 Pt 1): 894-9, 1999.

3. Joffe S, Ray GT, Escobar GJ, Black SB, Lieu TA: Cost-Effectiveness of Respiratory Syncytial Virus Prophylaxis Among Preterm Infants. Pediatrics 104(3 Pt 1): 419-27, 1999.

4. Higuchi LM, Joffe S, Neufeld EJ, Weisdorf S, Rosh J, Murch S, Devenyi A, Thompson JF, Lewis JD, Bousvaros A.: Inflammatory Bowel Disease Associated with Immune Thrombocytopenic Purpura in Children. J Pediatr Gastroenterol Nutr 33(5): 582-7, 2001.

5. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC: Quality of Informed Consent: A New Measure of Understanding Among Research Subjects. J Natl Cancer Inst 93(2): 139-47, 2001.

6. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC.: Quality of Informed Consent in Cancer Clinical Trials: A Cross-Sectional Survey. Lancet 358(9295): 1772-7, 2001.

7. Joffe S, Weeks JC: Views of American Oncologists About the Purposes of Clinical Trials. J Natl Cancer Inst 94(24): 1847-53, 2002.

8. Joffe S, Manocchia M, Weeks JC, Cleary PD.: What Do Patients Value in Their Hospital Care? An Empirical Perspective on Autonomy Centered Bioethics. J Med Ethics 29(2): 103-8, 2003.

9. Joffe S. : Public Dialogue and the Boundaries of Moral Community. J Clin Ethics 14(1-2): 101-8, 2003.

10. Joffe S, Harrington DP, George SL, Emanuel EJ, Budzinski LA, Weeks JC.: Satisfaction of the uncertainty principle in cancer clinical trials: retrospective cohort analysis. BMJ 328(7454): 1463, 2004.

11. Lee SJ, Joffe S, Kim HT, Socie G, Gilman AL, Wingard JR, Horowitz MM, Cella D, Syrjala KL: Physicians' Attitudes About Quality-of-Life Issues in Hematopoietic Stem Cell Transplantation. Blood 104(7): 2194-200, 2004.

12. Partridge AH, Hackett N, Blood E, Gelman R, Joffe S, Bauer-Wu S, Knudsen K, Emmons K, Collyar D, Schilsky RL, Winer EP. : Oncology Physician and Nurse Practices and Attitudes Regarding Offering Clinical Trial Results to Study Participants. J Natl Cancer Inst 96(8): 629-32, 2004.

13. Peppercorn JM, Weeks JC, Cook EF, Joffe S.: Comparison of Outcomes in Cancer Patients Treated Within and Outside Clinical Trials: Conceptual Framework and Structured Review. Lancet 363(9405): 263-70, 2004.

14. Little MO, Moczynski WV, Richardson PG, Joffe S.: Dana-Farber Cancer Institute

Ethics Rounds: Life-Threatening Illness and the Desire to Adopt. Kennedy Inst Ethics J 15(4): 385-93, 2005.

15. Hampson LA, Agrawal M, Joffe S, Gross CP, Verter J, Emanuel EJ: Patients' Views on Financial Conflicts of Interest in Cancer Research Trials. N Engl J Med 355(22): 2330-7, 2006.

16. Joffe S, Fernandez CV, Pentz RD, Ungar DR, Mathew NA, Turner CW, Alessandri AJ, Woodman CL, Singer DA, Kodish E: Involving Children in Decision-Making About Research Participation. J Pediatr 149(6): 862-8, 2006.

17. Joffe S, Miller FG. : Rethinking Risk-Benefit Assessment for Phase I Cancer Trials. J Clin Oncol 24(19): 2987-90, 2006.

18. Miller FG, Joffe S: Evaluating the therapeutic misconception. Kennedy Inst Ethics J 16(4): 353-66, December 2006 Notes: Reprinted in Miller FG. The ethical challenges of human research: selected essays. Oxford: Oxford University Press, 2012.

19. Hampson LA, Joffe S, Fowler R, Verter J, and Emanuel EJ. : The Frequency, Type, and Monetary Value of Financial Conflicts of Interest in Cancer Clinical Research. J Clin Oncol 25(24): 3609-14, 2007.

20. Henderson G, Churchill L, Davis A, Easter M, Grady C, Joffe S, Kass N, King NM, Lidz C, Miller FG, Nelson D, Peppercorn J, Rothschild B, Sankar P, Wilfond B, Zimmer C: Clinical Trials and Medical Care: Defining the Therapeutic Misconception. PLoS Med 4(11): 1735-8, 2007.

21. Joffe S, Mello MM, Cook EF, Lee SJ. : Advance Care Planning in Patients Undergoing Hematopoietic Cell Transplantation. Biol Blood Marrow Transplant. 13(1): 65-73, 2007.

22. Mello MM, Joffe S: Compact Versus Contract: An Ethical and Legal Analysis of Industry Sponsors' Obligations to Research Subjects. N Engl J Med 356(26): 2737-43, 2007.

23. Joffe S, Miller FG. : Bench to Bedside: Mapping the Moral Terrain of Clinical Research. Hastings Cent Rep 32(2): 30-42, 2008.

24. Kesselheim JC, Johnson J, Joffe S. : Pediatricians' Reports of Their Education in Ethics. Arch Pediatr Adol Med 162(4): 368-73, 2008.

25. Lee SJ, Astigarraga CC, Eapen M, Artz AS, Davies SM, Champlin R, Jagasia M, Kernan NA, Loberiza FR, Bevans M, Soiffer RJ, Joffe S. : Variation in Supportive Care Practices in Hematopoietic Cell Transplantation. Biol Blood Marrow Transplant 14(11): 1231-8, 2008.

26. Lee SJ, Joffe S, Artz AS, Champlin RE, Davies SM, Jagasia M, Kernan NA, Loberiza FR, Soiffer RJ, Eapen M. : Individual Physician Practice Variation in Hematopoietic Cell Transplantation. J Clin Oncol 26(13): 2162-70, 2008.

27. Mack JW, Joffe S, Hilden JM, Watterson J, Moore C, Weeks JC, Wolfe J. : Parents' Views of Cancer-Directed Therapy for Children with No Realistic Chance for Cure. J Clin Oncol 26(29): 4759-64, 2008.

28. Miller FG, Joffe S. : Benefit in Phase 1 Oncology Trials: Therapeutic Misconception or Reasonable Treatment Option? Clin Trials 5(6): 617-23, 2008 Notes: Reprinted in Miller FG. The ethical challenges of human research: selected essays. Oxford: Oxford University Press, 2012.

29. Miller FG, Mello MM, Joffe S. : Incidental Findings in Human Subjects Research: What Do Investigators Owe Research Participants? J Law Med Ethics 36(2): 271-9, 2008.

30. Peppercorn JM, Burstein H, Miller FG, Winer E, Joffe S. : Self-Reported Practices and Attitudes of U.S. Oncologists Regarding Off-Protocol Therapy. J Clin Oncol 26(36): 5994-6000, 2008.

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32. Kesselheim JC, Lehmann LE, Frumer Styron N, Joffe S. : Is Blood Thicker Than Water? The Ethics of Hematopoietic Stem Cell Donation by Biological Siblings of Adopted Children. Arch Pediatr Adol Med 163(5): 413-6, 2009.

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Results from a Survey of Pediatric Clinical Ethicists. Pediatrics 125: 742-746, 2010.

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49. Joffe S, Miller FG. : Equipoise: Asking the Right Questions for Clinical Trial Design. Nature Reviews Clin Oncol 9(4): 230-5, January 2012.

50. Kesselheim JC, Sectish T, Joffe S: Education in Professionalism: Results from a Survey of Pediatric Residency Program Directors. J Grad Med Educ 4(1): 101-105, March 2012.

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52. Denburg AE, Joffe S, Gupta S, Howard SC, Ribeiro RC, Antillon FA, Vasquez R, Sung L. : Pediatric Oncology Research in Low Income Countries: Ethical Concepts and Challenges. Pediatr Blood Cancer 58(4): 492-7, April 2012.

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al.*, Plaintiffs, v. HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	CASE NO. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF MELISSA GRANT IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

I, Melissa Grant, declare the following under 28 U.S.C. § 1746 and penalty of perjury:

1. I am the Chief Operations Officer ("COO") of FemHealth USA, Inc., which does business under the name carafem. I submit this declaration in support of Plaintiffs' motion for a temporary restraining order and/or preliminary injunction against enforcement of Section 39-15-218 of H.B. 2263/S.B. 2196 (the "Act").

2. As the COO of carafem, I am responsible for providing executive leadership and strategic direction to the organization, while ensuring the delivery of quality healthcare that is focused on the needs of the individuals we serve. I have provided day-to-day leadership of this organization for 6 years, since its inception. I have dedicated my professional career to ensuring access to safe, affordable reproductive health care services. The facts I state here are based on my supervision of carafem's staff and physicians and my review of carafem's business records, and other information and personal knowledge I have acquired in the course of my duties at

carafem. If called and sworn as a witness, I could and would testify competently to all of the facts set out in this declaration.

3. Carafem is a 501(c)(3) nonprofit organization dedicated to providing women's reproductive health services. We provide compassionate, respectful, evidence-based healthcare. Carafem operates a network of health centers, including one located in Mt. Juliet, Tennessee. In addition to its Mt. Juliet location, carafem has clinics located in Atlanta, Georgia; the Washington, D.C. metro area; and the north shore of Chicago, Illinois. Throughout this declaration, any reference to "carafem" will refer to the carafem Mt. Juliet clinic unless otherwise noted.

4. Carafem provides information and low-cost options for most methods of birth control and testing for sexually-transmitted infections, as well as medication abortion care up to and including 10 weeks and 6 days as dated from the first day of the patient's last menstrual period ("LMP") and procedural abortion care up to and including 13 weeks and 6 days LMP. We provide approximately 150 medication abortions per month at the Mt. Juliet clinic.

5. As part of our legal and ethical duties, carafem's healthcare providers—like the providers of any other healthcare service—obtain the patient's informed consent before performing any medical procedures. This means that we present a patient with medically accurate information about the medical care she is considering (that is, what the treatment involves and what she will experience); the risks and benefits of the treatment; and the alternatives available to her (including, in the context of abortion, carrying the pregnancy to term and adoption). We likewise answer any questions the patient has about the treatment and/or alternatives. Because our patients rely on us to inform them about the medical care they are considering, we take seriously our responsibility to provide them with medically accurate

information so they can make informed decisions about what is best for them. And because processing medical information can be overwhelming to a layperson without medical expertise, we focus on presenting relevant, non-extraneous facts in a straightforward manner.

6. For a patient considering abortion, part of the informed consent process involves confirming that the patient has made a firm decision to terminate her pregnancy before she commences any aspect of the abortion process. For medication abortion patients, we are careful to verify that the patient is confident in her decision to terminate the pregnancy before she takes mifepristone to begin the medication abortion regimen, and to communicate that if the patient is not certain, she should take more time and return if and when she is ready.

7. I understand that the Act would require us to tell our patients that it may be possible to "reverse" a medication abortion. In particular, I understand that the Act would require (1) that we post signs in our waiting room and consultation rooms stating in part that "[i]t may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken" and that patients should "consult with a healthcare professional immediately"; (2) that the physician who is to perform the medication abortion tell patients 48 hours before the abortion that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence," and that "[i]nformation on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website"; and (3) that we provide the patient with a written statement after administration of mifepristone containing the same text as the signs.[1] I further understand that it is a felony for our

[1] Tenn. Code Ann. §§ 39-15-218(b), (e), (f). The Department of Health has not, to my knowledge, put the required information about medication abortion "reversal" on its website.

physicians to provide medication abortions without satisfying these requirements, and that the clinic would be fined $10,000 per day for performing medication abortions without posting the required signs.

8. These requirements are deeply disturbing to carafem and its physicians. Our medical providers do not inform patients that a medication abortion is "reversible" because they counsel patients based upon reliable scientific evidence, which does not support the claim that a medication abortion can be "reversed." To the contrary, the American Congress of Obstetricians and Gynecologists ("ACOG")—the nation's leading authority in the field of women's healthcare—recently reiterated based on a review of the relevant scientific literature that there is "no evidence" to support the efficacy of treatments that purport to reverse a medication abortion, and that discontinuing the two-drug medication abortion regimen "may be associated with an increased risk of hemorrhage."[2] Why would the government compel us to say otherwise to our patients, and threaten our physicians with felony prosecution if we fail to spread this misinformation?

9. Our patients count on us to provide them not only with safe, patient-centered medical care, but also with medically accurate, relevant information. After all, most patients do not have a background in medicine, and they rightfully rely on us, as their medical provider, to give them accurate information to help them understand the medical care they are considering so they can make the right decisions for themselves. Presenting our patients with misinformation would corrupt the relationship of trust we have with our patients, and would violate our ethical duty as healthcare providers.

[2] ACOG, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1, 3 (2020).

10. More concretely, presenting inaccurate information to a patient making important medical decisions would jeopardize her ability to make a considered decision about her medical treatment, confusing and misleading her at the very time when she needs to be able to make a clear-headed, thoughtful decision. And the inaccurate speech that the government would insist that we recite—that a medication abortion is potentially "reversible"—undermines one of the core messages we seek to convey to patients in our counseling, which is that the patient should be firm in her decision to terminate before starting any aspect of the medication abortion regimen. I am concerned that the speech mandated by the Act could cause some patients to proceed with a medication abortion before they are ready under the mistaken notion that they can simply change course and "reverse" the abortion if they change their mind. Why would anyone want that to happen?

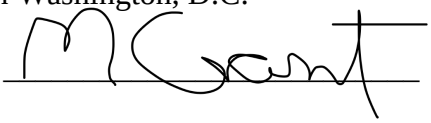
11. If the Act were to take effect, we would try to correct the misinformation the government would have us recite by informing patients that the information about medication abortion "reversal" is unsupported by science. That would be our ethical obligation as healthcare providers in order to avoid confusing or misinforming the patients we care for. But doing so would risk further confusing patients who are trying to digest a lot of new information about medical treatment. Imagine a patient who is trying to prepare for medical care being told, "please pay close attention to the information I'm about to provide you, which is critical to your health and well-being, but ignore the last thing I'm going to say, which is medically inaccurate, and please ignore the signs on our walls in the waiting room." Or "please look carefully at your discharge instructions, which give you vital health information about the medication abortion and aftercare, but note that the last page contains misinformation that you shouldn't believe." It is inevitable that this would cause confusion and anxiety, which is exactly what we want to avoid

in our patient counseling. And it would undermine the trust patients place in us as their healthcare providers.

12. Moreover, the Act requires us to post large signs promoting "reversal" treatments in waiting areas that are also used by those of our patients not seeking medication abortion. Such signs are irrelevant for them, and the language may be particularly confusing for patients seeking to obtain a procedural abortion, who may not know what a "chemical abortion utilizing mifepristone" means and whether it applies to them.

13. I am not aware of any other area of medical practice in which healthcare providers, against their medical judgment, are forced to provide scientifically unsupported information to patients or face felony prosecution, and patients must receive this false, misleading information prior to obtaining desired medical care. The Act goes against ethical healthcare practices, harms us and our patients, and damages the provider-patient relationship.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed this 31st day of August, 2020 in Washington, D.C.



Melissa Grant

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Planned Parenthood of Tennessee and North Mississippi, et al., Plaintiffs, v. Herbert H. SLATERY III, et al., Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF ASHLEY COFFIELD IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

I, Ashley Coffield, declare the following under penalty of perjury per 28 U.S.C. § 1746:

1. I am President and Chief Executive Officer ("CEO") of Planned Parenthood of Tennessee and North Mississippi ("PPTNM"), a Plaintiff in this lawsuit. I submit this declaration in support of Plaintiffs' motion for temporary and/or preliminary injunctive relief to enjoin enforcement of Tenn. Code. Ann. § 39-15-218 (effective October 1, 2020) ("the Act").

2. I have served as President and CEO of PPTNM since June 1, 2018, when PPTNM was formed through a merger between two other Planned Parenthood affiliates. Prior to the merger, I had served as President and CEO of one of those affiliates, Planned Parenthood Greater Memphis Region, since April 2013. As the CEO of PPTNM, I am responsible for the management and oversight of PPTNM's four health centers in Tennessee. I am familiar with clinic operations and patient care, including the services we provide and the communities we serve.

3. PPTNM is participating in this lawsuit on behalf of our patients, physicians, and staff because the Act would force us to give our patients—who trust us with their bodies and their

lives—false and misleading information about "reversing" a medication abortion, or else face crushing civil and criminal penalties such as felony convictions and mandatory fines of $10,000 per day.

Planned Parenthood of Tennessee and North Mississippi

4. PPTNM is a not-for-profit corporation operating health centers in Tennessee. For seventy-nine years, PPTNM and its predecessors' mission has been to provide accessible, affordable, evidence-based and high-quality reproductive healthcare. PPTNM's philosophy of care is to provide non-judgmental sexual and reproductive health care to all, ensuring patients receive unbiased, accurate, and complete information.

5. PPTNM operates four health centers: one in Nashville, one in Knoxville, and two in Memphis. All of our health centers provide a wide range of reproductive and sexual health services to patients, including services such as wellness visits (or "well-woman exams"), cancer screenings, birth control counseling, human papillomavirus ("HPV") vaccines, annual gynecological exams, pregnancy care, contraception, adoption referral, miscarriage management, and abortion care. PPTNM provides medication abortion through eleven weeks, as measured from the first day of a patient's last menstrual period ("LMP"), at three of these health centers. PP TNM also provides procedural abortions in two of these health centers. The three PPTNM health centers that provide abortion each provide more than fifty abortions per year.

PPTNM's Abortion Patients and Practice

6. Medication abortion is a method of early pregnancy termination using a combination of two medications: mifepristone and misoprostol. As medication abortion is provided at PPTNM, the patient takes the first medication, mifepristone, at the health center; the second medication, misoprostol, is generally taken twenty-four to forty-eight hours later at a place

of the patient's choosing. Medication abortion is available in Tennessee through seventy-seven days LMP.

7. So far in 2020, approximately 53% of PPTNM patients seeking an abortion at or under seventy-seven days LMP have chosen medication abortion rather than an in-clinic procedural abortion (which is also available to patients before seventy-seven days LMP, as well as later in pregnancy). Our physicians have noticed an increased rate of preference for medication abortion recently, due to the COVID-19 pandemic and the fact that medication abortion requires less in-person contact and less time at the health center than a procedural abortion.

8. As part of PPTNM's mission to provide high quality, evidence-based, and patient-centered health care, our physicians and staff strive to ensure that they give our patients the evidence-based information they need to make informed decisions about what is best for them and their families. Our physicians and staff take seriously their ethical obligation to obtain informed consent and ensure that patients are confident in their decisions prior to providing any medical service or treatment to a patient. This informed consent process includes explaining to the patient, in a clear, straightforward way, the risks, benefits, and alternatives of the procedure in question, as well as what to expect from the procedure; answering any of the patient's questions; and asking the patient questions to help elicit their preferences and facilitate the informed decision-making process.

9. During the informed consent process, our physicians never steer patients toward or against having an abortion. Nor do they steer patients toward a particular method of abortion. Our physicians' job, and their ethical responsibility, is simply to ensure that our patients receive all the information they need to make the right choices for them.

10. Most of our patients are confident in their decision when they first come to us. Before providing an abortion to any patient who chooses one, PPTNM physicians and staff always stress to the patient that she should be absolutely firm and resolute in her decision. This is true whether the patient is having a medication abortion or a procedural abortion.

11. PPTNM will not provide an abortion to a patient unless we are confident that she is resolute in her decision. If a patient says that she is unsure, or if she appears hesitant or undecided, our physicians and staff tell the patient to take more time to think about her decision and offer to reschedule the appointment for a later date. When discussing options with our patients, our physicians and staff always remind them that just because they are speaking to us about this decision does not mean that they have committed to any course of action. We also tell patients that our doors are always open to them should they choose to come back on another day. No matter what, our physicians and staff always stress to each patient that we support and respect *whatever* decision they arrive at, whether that be to obtain an abortion, to wait a while longer to make the decision, or to carry their pregnancy to term.

12. It would be unethical and contrary to PPTNM's mission and philosophy of care for PPTNM physicians or staff to give our patients medical information that is not supported by medical evidence, or information that is inaccurate or contrary to their best medical judgment.

13. Specifically, giving patients false, misleading, or inaccurate medical information impedes and undermines the informed consent and decision-making process.

14. Also, providing false, misleading, or inaccurate statements to our patients would undermine their trust in PPTNM and its medical providers. The practice of medicine relies on a relationship of trust between patients and physicians. Our patients must be able to trust that our physicians and staff will tell them the truth, will give them accurate and relevant information that

takes into account their individual medical histories, situations, values, and choices, and will help them decide what medical services, if any, are best for them. Our patients also need to trust PPTNM, our physicians, and our staff so that they feel confident enough to tell their medical providers relevant information and ask any questions they have—even information or questions that are deeply personal.

15. As explained above, PPTNM's philosophy of care is to provide non-judgmental, evidence-based sexual and reproductive health care to all. Providing unbiased, accurate, and relevant information to patients is fundamental to that philosophy. Giving patients false, misleading, or inaccurate information completely violates PPTNM's core principles as well as its physicians' and staff's ethical obligations to our patients.

The Act and Its Effects on PPTNM's Patients, Physicians, and Staff

16. I have reviewed the Act and understand that it requires physicians performing medication abortions in Tennessee to tell their patients, at least forty-eight hours prior to a medication abortion, that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and that "information on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." I understand that the department of health website, in turn, is required to post information "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind" and must provide "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion."

17. I further understand that the Act requires the following language to be displayed on a sign in any waiting room and patient consultation room utilized by patients obtaining abortions

and provided to medication abortion patients in writing alongside medical discharge instructions: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately."

18. I am deeply concerned about the effect the Act will have on our patients. Our physicians and staff always emphasize during informed consent that our patients should not proceed with an abortion unless they are absolutely certain that abortion is the right decision for them. If a patient seems at all hesitant, we counsel the patient to take more time to think about her decision and to not proceed with the abortion unless the patient is sure abortion is the right choice for her.

19. PPTNM would never want one of our patients to take mifepristone under the mistaken impression that she could change her mind afterwards, because the risk would be too great that she would take the mifepristone and effectively terminate her pregnancy before she has come to a full decision. That is simply not in the best interest of the patient.

20. As required by medical ethics and PPTNM's own values and medical standards, patients seeking medication abortion must decide that abortion is right for them *before* they start the process by taking mifepristone. They cannot initiate a medication abortion under the misunderstanding that it can be "reversed" if they change their mind later. As discussed above, PPTNM physicians and staff always tell our patients that they must be completely certain in their decision before they begin the abortion process, and specifically that they must be certain before taking the mifepristone at our health center, since mifepristone will likely end the pregnancy on its own.

21. The Act distorts this important message by forcing PPTNM's physicians to communicate to patients, at least two days before the abortion, information that falsely suggests that patients can change their minds after the medication abortion process begins.

22. I strongly object to PPTNM having to provide this kind of misleading statement, either through posters on health center walls or through communications from our physicians. It is crucial for each patient to make a full and final decision to terminate their pregnancy before they begin the medication abortion process by taking mifepristone. PPTNM and our physicians strongly object to running any risk that a PPTNM patient will initiate a medication abortion before she is ready as a result of mandatory statements indicating that the process may be "reversible."

23. Moreover, many of our waiting and counseling rooms are used by patients seeking medication abortions, procedural abortions, and non-abortion health care. The Act will force patients who are not even seeking medication abortions to see these signs. I worry that this will be particularly confusing for patients seeking procedural abortions, who may not know what a "chemical abortion utilizing mifepristone" means.

24. The Act's signage requirement includes a statement that "[r]ecent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy." I worry that such a statement is confusing and implies that "recent developing research" has shown medication abortion to be ineffective, or less effective than previously thought. Such a statement may therefore mislead patients as to the demonstrated efficacy of medication abortion. I worry that this will affect our patients' choice of abortion method based on a misunderstanding of the demonstrated efficacy of medication abortion and may, in turn, result in patients choosing procedural abortion even when medication abortion would otherwise be their preferred method. I am particularly concerned about patients being misled into choosing a procedural abortion when

medication abortion may be the preferable method for them given the COVID-19 pandemic and the increased time required in the health center for a procedural abortion appointment.

25. My understanding is that the Act's required statements are based on claims that administering progesterone to patients after they have taken mifepristone, and before they have taken misoprostol, will "reverse" the effects of mifepristone. I understand that the American College of Obstetricians and Gynecologists ("ACOG"), the preeminent professional association of OBGYNs, has rejected these claims because there is no evidence that such treatments are effective.[1]

26. I understand that ACOG has also cautioned that "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[2] This is an additional reason why it is so important that a patient be certain of her decision before starting the abortion process.

27. The Act requires PPTNM and our physicians and staff to refer patients for "information and assistance on" obtaining "reversal" treatment from the Tennessee department of health website. I do not know what information or assistance the website will provide and, to my knowledge, no such information has been posted on the department of health website yet. The only "resource" I know of that purports to provide information or referrals for "reversal" treatments is the Abortion Pill Rescue Network, which I understand is associated with Heartbeat International, an organization that opposes abortion and contraception, even for health reasons or infectious disease prevention.[3]

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[1] ACOG Practice Bulletin Number 225, Vol. 136, No. 4 (October 2020).
[2] *Id.*
[3] Abortion Pill Rescue, *Can the Abortion Pill be Reversed?*, https://www.abortionpillreversal.com/abortion-pill-reversal ("Abortion Pill Rescue is a program of Heartbeat International, Inc."); Heartbeat International, Inc., Our Commitment, https://www.heartbeatinternational.org/about/our

28. It would violate PPTNM's mission and philosophy of care, as well as our medical providers' professional ethics, to be forced by the Act to communicate that a medication abortion may be "reversible" when there is no scientific evidence to support that claim. Communicating to our patients misleading information that undermines their informed decision-making process, and directing them towards unproven treatments that may not be safe, risks subjecting our patients to harm. We oppose being forced to do this to our patients.

29. Additionally, providing medically inaccurate information to patients harms our patients' trust in PPTNM. Patients are already upset about the numerous hoops they have to jump through to obtain an abortion in Tennessee and these mandatory statements about "reversal" just add to the confusing and unnecessary barriers that our patients face. These barriers to access are extremely frustrating for our patients and for us, particularly when we are not able to justify these barriers to patients on any medical ground.

30. The penalties for violating the Act include possible felony convictions for physicians. I oppose forcing our physicians to provide misinformation or face criminal liability. Moreover, by putting physicians in such an impossible situation, I worry that the Act will make it more difficult for me to recruit and retain physicians. How many doctors will be willing to mislead and lie to patients about unproven treatments, upon threat of a possible felony conviction?

31. The Act also imposes penalties for violations on our health centers, including a possible fine of $10,000 *per day* for failing to comply with the Act's signage requirements as well as possible licensing penalties. The Act thus forces PPTNM and all of our physicians and staff to violate our foundational duty to act in the best interest of our patients.

-commitment ("Heartbeat international does not promote birth control (devices or medications) for family planning, population control, or health issues, including disease prevention.").

I declare under penalty of perjury that the foregoing is true and correct.

Dated this 31 day of August, 2020.

Ashley Coffield

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al.*, Plaintiffs, v. HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	CASE NO. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF CORINNE ROVETTI, FNP, APRN-BC
IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

I, Corinne Rovetti, FNP, APRN-BC, declare the following under 28 U.S.C. § 1746 and penalty of perjury:

1. I am a Family Nurse Practitioner and Co-Director of the Knoxville Center for Reproductive Health ("KCRH"), a non-profit reproductive health center in Knoxville, Tennessee, that has been providing high-quality reproductive health care services to patients since 1975. I submit this declaration in support of Plaintiffs' Motion for Temporary Restraining Order and/or Preliminary Injunction against Section 39-15-218 of H.B. 2263/S.B. 2196 (the "Act"). If called and sworn as a witness, I could and would testify competently to all of the facts set forth below.

2. KCRH provides a range of reproductive health services, including cancer screenings, testing and treatment for sexually transmitted infections, procedural abortion care (sometimes called "surgical abortions") up to 14 weeks and 6 days of pregnancy, as dated from

the first day of the patient's last menstrual period ("LMP"), and medication abortion care up to 10 weeks and 6 days LMP. In recent years, approximately 25–30% of the abortions we provided were medication abortions (totaling over 400 per year). During the COVID-19 pandemic, however, more patients have gravitated toward medication abortion because it involves less in-person contact than procedural abortion. Since April, approximately 60% of the abortions we have provided have been medication abortions.

3. I perform both clinical services and management and administrative functions for KCRH. In my capacity as a Family Nurse Practitioner, I provide virtually all of KCRH's routine gynecological and family planning services, such as pap smears, insertion of long-acting intrauterine contraceptive devices, and testing and treatment for sexually transmitted infections.

4. In my capacity as Co-Director of KCRH, I jointly oversee clinical operations and protocols, hire and supervise staff, engage in advocacy efforts relating to the clinic's mission and values, and take on countless other tasks—from answering phones to recordkeeping—at our small clinic to keep operations running smoothly and safely and ensure that we can continue to provide our patients with excellent care. I have spent more than three decades of my life serving KCRH's patients.

5. I am familiar with the Act's requirements that abortion providers tell medication abortion patients that a medication abortion is potentially "reversible," and I am disturbed by them. I understand that the Act would require that KCRH post signs in the waiting room and consultation rooms telling patients that "[i]t may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken" and to "consult with a healthcare professional immediately"; that we include this same text in the written discharge instructions we provide medication abortion patients; and that the

physician who performs the abortion inform the patient 48 hours in advance that "[i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence," and that "[i]nformation on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." It is my understanding that violating these requirements is a felony subjecting our physicians to years of imprisonment, and that the clinic would be fined $10,000 per day for performing a medication abortion without posting the required signs.[1]

6. These requirements are extremely troubling. We do not inform our patients that their medication abortions are potentially "reversible" and are strongly opposed to doing so because the statement is medically inaccurate, misleading, and harmful to both our patients' well-being and the relationship of trust we strive to develop with them.

7. Among our basic responsibilities as healthcare providers is to provide patients with clear, medically accurate, and relevant information so that they are able to make informed decisions about the medical treatment they are considering. Providing medically accurate information to allow patients to make the best decisions for themselves is central to our mission. One core aspect of our patient counseling is informed consent, which is the process by which we inform the patient about the medical care she is seeking (such as medication abortion); discuss alternatives available to the patient (including other abortion methods, as well as options like carrying the pregnancy to term and adoption); review the risks and benefits of these options; and answer any questions the patient has. Patients can ask questions when they initially contact the clinic; during the pre-abortion counseling; on the schedule day of their abortion; or at any point by contacting the clinic. Our counseling process is non-directive—we do not steer patients

[1] Tenn. Code Ann. §§ 39-15-218(b), (e), (f).

toward any particular pregnancy option (abortion vs. carrying to term), nor do we steer patients toward any particular abortion method. Our goal is to empower the patient with information so that she can make the decision that is best for her.

8. Providing medically inaccurate information to our patients would be utterly contrary to that goal. The information we present to patients is based on medical evidence. Patients trust us to give them accurate information so that they can make thoughtful decisions about important medical matters, and it would violate our ethical obligations as healthcare providers to make medically inaccurate statements to patients. The statements about medication abortion "reversal" compelled by the Act are not supported by medical evidence. As the American Congress of Obstetricians and Gynecologists—the leading authority in the field of women's healthcare—has determined, based on a review of the relevant medical literature, that there is no evidence to support the efficacy of medication abortion "reversal" treatments.[2] By forcing us to say otherwise to our patients—in posted signs, discharge instructions, and our physicians' own voices—or face incarceration and crippling monetary penalties, the Act puts us in an untenable position.

9. Forcing us to post signs with these statements in waiting and counseling rooms will not only misinform our medication abortion patients, but will be confusing to our patients seeking procedural (i.e., surgical) abortions. The waiting and counseling spaces at KCRH are utilized by patients seeking both types of abortion care. The required language on the sign—that it may be possible to "reverse" a "chemical abortion"—would be seen by all of our patients, leading to confusion not only among medication abortion patients but patients seeking

[2] ACOG, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1, 3 (2020).

procedural abortion care as well, who may not understand what the term "chemical abortion" refers to and may well be misled by the signage.

10. The statements compelled by the Act would not only misinform our patients, but would undermine an important message we need to communicate during our counseling—that the patient needs to be certain in her decision before starting the abortion process. We emphasize to all our patients that they must make a truly final decision to terminate the pregnancy before the abortion starts, precisely because an abortion is permanent and irreversible. For medication abortion patients, this means being resolute in their decision before we administer the first drug in the two-drug regimen, because that first step alone can and often does end the pregnancy. If a patient expresses any hesitation, we will not perform the abortion, and will instead encourage her to take the time she needs to decide what is best for her; only when a patient is certain that abortion is the right decision for her should she proceed. The disclosures mandated by the Act—forcing us to tell patients that a medication abortion is potentially "reversible"—would undercut our emphasis on the importance of decisional certainty, suggesting to patients that they can begin the medication abortion process and later reverse course and continue the pregnancy if they change their minds.

11. I am also concerned about being forced to display signs telling patients to "consult with" physicians who claim to be able to provide this unproven, experimental treatment. By compelling us to advise patients that they should consult with physicians performing medication abortion "reversal" treatments, the Act effectively makes us advertise a practice that lacks medical evidentiary support, which we—and the mainstream medical community—believe patients should avoid because it is unproven and potentially harmful. Telling patients to consult with unknown practitioners offering an experimental procedure would suggest to the patient that

we—the patient's chosen healthcare provider—think the procedure is evidence-based and the physicians performing it are doing so appropriately, when the opposite is true.

12. Indeed, we at KCRH have had a recent experience with a Tennessee practitioner offering this treatment, and it is very troubling. This summer, we received a frantic call from one of our recent medication abortion patients. Earlier that week, after pre-abortion counseling and informed consent, she was confident in her decision to terminate her pregnancy; took the first pill in the medication abortion regimen, mifepristone; and went home with the second pill and after-care instructions. But, as she explained to me on the call, when she saw a sign advertising "medication abortion reversal," something came over her and she panicked and called the number on the sign. She spoke to a physician who urged her to come in immediately, telling her the "reversal" treatment cost $300. When she informed him that she did not have that kind of money, he said that someone else might pay for some or all of it, but that she should meet with him immediately, and gave her an address. (I do not know whether she ultimately paid for some or all of the treatment).

13. She went to the address he provided, which was not a medical office but a residence. Confused, she tried calling the number back, and no one answered, nor was there a medical office answering machine or service as she would have expected. Ultimately, she went inside this man's home, where he performed an injection, instructed her not to take the second pill in the medication abortion regimen, and sent her home.

14. Shortly after the injection, she started bleeding and passing the pregnancy. She called our clinic in a panic—she was concerned about the level of bleeding, and was scared and upset that she had departed from the course of care we prescribed by getting an injection from this doctor and by not taking the second medication abortion pill. We assessed the level of

bleeding over the phone, determined that it was within a normal range, and instructed her on how to monitor her bleeding. She was reassured and expressed gratitude for our care and regret that she had contacted the physician offering "reversal" injections, describing the entirety of her experience with him—from the pressuring telephone conversation to the performance of a medical procedure in his house—as an overwhelmingly negative one. Fortunately, to my knowledge, no other patient of ours has attempted to pursue medication abortion "reversal," and no other patient has ever asked about it.

15. We should not be forced by the government to advise patients to "consult with" such practitioners, speak to patients about the practice, post signs about it on our walls, or include information about it in discharge instructions. Tennessee does not force healthcare providers in any other area of medicine to mislead their patients and disrupt the informed consent process by mandating disclosures of inaccurate information. I am dismayed that it has done so for patients seeking abortion care. Abortion patients—no less than anyone else seeking medical care in Tennessee—deserve to be able to rely on their medical provider to give them medically accurate information supported by evidence, not government-mandated misinformation.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed this 31st day of August, 2020 in Knoxville, Tennessee.

Corinne Rovetti APRN-BC

Corinne Rovetti

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, et al., Plaintiffs, v. HERBERT H. SLATERY III, et al., Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF REBECCA TERRELL IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

REBECCA TERRELL hereby declares under penalty of perjury that the following statements are true and correct:

1. I am the Executive Director of CHOICES: Memphis Center for Reproductive Health, an independent healthcare clinic in Memphis, Tennessee ("Choices Memphis" or the "Clinic"). Memphis Center for Reproductive Health, the nonprofit organization that runs Choices Memphis, is a plaintiff in this case.

2. Choices Memphis opened in Memphis in 1974. Its mission is to provide patient-centered medical care and to champion sexual and reproductive rights. This includes respecting patient autonomy, ensuring patients receive accurate, relevant, and unbiased information when making healthcare decisions, and providing care in a non-judgmental, supportive way. We serve stigmatized populations in the community and provide holistic, comprehensive reproductive

healthcare that integrates abortion and family planning care into mainstream medical practice rather than isolating those services and the patients who need them.

3. Choices Memphis provides the full spectrum of reproductive healthcare, including abortion up to 16 weeks of pregnancy (as measured from the first day of patients' last menstrual period, or "LMP"), gynecological care, birth control and family planning, testing and treatment for sexually transmitted infections, HIV testing and referrals, LGBTQ services (including hormone therapy for transgender patients), preconception counseling, pregnancy testing, pregnancy options counseling, adoption referral, ultrasound services, prenatal care, birthing and midwifery care, and postpartum care.

4. I have been the Executive Director of Choices Memphis for over ten years. As Executive Director, I oversee all aspects of the clinic's work, including day-to-day clinic operations. I supervise the medical director, director of finance and operations, and director of external affairs. I am familiar with all aspects of clinic operations and patient care.

5. We have just concluded the construction of a new health center housing the first licensed birthing center in Memphis, Tennessee, with a midwifery practice for patients seeking out-of-hospital birthing services, along with all of the other services currently provided at Choices Memphis. The new health center is currently scheduled to open this fall.

6. I am offering this declaration in support of Plaintiffs' Motion for Temporary Restraining Order and/or Preliminary Injunction against Section 39-15-218 of Tennessee House Bill 2263/Senate Bill 2196 (the "Act"), codified at Tenn. Code Ann. § 39-15-218. I understand that the Act imposes a number of speech requirements on physicians, clinics, and staff related to so-called medication abortion "reversal," including requiring our physicians to provide

government-mandated information about "reversal" to any medication abortion patient at least 48 hours prior to the abortion.

7. Choices Memphis strenuously objects to being forced to convey the mandatory disclosures required by the Act to our patients. Requiring us to inform patients about medication abortion "reversal," which is an experimental treatment unsupported by scientific or medical evidence, undermines our ability to ensure that our patients are providing informed consent; forces us to lie to and mislead patients; damages the relationship of trust that is paramount to the safe, responsible provision of healthcare; and is antithetical to our mission and values.

8. I base the facts set forth below on my experience, my extensive and close interaction with and supervision of Choices Memphis's clinicians and staff members who work directly with patients, my review of Choices Memphis's business records, and other information and personal knowledge I have acquired over the course of my time at Choices Memphis. If called and sworn as a witness, I could and would testify competently to all of the facts set out in this declaration.

Provision of Abortion Care at Choices Memphis

9. Choices Memphis provides two types of abortion care: medication abortion up to 11 weeks LMP and procedural abortion up to 16 weeks LMP.

10. Medication abortions provided at Choices Memphis use a regimen consisting of a combination of two medications: mifepristone and misoprostol.

11. In 2019, approximately 40% of the abortions performed at Choices Memphis were medication abortions. However, this percentage has gone up in 2020 to approximately 46% thus far. During the COVID-19 pandemic, more patients have opted for medication abortions, as they involve less in-person contact than procedural abortions.

12. Patients who come to Choices Memphis seeking abortion care do so for a variety of medical, familial, financial, and personal reasons. Most of our patients are already parents, and most are poor or low-income. Some patients seek abortion care because they face serious health issues that make it dangerous to carry a pregnancy to term. Others are in abusive relationships and fear for their safety.

13. As part of the Clinic's legal and ethical duties in providing healthcare, our physicians and staff obtain the patient's informed consent prior to performing any medical treatment or procedure, including but not limited to medication abortion. This includes discussing the benefits and risks of, and alternatives to, the treatment provided, and answering any questions the patient has in a clear, straightforward manner to ensure that the patient is making an informed decision about whether the treatment is right for them. We take our responsibility to provide clear, relevant, accurate medical information to patients very seriously. We do not provide any medical treatments or perform any procedures without first obtaining the patient's informed consent.

14. In addition, as part of the pre-abortion counseling process, the physicians and staff at Choices Memphis always convey to our patients the importance of being firm and confident in their decision to obtain an abortion. The vast majority of patients arrive at the clinic certain of their decision. We would never knowingly provide an abortion to a patient who was not resolved and confident that having an abortion was the right decision for them, and this includes providing mifepristone as part of a medication abortion. In the rare case that a patient expresses any ambivalence or uncertainty, we encourage the patient to take as much time as they need to make the decision that is right for them and not to undertake an abortion until they are sure. We will not provide an abortion unless and until the patient communicates that they are certain in their decision.

15. This is part of the Clinic's philosophy of providing non-judgmental healthcare. We make sure to explain all options to our patients, including different types of abortions for which the patient is eligible, adoption, and parenting, and we never tell a patient what decision they should make. For patients who choose abortion, we provide abortion care. For patients who wish to explore adoption, we refer them to adoption services. For patients who choose parenting, we offer a midwifery practice and can provide support in carrying to term and giving birth. We are committed to supporting patients in making the decisions that they have decided are best for them and their families. This approach is fundamental to the Clinic's mission and values.

The Act and its Effects

16. I understand that the Act would force our physicians providing medication abortions to inform patients at least 48 hours before providing a medication abortion to them that "(1) [i]t may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence; and (2) [i]nformation on and assistance with reversing the effects of a chemical abortion utilizing mifepristone is available on the department of health website." I understand that the department of health is required to post on its website, within 90 days of the Act's effective date of October 1, materials "designed to inform the woman of the possibility of reversing the effects of a chemical abortion utilizing mifepristone if the woman changes her mind and information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion."

17. I also understand that the Act would require Choices Memphis to "conspicuously" post signs in all patient waiting and consultation rooms used by abortion patients that state, in bold, ¾-inch font: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended

effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately." I understand that this requirement is not limited to waiting and consultation rooms used by medication abortion patients, but rather applies to waiting and consultation rooms used by any type of abortion patient.

18. I also understand that the Act requires our physicians or physicians' agents to provide written medical discharge instructions to all patients who have received mifepristone as part of a medication abortion that contain the same statement found on the required signs.

19. I understand that violations of the Act may result in felony charges for our physicians (including potential jail time), medical licensure penalties, civil liability, and fines of $10,000 per day imposed on a clinic for providing medication abortions without posting the required signage.

20. I understand that there is no medically acceptable or reliable evidence demonstrating that a medication abortion can be "reversed." According to the American College of Obstetricians and Gynecologists ("ACOG"), the leading professional organization in the nation for obstetricians and gynecologists, there is no evidence supporting medication abortion "reversal."[1] As a result, the Act would essentially force Choices Memphis, its physicians, and its staff to lie to our patients.

21. A fundamental component to the Clinic's approach to providing safe, high-quality, non-judgmental medical care involves giving our patients relevant, medically accurate information that is supported by reliable evidence. The Act contradicts this by forcing us to provide our patients

[1] ACOG, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1, 3 (2020).

with misinformation about a controversial, experimental, and unproven procedure that is not supported by sound scientific research.

22. Even worse, ACOG has cautioned that not completing the full medication abortion process (specifically, failing to take misoprostol after taking mifepristone) may be associated with increased health risks.[2] Thus, by forcing our physicians to share information about this experimental "reversal" treatment (which involves a patient taking mifepristone and then not taking misoprostol, but receiving progesterone instead) with patients and forcing the Clinic to post signs and disseminate written instructions referencing medication abortion "reversal," the Act requires us to expose our patients to potential harm, which is not only dangerous, but also undermines our responsibilities as healthcare providers to provide safe, high-quality medical care.

23. The Act also undermines our ability to obtain informed consent from our patients. As I described above, for a patient to provide informed consent to a medical treatment or procedure, the patient must receive relevant, accurate information about the treatment's risks, benefits, and alternatives. We do not provide abortions to patients unless they are certain, after receiving such information, that they are making the decision that is right for them. However, the Act would force our physicians to provide patients with misleading, unsupported information about medication abortion "reversal," which may actually create the risk that a patient will begin a medication abortion without being sure of their decision, under the mistaken impression that they can change their minds after taking mifepristone. This is dangerous and misleading because I understand that mifepristone alone is often sufficient to end a pregnancy. We would never encourage a patient to start a medication abortion before they were certain they wanted to go through with it. But that is precisely what the Act seems designed to force us to do.

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[2] *Id.*

24. Further, the mandatory disclosures required by the Act are irrelevant to our patients' decisions regarding whether or not to have an abortion. As discussed above, the mandatory disclosures are misleading and confusing, and undermine our ability to obtain informed consent from our patients. They are also particularly likely to be misleading and confusing to patients who are not even at the Clinic to obtain a medication abortion. I understand that the Act requires the "reversal" signage to be placed in all patient waiting rooms and consultation rooms used by any abortion patients, regardless of whether the patient is receiving a medication or procedural abortion. Currently, our patient waiting rooms are used by all our patients, including those seeking medical care other than abortion, and our consultation rooms are all used by patients receiving both medication and procedural abortions. Once we move to the new health center this fall, we will similarly have one waiting room for all patients, as well as some patient consultation rooms used for patients receiving both medication and procedural abortions. This means patients who are not even receiving medication abortions, and patients who are not receiving abortion care at all, will be exposed to misleading, irrelevant information that has no bearing on the care they are receiving, but nevertheless may confuse them.

25. Choices Memphis, our physicians, and our staff further object to being forced to deliver an ideological message that goes against our mission and values. Our guiding principle is that we do not judge patients, and we support them in making autonomous, fully informed healthcare decisions. By requiring us to tell patients that they can change their mind after starting the medication abortion process, the Act forces us to send the message that we do not believe in or trust their decision. I believe the required disclosures create the impression that we do not believe the patient is making the right decision, and that they will have a chance to correct that a later juncture.

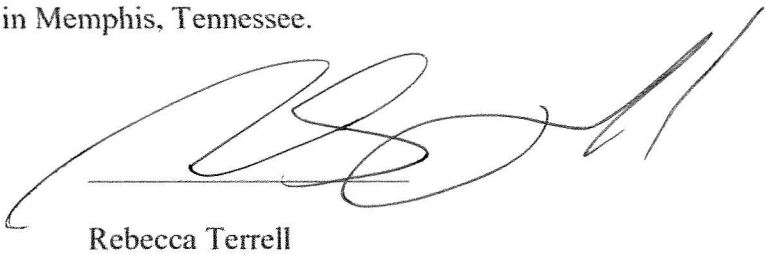
26. The Act also damages the relationship of trust between providers and patients that is fundamental to our ability to provide healthcare. Many of our patients experience stigma from other individuals and the community at large when seeking information about abortion care. It is often difficult for patients to get reliable information on their pregnancy options. Accordingly, it is vital that patients feel comfortable and confident that, when they come to Choices Memphis, they can trust that the information we are providing them is honest, accurate, and based in scientific and medical evidence. They are entitled to this information when making critical decisions around medical care. Requiring our physicians and staff to communicate information to patients that is false, misleading, harmful, and not based on science undermines our relationship of trust with our patients. How can our patients trust us if we must provide them information about an experimental treatment that is not based in scientific evidence, and worse still, may be affirmatively harmful to them?

27. My staff and I strongly object to being compelled to provide our patients with a government-mandated message about medication abortion "reversal" with which we, and the mainstream medical community, disagree. We believe this message is inaccurate, misleading, and potentially harmful to patients. We are here to support our patients in obtaining the healthcare they want and need, and requiring us to mislead them by providing them information unsupported by scientific evidence goes against everything that we stand for an as organization.

28. I know of no other type of medical care in which providers are forced, against their medical judgment, to provide information that is false, misleading, potentially harmful, and not based in scientific evidence to their patients, and patients are forced to receive this information as a prerequisite to obtaining the medical care they want and need.

29. Because the penalties for not complying with the Act include criminal and licensure penalties, civil liability, and fines, the Act puts the Clinic, its physicians, and its staff in the untenable position of either lying to our patients and exposing them to potential harm, or subjecting our physicians to possible jail time, licensure penalties, and civil liability and the Clinic to monetary penalties for violating the Act.

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed this 1st day of September, 2020 in Memphis, Tennessee.



Rebecca Terrell

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

Planned Parenthood of Tennessee and North Mississippi; *et al*., Plaintiffs, v. Herbert H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	Case No. 3:20-cv-00740 JUDGE CAMPBELL

DECLARATION OF AUDREY LANCE, M.D., M.S.,
IN SUPPORT OF PLAINTIFFS' MOTION FOR
TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION

Audrey Lance, M.D., M.S., declares the following under penalty of perjury:

1. I am a Plaintiff in this lawsuit and submit this declaration in support of Plaintiffs' motion for temporary and/or preliminary injunctive relief to enjoin enforcement of Tenn. Code Ann. § 39-15-218 (effective October 1, 2020) ("the Act").

2. I am a board-certified obstetrician/gynecologist ("OBGYN"). I am licensed to practice in Tennessee, Michigan, and Pennsylvania. I have been practicing medicine for over thirteen years and have been providing abortion care for over ten years. I have been providing abortions, including medication abortions, to patients at Planned Parenthood of Tennessee and North Mississippi ("PPTNM") since January 2019.

3. The Act puts me in the impossible situation of having to violate my ethical obligation to my patients and my values and principles as a physician, upon threat of being charged with a Class E felony and/or facing other civil liability or licensure penalties.

My Background

4. I obtained my medical degree from the George Washington University School of Medicine in 2007. I completed my residency at the University of Michigan Health System, Ann Arbor in the Department of Obstetrics and Gynecology in 2011, and a fellowship in Family Planning at the University of Michigan Health Center, Ann Arbor in 2013. I received a Master of Science in Health and Health Services Research from the University of Michigan, Ann Arbor in 2013. I have been a board-certified OBGYN since 2013.

5. I served as the Director of the Ryan Residency Training Program in Abortion and Family Planning at Magee-Womens Hospital of the University of Pittsburgh Medical Center ("UMPC") from July 2014 to September 2018. I taught at Magee-Womens Hospital as an Assistant Professor from 2013 to 2018 and served as Director of its outpatient clinic from May 2016 to September 2018. I have also taught as a Clinical Lecturer at the University of Michigan School of Medicine.

6. I am a member of a number of professional associations, including the American College of Obstetricians and Gynecologists ("ACOG"), where I am a fellow; the Society of Family Planning ("SFP"), where I am a junior fellow; the Association for Reproductive Health Professionals; the American Society of Reproductive Medicine; the Norman F. Miller Gynecologic Society at the University of Michigan; and the National Abortion Federation. I am also a reviewer for several journals including *Obstetrics & Gynecology*, the *International Journal for Gynecology & Obstetrics*, *Contraception*, and *MedEd Portal*.

7. I base the opinions herein on my personal knowledge; my background, training, and expertise in the field of obstetrics and gynecology and abortion in particular; and my experience providing reproductive health care, including abortion care, to my patients.

8. My curriculum vitae is attached hereto as Exhibit A.

My Abortion Patients and Practice

9. Patients seek abortions for any number of reasons, including familial, financial, personal, medical, and emotional reasons. Many of my patients already have children. Some patients simply feel that now is not the right time to become a parent. Some of my patients do not wish to become a parent at all.

10. Generally, abortion patients within eleven weeks (77 days) from the start of their last menstrual period ("LMP")[1] can choose between medication abortion and procedural abortion.

11. Medication abortion generally involves a two-drug regimen: mifepristone, which is provided at a health center, followed by misoprostol, which is taken later, at a location of the patient's choosing (often their home).

12. Taken alone, the mifepristone administered as part of a medication abortion will terminate a significant percentage of pregnancies, but not all.[2] Taken together, the two-drug medication abortion regimen is highly effective at terminating a pregnancy.

13. As mentioned above, patients who are within eleven weeks of pregnancy generally have the option of either medication abortion or procedural abortion. Some patients prefer medication abortion because it feels less invasive and more natural than procedural abortion, and because completing the process at home allows them more privacy and control. In particular, patients with a history of sexual trauma may strongly prefer medication abortion in order to avoid the emotional distress that may result from having instruments inserted vaginally, as would be necessary for a procedural abortion. I have also cared for many patients in abusive relationships,

[1] In the medical context, pregnancy is measured from the first day of a patient's LMP.
[2] David Grossman & Kari White, *Abortion "Reversal" — Legislating Without Evidence*, 379(16) N. Eng. J. Med. (2018) 1491, 1491-1492 (noting studies documenting rates of continuing pregnancy after taking mifepristone alone at 8%-46%).

who prefer medication abortion because it is more private and thus may be less likely to subject them to further abuse. And for some patients with certain medical conditions, which would make a procedural abortion difficult, medication abortion may be medically preferable.

14. Providing high quality, evidence-based, and patient-centered health care to my patients is core to my values and principles and I take seriously my ethical obligations to my patients.

My Abortion Practice

15. Consistent with my values and ethical obligations, I obtain my patients' informed consent for any medical care I provide them, including medication abortions.

16. I consider the informed consent process to be essential to the ethical practice of medicine. The informed consent process ensures that my patients can make informed decisions about their health care and choose what is right for them.

17. As part of the informed consent process, I provide my patients with evidence-based, relevant information about the risks and benefits of any treatment or procedure under consideration, as well as the risks and benefits of the alternatives. Thus, for my patients seeking abortion care, I provide them with information about the risks and benefits of the different methods of abortion, as well as childbirth. I also discuss with them the alternatives to abortion (parenting and adoption).

18. During this process, I exercise my best medical judgment in determining how to provide accurate, relevant information to my patients to ensure that they understand it and can use it to inform their decision-making process.

19. Trust between me and my patients is crucial, both for ensuring that I can provide them with the best medical care and for facilitating informed consent. My patients need to be able to trust me enough to reveal their private medical information to me and ask me personal or

uncomfortable questions. My patients also need to be able to trust that I am giving them accurate, evidence-based information and medical advice that is in their best interests. My patients' decisions are theirs alone to make, and they need to be able to trust me to provide them with the information they need to make that decision in an informed way.

20. Before providing an abortion to any patient, I always stress to the patient that she should be absolutely firm and resolute in her decision, whether she is having a medication or procedural abortion.

21. Most of my patients are confident in their decisions when they first come to me. If any patient expresses any doubt or seems hesitant, I tell them that they need to be confident in their decision before they start, and so they should take more time.

22. I never provide an abortion for a patient unless I am confident that they have come to a full and informed decision that this is the best option for them.

23. No matter what, I always stress to each patient that I support and respect *whatever* decision they arrive at, whether that be to obtain an abortion, to wait a while longer to make their decision, or to carry their pregnancy to term.

24. It would be unethical for me to give a patient medical information that is contradicted or unsupported by medical evidence, or information that I do not believe is accurate based on my training, experience, and medical judgment.

25. I would also consider it unethical to communicate statements to my patients that I believe are likely to mislead them, particularly if such statements may mislead them in a way that interferes with their informed decision-making.

26. Finally, I would consider it misleading to direct my patients to any medical treatment that was not demonstrated to be safe or effective.

The Act

27. I have reviewed Tenn. Code. Ann. § 39-15-218.

28. I understand that the Act requires that, prior to providing any patient with a medication abortion, a physician must, at least 48 hours earlier, inform the patient that "[i]t may be possible to reverse the intended effects of a chemical abortion" and that "[i]nformation on and assistance with reversing the effects of a chemical abortion . . . is available on the department of health website." [3]

29. In addition, I understand that the Tennessee Department of Health is required, within ninety days of the Act's effective date, to publish information on its website "designed to inform the woman of the possibility of reversing the effects of a chemical abortions utilizing mifepristone" and is required to provide "information on and assistance with the resources that may be available to help reverse the effects of a chemical abortion."[4] I understand that the Department of Health has not yet published these materials on their website.

30. I also understand that the Act requires that any clinic providing more than fifty "elective" abortions in the previous calendar year must post a sign in all waiting rooms and patient consultation rooms used by patients obtaining abortions that states: "Recent developing research has indicated that mifepristone alone is not always effective in ending a pregnancy. It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken. Please consult with a healthcare professional immediately."[5]

[3] Tenn. Code Ann. § 39-15-218(e).
[4] Tenn. Code Ann. § 39-15-218(h).
[5] Tenn. Code Ann. § 39-15-218(b).

31. I understand that the Act requires this same statement be provided to medication abortion patients in writing upon discharge.[6]

32. Finally, I understand that a violation of the Act is Class E felony and may subject physicians to civil liability and potential licensure penalties.[7] I further understand that under the Act, medical facilities may be fined $10,000 per day for noncompliance.[8]

The Act and its Effects on My Practice and Patients

33. I am deeply concerned about the effect the Act will have on my patients.

34. I am concerned the Act will force me to provide inaccurate and misleading information to patients that is not relevant to their decision to have an abortion, and that this will undermine their trust in me as a physician.

35. I am also deeply concerned that the Act's mandated communications will mislead my patients into believing that, contrary to what I have emphasized to them, they do not need to be confident in their decision at the time they take the mifepristone, under the mistaken understanding that they can "reverse" the procedure later. This creates a risk of harm to my patients that is simply unacceptable.

36. I am also gravely concerned that the Act will force me to direct my patients to treatments that have not been demonstrated to be safe or effective.

37. I am familiar with the theory behind so-called medication abortion "reversal" treatments: that large doses of a progestin medication administered after a patient takes mifepristone but before the patient takes misoprostol may "reverse" the effects of mifepristone, which is a progesterone antagonist. I know of no evidence to support this theory and that "reversal"

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[6] Tenn. Code Ann. § 39-15-218(f).
[7] Tenn. Code Ann. §§ 39-15-218(j), (l).
[8] Tenn. Code Ann. § 39-15-218(k).

treatments have not been demonstrated to have any effect on continuing rates of pregnancy after mifepristone ingestion. No randomized controlled trials have been conducted that demonstrate the safety or effectiveness of "reversal" treatments.

38. I am aware that ACOG, the leading professional association of OBGYNs, has concluded based on the evidence that "there is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing."[9]

39. I do not personally know any physicians that offer medication abortion "reversal" treatments. This is not surprising, given that it is not a treatment that is accepted by the mainstream medical community.

40. The only randomized controlled study of the effect of progesterone after mifepristone is taken and before misoprostol is taken was halted due to safety concerns raised when three participants experienced severe hemorrhage requiring hospital transport.[10]

41. After review of this study, ACOG has advised that "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[11]

42. I strongly object to being forced to provide my patients with untruthful, misleading statements about abortion "reversal," which is not relevant to their decision-making; being forced to provide information that is going to confuse and possibly mislead my patients, undermining their informed decision-making; and being forced to direct my patients to unproven treatments that

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[9] ACOG, *Practice Bulletin Number 225*, 136 Obstetrics & Gynecology 1, 3 (2020) (Oct. 2020) (hereinafter "ACOG/SFP Guidelines").
[10] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medication Abortion: A Randomized Controlled Trial*, 135 Obstetrics & Gynecology 158, (Jan. 2020).
[11] ACOG/SFP Guidelines, *supra* n.9, at 3.

may be unsafe. I strongly object to being forced to do these things under threat of criminal prosecution.

43. I take my obligations to my patients very seriously. The Act would force me to either risk criminal, civil, and licensure penalties or violate my core principles and ethical obligations to be honest with my patients, to do what is in their best interest, and to "do no harm" to them.

44. I am aware of no other field in healthcare where healthcare providers are required to communicate false or misleading statements to patients, or direct patients towards unknown treatments with no basis in medical evidence and which have not been demonstrated to be safe.

Dated: August __, 2020

Audrey Lance, M.D., M.S.

EXHIBIT A

Audrey A. Lance, MD, MS, FACOG

Education and Training

Undergraduate:

August 1999 - August 2000	Michigan State University, East Lansing, MI
September 2000 - April 2003	BA in Women's Studies, With Distinction University of Michigan, Ann Arbor, MI

Graduate:

August 2003 - May 2007	MD George Washington University School of Medicine, Washington, D.C.
July 2004	Medical Students for Choice Reproductive Health Externship, Johns Hopkins Bayview Medical Center and Planned Parenthood of Baltimore and Annapolis

Postdoctoral Training:

July 2007 - June 2011	Residency - Department of Obstetrics and Gynecology, University of Michigan Health System, Ann Arbor,
July 2011 – June 2013	Fellowship in Family Planning - Department of Obstetrics and Gynecology, University of Michigan Health System, Ann Arbor, MI
July 2011 – June 2013	Master of Science in Health and Health Services Research Rackham Graduate School, University of Michigan, Ann Arbor, MI
October 2012 – May 2013	Physicians for Reproductive Health – Leadership Training Academy
May 2016	Physicians for Reproductive Health – Leadership Training Academy Alumni Course
July 2016	AAMC Early Career Women Faculty Professional Development Seminar, Englewood, CO

Certification and Licensure

July 2007 – Present	Certified – Basic Life Support (BLS)
September 2018 – Present	Certified – Advanced Cardiac Life Support (ACLS)
July 2011 – Present	DEA Controlled Substance License

November 2013 – Present	Board Certification: American Board of Obstetrics & Gynecology
May 2013 – Present	Commonwealth of Pennsylvania Permanent Medical License
July 2011 – December 2014	State of Michigan Permanent Medical License
August 2018 - Present	State of Michigan Permanent Medical License
November 2018 – Present	State of Tennessee Medical License

Clinical, Academic, and Administrative Appointments

Clinical:

June 2012 – June 2013	Staff Physician – Planned Parenthood of Mid and South Michigan, Ann Arbor, MI
August 2013 – Sept 2018	Staff Physician – Planned Parenthood of Western Pennsylvania, Pittsburgh, PA
August 2018 – Present	Maven Physician – MavenClinic.com
October 2018 – Present	Staff Physician – Northland Family Planning Centers, Michigan
December 2018 – Present	Staff Physician – Planned Parenthood of Tennessee and Northern Mississippi
April 2019 – Present	Clinical privileges at Detroit Medical Center
September 2019 – Present	Physician with Simple Health, Inc

Academic:

July 2011 – June 2013	Clinical Lecturer – Department of Obstetrics and Gynecology, University of Michigan Medical School, Ann Arbor, MI
August 2013 – Sept 2018	Assistant Professor – Department of Obstetrics, Gynecology & Reproductive Sciences, Magee-Womens Hospital of UPMC, Pittsburgh, PA
August 2013 – Sept 2018	Co-Investigator – Center for Family Planning Research, Magee-Womens Hospital of UPMC, Pittsburgh, PA

Administrative:

July 2014 – Sept 2018	Director – Kenneth J. Ryan Residency Training Program in Abortion and Family Planning, Magee-Womens Hospital of UPMC, Pittsburgh, PA

May 2016 – Sept 2018 Medical Director – Magee-Womens Hospital Outpatient Clinic, Magee-Womens Hospital of UPMC, Pittsburgh, PA

Grants

Past:

Sponsor: Dr. Barnett A. Slepian Memorial Fund
Title: Clinical Abortion Training Grant
Grant Recipient: Audrey A. Lance
Dates: June 2004 – July 2004
Funding Amount: $2,000

Sponsor: Milton Goldrath Resident Research Award
Title: Predictors of patient use and continuation of highly effective post-partum contraception
Principal Investigator: Audrey A. Lance, MD, MS
Co-Investigators: Vanessa Dalton, MD, MPH and Jamie McGuire, MD
Dates: January 2009 – July 2013
Funding Amount: $2,000

Sponsor: Society of Family Planning Research Fund
Title: Can *16 and Pregnant* affect attitudes towards teen pregnancy among young women? A randomized controlled trial
Principal Investigator: Audrey A. Lance, MD, MS
Co-Investigators: Lisa Harris, MD, PhD, Vanessa Dalton, MD, MPH
Dates: April 2012 – July 2013
Funding amount: $70,000

Sponsor: Kenneth J. Ryan Residency Training Program in Abortion & Family Planning
Title: Ryan Residency Training Program Grant – University of Pittsburgh
Principal Investigator: Audrey A. Lance, MD, MS
Dates: July 2014 – June 2015
Funding Amount: $ 283,587

Sponsor: Kenneth J. Ryan Residency Training Program in Abortion & Family Planning
Title: Ryan Residency Training Program Grant – University of Pittsburgh
Principal Investigator: Audrey A. Lance, MD, MS
Dates: July 2015 – June 2016
Funding Amount: $ 246,665

Honors and Awards

September 2003 Dr. Bernard and Mildred S. Katzen Medical Education Award, George Washington University School of Medicine

2004	Arnold P. Gold Foundation Humanism in Medicine Honor Society, George Washington University School of Medicine
October 2006	Edith SeVille Coale Award – Zonta Club of Washington D.C.
May 2007	Rachel Morris Dominick Award for Excellence in Obstetrics & Gynecology, George Washington University School of Medicine, Department of Obstetrics & Gynecology
2008	Wyeth Pharmaceuticals New Leaders Award (Scholarship to Association of Reproductive Health Professionals Annual Meeting)
2009	Dr. Milton Goldrath Resident Research Award, University of Michigan Department of Obstetrics & Gynecology
2011	Golden Pen Award, University of Michigan Department of Obstetrics & Gynecology
May 2011	Best Consultant Award, University of Michigan Certified Nurse Midwife Service
2012 - 2013	National Institutes of Health (NIH) Extramural Loan Repayment Program Award in Contraception & Infertility Research
2007-2012	Five-time recipient of Making a Difference Award, University of Michigan Health System, Ann Arbor, MI
July 2016	AAMC Early Career Women Faculty Professional Development Seminar
September 2016	AAMC Medical Education Research Certificate Program – University of Pittsburgh
June 2017	MyTip Award – University of Pittsburgh OB/GYN Residency Program
June 2018	MyTip Award – University of Pittsburgh OB/GYN Residency Program

Membership in Professional Societies

2003 – Present	Medical Students for Choice
2005 – Present	Association of Reproductive Health Professionals
2006 – 2013	American College of Obstetricians & Gynecologists Junior Fellow
2011 – Present	American Society of Reproductive Medicine
2011 – Present	Society of Family Planning (currently Junior Fellow)
2011 – Present	Norman F. Miller Gynecologic Society, University of Michigan
2012 – Present	Physicians for Reproductive Health
2012 – Present	National Abortion Federation
2013 – Present	American College of Obstetricians & Gynecologists Fellow

Editorial Positions, Boards, and Peer-Review Service

2006 – 2007	Board of Directors – Medical Students for Choice
2012 – Present	Reviewer - International Journal of Gynecology & Obstetrics (IJGO)
January 2014 – Present	Reviewer - Obstetrics & Gynecology
February 2014 – Present	Emmi Solutions Medical Advisory Board
February 2014 – Present	Nexplanon® Clinical Training Faculty (Merck)
May 2015	Magee-Womens Hospital OB/GYN Resident & Fellow Research Day Poster Judge

May 2016 – Present	Reviewer – Contraception
Sept 2017 – Present	Reviewer – MedEd Portal

Teaching

University of Michigan

July 2011 – June 2013	Obstetrics & Gynecology 3rd Year Clerkship – clinical teaching. University of Michigan Medical School, Ann Arbor, MI.
November 15, 2011	"Values Clarification." University of Michigan Medical Students for Choice, Ann Arbor, MI.
March 14, 2012	"Ectopic Pregnancy". University of Michigan Obstetrics and Gynecology Resident Core Curriculum, Ann Arbor, MI.
March 12, 2012	"Health Services for Early Pregnancy Failure: Using Women's Treatment Preferences to Improve Quality". Women's Studies 400: Women's Health, University of Michigan, Ann Arbor, MI.
March 13, 2012	"Contraceptive Myth-Busting". University of Michigan Medical Students for Choice, Ann Arbor, MI.
April 9, 2012	"Women's Healthcare Provider Panel". Women's Studies 400: Women's Health, University of Michigan, Ann Arbor, MI.
April 2012	"Introduction to Laparoscopy". Simulation laparoscopy lab for visiting Ghanaian medical students. University of Michigan, Ann Arbor, MI.
Aug 2012 – June 2013	"Contraception & Abortion". Third-year Medical Student OB/GYN Clerkship Lecture, University of Michigan Medical School, Ann Arbor, MI; Recurring lecture every 8 weeks.
August 22, 2012	"Contraception". University of Michigan Obstetrics and Gynecology Resident Core Curriculum, Ann Arbor, MI.
November 14, 2012	"Difficult Pregnancies: Miscarriage, Stillbirth, Prematurity, Delivery. Who is the Patient? Legal Ideas of Autonomy and Medical Ideas of Beneficence." Women's Studies 432: University of Michigan, Ann Arbor, MI.
December 13, 2012	"Values Clarification." University of Michigan Medical Students for Choice, Ann Arbor, MI.
March 12, 2013	"Contraceptive Myth-Busting". University of Michigan Medical Students for Choice, Ann Arbor, MI.
March 12, 2013	"Contraception". Second-year Medical Student Reproduction Sequence, University of Michigan Medical School, Ann Arbor, MI.
March 18, 2013	"Medical Facts of Abortion". Second-year Medical Student Reproduction Sequence, University of Michigan Medical School, Ann Arbor, MI.
March 26, 2013	"Contraception". Fourth-year Medical Student "OB/GYN Boot Camp", University of Michigan Medical School, Ann Arbor, MI.

International

September 2012	"Sexually Transmitted Diseases & Pelvic Inflammatory Disease." Millennium Medical College, Addis Ababa, Ethiopia.
September 2012	"First Trimester Abortion and Post-Abortion Care". Millennium Medical College, Addis Ababa, Ethiopia.
September 2012	"Uterine Fibroids: Diagnosis and Treatment". Millennium Medical College, Addis Ababa, Ethiopia.
September 2012	"Contraception & Family Planning". Millennium Medical College, Addis Ababa, Ethiopia.
September 2012	"Contraception & Family Planning." Hayat Medical School, Addis Ababa, Ethiopia.

University of Pittsburgh

August 2013 – 2018	Obstetrics & Gynecology 3rd Year Clerkship – clinical teaching. University of Pittsburgh School of Medicine, Pittsburgh, PA.
October 2013 – 2018	Family Planning Fellow Didactic Education, University of Pittsburgh Fellowship in Family Planning, Pittsburgh, PA. Participate in didactic education sessions every 2 weeks.
October 11, 2013	"Endometrial Procedures Workshop." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
October 2013 - 2018	"Medical Facts of Abortion". Third-year Medical Student OB/GYN Clerkship, University of Pittsburgh, Pittsburgh, PA. Recurring lecture 4 times per year.
October 31, 2013	"Values Clarification". Magee-Womens Hospital of UPMC Obstetrics and Gynecology Resident Core Curriculum, Pittsburgh, PA.
November 2013 –2018	Responsible for weekly Gynecology Resident evaluations for the Division of Gynecologic Specialties, Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency, Pittsburgh, PA.
January 2014 - 2018	Practice-Based Learning Facilitator for OB/GYN 3rd year Clerkship; University of Pittsburgh School of Medicine, Pittsburgh, PA. Recurring small-group sessions 8 times per year.
January – April 2014	Behavioral Medicine Course Small Group Facilitator (required course for 1st year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 2014 - 2017	Reproductive and Developmental Biology Course Small Group Facilitator (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February – June 2014	Didactic teaching in abortion & contraception one hour per week with residents on their family planning rotation, Magee-Womens Hospital of UPMC, Pittsburgh, PA.
February 11-12, 2014	Breast & Pelvic Exam Small Group Instructor (required physical exam course for 2nd year medical students) University of Pittsburgh School of Medicine, Pittsburgh, PA.

May 2014 – Sept 2018	Gynecology Resident Oral Exams (exam given during inpatient gynecology rotation). Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency, Pittsburgh, PA. Exams given to 1st & 2nd year residents 3 times per year.
June 2014	Developed Family Planning curriculum (didactic and simulation training) for the Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency, Pittsburgh, PA.
July 2014 – June 2018	Official Academic Mentor for Dr. Kavita Vani, Obstetrics & Gynecology Resident, Magee-Womens Hospital, Pittsburgh, PA.
July 2014 – 2018	Didactic teaching in abortion & contraception two hours per week with residents on their family planning rotation. Magee-Womens Hospital of UPMC, Pittsburgh, PA.
July 2014 – 2018	Simulation training in D&C and D&E every 5 weeks with residents on their family planning rotation. Magee-Womens Hospital of UPMC, Pittsburgh, PA.
July 10, 2014	"Contraception Fundamentals". Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
Sept 2014 – June 2015	"Emergency Contraception & First Trimester Abortion". University of Pittsburgh Internal Medicine Women's Health Track Resident Core Curriculum, Pittsburgh, PA. Recurring lecture every 8 weeks.
September 12, 2014	"Endometrial Procedures & Verbal Anesthesia Workshop." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
September 18, 2014	"Contraceptive Implant Training". Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
November 10, 2014	"IUD Workshop." University of Pittsburgh Medical Students for Choice, Pittsburgh, PA.
November 14, 2014	"Contraception Workshop." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
January 22, 2015	"Contraception Myths." University of Pittsburgh School of Medicine OB/GYN Interest Group, Pittsburgh, PA.
February 5, 2015	"Salpingectomy for Sterilization." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum Journal Club, Pittsburgh, PA.
February 10, 2015	"OB/GYN Provider Panel". University of Pittsburgh OB/GYN Interest Group, Pittsburgh, PA.
February 12, 2015	"The Papaya Model: Learning Manual Vacuum Aspiration" University of Pittsburgh Medical Students for Choice, Pittsburgh, PA.
February 16, 2015	"Contraception." Reproductive and Developmental Biology Course (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 17, 2015	"Spontaneous & Induced Abortion." Reproductive and Developmental Biology Course (required course for 2nd year medical

	students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 18 & 25, 2015	Breast & Pelvic Exam Small Group Instructor (required physical exam course for 2nd year medical students) University of Pittsburgh School of Medicine, Pittsburgh, PA.
July 2015 – 2018	Family Planning Journal Club - Founder. Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency, Pittsburgh, PA. (Family Planning division holds journal club ~3 times per year).
July 2, 2015	"Contraceptive Implant Training". Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
September 17, 2015	"Contraception Fundamentals". Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
October 23, 2015	"Contraception Workshop." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
November 20, 2015	"Endometrial Procedures & Verbal Anesthesia Workshop." Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
January 2016	Advanced Medical Interviewing (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 10, 2016	"The Papaya Model: Learning Manual Vacuum Aspiration & IUD Insertion" University of Pittsburgh Medical Students for Choice, Pittsburgh, PA.
February 15, 2016	"Contraception." Reproductive and Developmental Biology Course (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 16, 2016	"Spontaneous & Induced Abortion." Reproductive and Developmental Biology Course (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 16, 2016	"Contraception Myths." University of Pittsburgh School of Medicine OB/GYN Interest Group, Pittsburgh, PA.
April 4, 2016	"Values Clarification Workshop" University of Pittsburgh Medical Students for Choice, Pittsburgh, PA.
April 28, 2016	"Postpartum Tubal Ligation" University of Pittsburgh, OB Anesthesia Fellowship Lecture Series, Pittsburgh, PA
July 28, 2016	"Contraception: Management of Challenging Scenarios, Side Effects, & Complications", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
August 19, 2016	"Contraception Workshop", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.

November 29, 2016	"Contraception: Management of Challenging Scenarios, Side Effects, & Complications" University of Pittsburgh Student Health, Pittsburgh, PA
Nov 2016 – June 2017	"Emergency Contraception & First Trimester Abortion". University of Pittsburgh Internal Medicine Women's Health Track Resident Core Curriculum, Pittsburgh, PA. Recurring lecture every 8 weeks.
November 18, 2016	"How to function in the clinic", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
November 18, 2016	"Endometrial Procedures Workshop", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
December 8, 2016	"Post-placental IUD training workshop", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
February 13, 2017	"Contraception." Reproductive and Developmental Biology Course (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 13, 2017	"The Papaya Model: Learning Manual Vacuum Aspiration" University of Pittsburgh Medical Students for Choice, Pittsburgh, PA.
February 14, 2017	"Spontaneous & Induced Abortion." Reproductive and Developmental Biology Course (required course for 2nd year medical students). University of Pittsburgh School of Medicine, Pittsburgh, PA.
February 27, 2017	Breast & Pelvic Exam Small Group Instructor (required physical exam course for 2nd year medical students) University of Pittsburgh School of Medicine, Pittsburgh, PA.
April 27, 2017	"Postpartum Tubal Ligation" University of Pittsburgh, OB Anesthesia Fellowship Lecture Series, Pittsburgh, PA
June 22, 2017	"Contraception: Management of Challenging Scenarios, Side Effects, & Complications", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Resident Core Curriculum, Pittsburgh, PA.
August 18, 2017	"Contraception Workshop", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
September 15, 2017	"How to function in the clinic and work effectively as a team", Magee-Womens Hospital of UPMC Obstetrics & Gynecology Residency Intern Education Series, Pittsburgh, PA.
January – February 2018	Development of Physician Advocacy Mini-Elective for MS1 & MS2. University of Pittsburgh School of Medicine, Pittsburgh, PA. Curriculum development and Course Director.

Mentorship Activities

June – July 2014	Dr. Nicole Falls, OBGYN Resident at Magee-Womens Hospital of UPMC – Mentor for Grand Rounds Presentation on Postpartum Sterilization
June – July 2016	Dr. Jessica Rose, OBGYN Resident at Magee-Womens Hospital of UPMC – Mentor for Grand Rounds Presentation on Manual Vacuum Aspiration
December 2016 – Present	Tejasvi Gowda, University of Pittsburgh Medical Student Mentor for medical school scholarly research project
June – July 2017	Dr. Misha Pangasa, OBGYN Resident at Magee-Womens Hospital of UPMC – Mentor for Grand Rounds Presentation on the ACA
August 2017 – Sept 2018	Colleen Judge, University of Pittsburgh MD/PhD Student Clinical Mentor for longitudinal clinical experience
August 2017 – June 2018	FAST (Faculty & Students Together) Advising – University of Pittsburgh Medical School

Committee, Organizational and Volunteer Service

University of Michigan

2010 – 2011	Residency Advisory Committee, University of Michigan Obstetrics & Gynecology Residency Program, Ann Arbor, MI
2011 – 2013	Faculty Advisor – Medical Students for Choice, University of Michigan Chapter, Ann Arbor, MI
2011 – 2013	Fetal Loss Committee & Task Force on Education, University of Michigan Health System, Ann Arbor, MI
2011 – 2013	Fellowship Advisory Committee, University of Michigan Department of Obstetrics & Gynecology, Ann Arbor, MI
2011 – 2013	University Hospital Adult Ethics Committee, University of Michigan Health System, Ann Arbor, MI

George Washington University

2004 – 2005	Chapter Coordinator - Medical Students for Choice, George Washington University School of Medicine, Washington, D.C.
2004 – 2007	Founder & Co-President, Sexual Violence Awareness Group, George Washington University School of Medicine, Washington, D.C.

University of Pittsburgh

2014 – 2018	Multidisciplinary Emergency Service Committee, Magee-Womens Hospital of UPMC, Pittsburgh, PA

2014 – 2018	Faculty Advisor – Medical Students for Choice, University of Pittsburgh Chapter, Pittsburgh, PA
2016 – 2018	Clinic Improvement Committee
2017 – Present	Family Planning Fellowship Guide to Learning Revision Committee
2017	North American Forum on Family Planning's Scientific Abstract Committee
2017 – 2018	Reproductive Bridges Coalition of Pittsburgh Founding Member

Regional

2004 – 2005	Region 9 Coordinator – Medical Students for Choice
2016 – 2018	Council Member, Pennsylvania Section of American College of Obstetricians & Gynecologists

National

2006 – 2007	National Coordinator – Medical Students for Choice
2006 – 2007	Fundraising & Nominating Committee Members, Medical Students for Choice Board of Directors

International

July-August 2002	HIV/AIDS Educator – South African Red Cross
September 2012	Family Planning Educator - St. Paul's Hospital & Millennium Medical College, Addis Ababa, Ethiopia

Volunteer Service

2000 – 2001	Peer Education Volunteer, University of Michigan Sexual Assault Prevention and Awareness Center, Ann Arbor, Michigan
2002	Health Educator, Washtenaw County Jail, Ann Arbor Michigan
2004 – 2007	Crisis Hotline Volunteer – Sexual Assault Response & Awareness Program, Alexandria Office on Women, Alexandria Virginia

Visiting Professorships & Extramural Invited Presentations

April 2006	"Filling the Gap: Abortion Education Throughout Medical Training". American Medical Student Association 56th Annual Convention.
June 2005	"On Being a Pro-Choice Medical Student". National Gloria Steinem Leadership Institute. Washington, D.C.
June 14, 2006	"Access to Abortion Services: Where Are We Now and Where Are We Headed?" National Family Planning and Reproductive Health Association (NFPRHA) 33rd National Conference. Washington, D.C.
July 2006	"On Being a Pro-Choice Medical Student". National Gloria Steinem Leadership Institute. Washington, D.C.
November 2008	"The Papaya Model: Learning Manual Vacuum Aspiration". Medical Students for Choice National Conference, St. Louis, MO.
April 2010	"The Papaya Model: Learning Manual Vacuum Aspiration". Medical Students for Choice, Michigan State University Chapter, East Lansing, MI.

February 2011	"The Papaya Model: Learning Manual Vacuum Aspiration". Medical Students for Choice, Michigan State University Chapter, East Lansing, MI.
March 2011	Grand Rounds - "Michigan's Reproductive Health Laws". University of Michigan Department of Obstetrics and Gynecology, Ann Arbor, MI.
April 2011	"The Papaya Model: Learning Manual Vacuum Aspiration". Medical Students for Choice Regional Conference, Detroit, MI.
November 2011	"What Effect Would Defunding Planned Parenthood Have on Women's Health?" Michigan State University Law Students for Reproductive Justice, East Lansing, MI.
March 2012	"The Papaya Model: Learning Manual Vacuum Aspiration". Medical Students for Choice, Michigan State University Chapter, East Lansing, MI.
September 2012	"Update on Contraception". St. Paul's Hospital Department of Obstetrics and Gynecology, Addis Ababa, Ethiopia.
September 2012	"Surgical Techniques for Second Trimester Abortion". St. Paul's Hospital Department of Obstetrics and Gynecology, Addis Ababa, Ethiopia.
November 2012	Grand Rounds - "Entertainment-Education: Rethinking Patient Education and Public Health." University of Iowa Department of Obstetrics and Gynecology, Iowa City, IA.
April 18, 2013	Grand Rounds - "Entertainment-Education: Rethinking Patient Education and Public Health." University of Michigan Department of Obstetrics and Gynecology, Ann Arbor, MI.
April 9, 2014	"Abortion Stigma". North American Society for Psychosocial Obstetrics and Gynecology 2014 Annual Meeting, Columbus, OH.
April 26, 2014	"Ryan Program 101: Tips & Tricks." 15th Annual Fellowship in Family Planning Meeting, Chicago, IL.
March 30, 2015	"Implications of Targeted Regulation of Abortion Providers". Reproductive Health, Rights, Access & Action Conference, University of Pittsburgh, Pittsburgh, PA.
December 7, 2015	"Physician Advocacy in Reproductive Health." Internal Medicine Women's Health Lecture Series, University of Pittsburgh, Pittsburgh, PA.
January 29, 2016	"The Papaya Model: Learning Manual Vacuum Aspiration." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
January 30, 2016	"First Trimester Abortion." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
January 30, 2016	"Second Trimester Abortion Simulation Model." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
April 1, 2016	"Access to Contraception in the Era of the ACA." University of Pittsburgh Center for Bioethics and Health Law 25th Annual Medical Ethics Update 2016, Pittsburgh, PA.
April 1, 2016	"First Trimester Abortion." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
April 2, 2016	"The Papaya Model: Learning Manual Vacuum Aspiration." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
April 2, 2016	"Second Trimester Abortion Simulation Model." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.

May 15, 2016	"Orientation to the Family Planning Fellowship." 17th Annual Fellowship in Family Planning Meeting, Washington, D.C.
February 25, 2017	"Second Trimester Abortion & Simulation Model." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
February 25, 2017	"Advocacy in Reproductive Health." Medical Students for Choice Abortion Training Institute, Philadelphia, PA.
March 28, 2017	"Contraception in the Transplant Patient." UPMC Presbyterian Heart & Lung Transplant Division, Pittsburgh, PA.
May 5, 2017	"D&E Bans: Understanding the Implications." 18th Annual Fellowship in Family Planning Meeting, San Diego, CA.
June 16, 2017	"First & Second Trimester Abortion & Reproductive Health Advocacy" – Michigan State University College of Osteopathic Medicine Chapter of Medical Students for Choice, Detroit, MI.
October 13, 2017	"Immediate Postpartum LARC: Successes and Challenges." Ryan Residency Training Program Meeting (at the Forum), Atlanta, GA.
October 13, 2017	Moderator – First Year Fellows' Research Presentations – Reproductive Health Group. North American Forum on Family Planning, Atlanta, GA.
April 25, 2018	"Best Practices in Contraceptive Counseling & Provision" – West Virginia University Hospital Department of Obstetrics & Gynecology – Grand Rounds, Morgantown, WV.
February 25, 2019	"Immediate Postpartum LARC" – Erlanger Health System, Chattanooga, TN.
April 10, 2019	"Immediate Postpartum LARC" – Sanford Health System, Sioux Falls, SD.
August 14, 2019	"Contraceptive Counseling" – Prisma Health System, Greenville, SC.

Bibliography

Peer-Reviewed Publications

1. Chen BA, Blithe DL, Muraguri GR, **Lance AA**, et al. "Acceptability of the Woman's Condom in a Phase III multicenter open-label study". *Contraception*, 99(6), 357-362. doi:10.1016/j.contraception.2019.02.006

Non-Peer-Reviewed Publications

1. **Lance, AA**. "Stop Michigan GOP's Attacks on Women's Rights". Letter to the Editor. Detroit Free Press. February 15, 2013.
2. **Lance, AA.** "This Year's Election is a Big One for PA Women." Letter to the Editor. The Patriot News. October 30, 2014.
3. **Lance, AA.** "My Patients Deserve Better: Abortion bill would deny women safe choices in Pennsylvania." Op-Ed. Pittsburgh Post-Gazette. April 14, 2016.
4. Paruchuri Y, **Lance AA**. "The Benefits and Barriers to Inpatient Nexplanon." Pennsylvania Section of ACOG Newsletter Spring 2016.
5. **Lance AA**, Hauspurg A, Tarleton J. "Dangerous to Women: This restrictive abortion bill is hazardous to women's health." Op-Ed. Pittsburgh Post-Gazette. May 27, 2017.

Oral Abstracts

1. **Lance AA**. Predictors of Patient Use of Highly Effective Postpartum Contraception. Oral Presentation: Michigan Section of American College of Obstetricians and Gynecologists Junior Fellow Research Day. Lansing, MI; May 2010.
2. **Lance AA**. Predictors of Patient Use of Highly Effective Postpartum Contraception. Oral Presentation: 25th Annual Sager Lecture and Research Day, University of Michigan Department of Obstetrics and Gynecology, Ann Arbor, MI; May 2010.
3. **Lance AA**. *16 and Pregnant*: A mixed-methods analysis of a reality television show about unplanned teen pregnancy. Oral Presentation: Michigan Section of American College of Obstetricians and Gynecologists Junior Fellow Research Day. Lansing, MI; May 2012.
4. **Lance AA**, Wallet SM, Lorber B, Harris LH. *16 and Pregnant*: A content analysis of a reality television program about unplanned teen pregnancy. Oral Presentation: North American Forum on Family Planning. Denver, CO; October 2012.
5. **Lance AA,** Dalton VK, Harris LH. Can *16 and Pregnant* affect attitudes towards teen pregnancy among young women? A randomized controlled trial. Oral Presentation: Michigan Section of American College of Obstetricians and Gynecologists Junior Fellow Research Day. Lansing, MI; May 2013.
6. **Lance AA**, Falls NM, Kamp K. Reviews of abortion providers on physician-rating websites: A content analysis. National Abortion Federation 2016 Annual Meeting. Austin, TX; April 2016.
7. Rindos NB, **Lance AA**, Davis AC, Hamad G. Management of Perforated IUDs. 45th AAGL Global Congress of Minimally Invasive Gynecology. Orlando, FL; November 2016.

Posters

1. Roose R, **Lance AA**, Berglund K. Future physicians' attitudes on reproductive choice: Implications for addressing provider shortage. Poster Presentation: Medical Students for Choice National Conference. New Orleans, LA; April 2004.
2. **Lance AA**, McGuire J, Dalton VK. Predictors of Patient Use of Highly Effective Post-Partum Contraception. Poster Presentation: Association of Reproductive Health Professionals. Atlanta, GA; September 2010.
3. McGuire J, **Lance AA**, Dalton VK. Barriers to Postpartum IUC Use: Implications for patient contraceptive preferences and satisfaction with health services. Poster Presentation: Association of Reproductive Health Professionals. Atlanta, GA; September 2010.
4. **Lance AA,** Dalton VK, Harris LH. Can *16 and Pregnant* affect attitudes towards teen pregnancy among young women? A randomized controlled trial. Poster Presentation: North American Forum on Family Planning. Seattle, WA; October 2013.
5. Dunn A, Shupe AG, Gostic L, **Lance AA**. Immediate Postpartum Insertion of the Nexplanon Contraceptive Implant. Poster Presentation: UPMC Nurses Week 2016. Allison Park, PA; April 2016.
6. Gowda T, O'Connor T, Chang J, **Lance AA**. Understanding how American politics and policies influence the experiences of physicians who provide reproductive healthcare. Poster Presentation: University of Pittsburgh School of Medicine Dean's Summer Research Program Poster Session. Pittsburgh, PA; September, 2017.

7. Gowda T, O'Connor T, Chang J, **Lance AA**. Understanding how American politics and policies influence the experiences of physicians who provide reproductive healthcare. Poster Presentation: Adagio Women's Health Symposium. Pittsburgh, PA; March, 2018.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

Planned Parenthood of Tennessee and North Mississippi; *et al*., Plaintiffs, v. Herbert H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	CASE NO. 3:20-cv-00740 JUDGE CAMPBELL

[PROPOSED] ORDER GRANTING MOTION FOR A TEMPORARY RESTRAINING ORDER and/or PRELIMINARY INJUNCTION

This matter having come before the Court on Plaintiffs' *Motion for a Temporary Restraining Order and/or Preliminary Injunction*, and for good cause shown, it is hereby ORDERED that Plaintiffs' Motion for a Temporary Restraining Order and/or Preliminary Injunction is GRANTED.

Pursuant to Federal Rule of Civil Procedure 65(b), Plaintiffs Planned Parenthood of Tennessee and North Mississippi, Memphis Center for Reproductive Health, Knoxville Center for Reproductive Health, FemHealth USA, Inc., d/b/a carafem, and Dr. Audrey Lance (together, "Plaintiffs"), moved this Court for a temporary and/or preliminary injunction to prevent Defendants from enforcing a mandatory disclosure requirement enacted in July 2020 through H.B. 2263/S.B. 2196 (codified at Tenn. Code Ann. § 39-15-218) (the "Act"), and set to go into effect October 1, 2020, pending full litigation on the merits.

Having considered the memorandum of law, declarations, and other papers on file with the Court, and the arguments in support of Plaintiffs' Motion, the Court finds as follows:

The Act forces physicians to advise their patients that the effects of a medication abortion may be reversed, ceased, or avoided once begun, a claim that is wholly unsupported by reliable scientific evidence and that has been rejected by medical authorities. The Act's mandatory disclosure gravely undermines informed consent and is so misleading as to give patients the false impression that they need not be certain in their decision to terminate their pregnancy before beginning a medication abortion. Moreover, the Act effectively enlists Plaintiffs, their staff, and their physicians to promote an unproven and potentially dangerous experimental medical treatment to their patients. Once effective, the Act would force Plaintiffs and their physicians and staff to violate their ethical obligations to their patients, as well as their principles and organizational missions, or risk criminal and civil penalties. *See id.* §§ 39-15-218(j)–(*l*). No other medical care is subject to such a regulation: Tennessee has imposed these dangerous and unethical requirements on abortion providers and abortion patients alone.

Plaintiffs have established that they are likely to succeed on their claims that the Act violates their First Amendment right against compelled speech; their patients' Fourteenth Amendment right to decide whether to terminate a pregnancy without undue state interference; and their and their patients' respective Fourteenth Amendment rights to equal protection. *See Nat'l Inst. of Fam. & Life Advoc. v. Becerra*, 138 S. Ct. 2361, 2371–74 (2018); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 887 (1992); *City of Cleburne, Tex. v. Cleburne Living Ctr.*, 473 U.S. 432, 448–50 (1985); *U.S. Dep't of Agric. v. Moreno*, 413 U.S. 528, 534 (1973).

Further, absent a temporary and/or preliminary injunction, Plaintiffs and their patients would suffer immediate irreparable harm from Plaintiffs and their physicians being forced to deliver a government-scripted message that will misinform and mislead patients, undermine patients' ability to provide informed consent, erode the trust on which the physician-patient relationship is founded, and potentially expose patients to harm, all in blatant violation of medical ethics. Those who refuse to subject their patients to these harms will face the threat of severe civil and criminal penalties starting on the Act's imminent effective date of October 1, 2020. By contrast, an injunction preserving the status quo would not cause any harm to Defendants, and thus the balance of equities tips in favor of granting Plaintifs' motion. Further, granting an injunction will serve the public interest. The Plaintiffs have thus met their burden, *Am. C. L. Union Fund of Mich. v. Livingston Cty.*, 796 F.3d 636, 642 (6th Cir. 2015), and accordingly, I find that temporary and/or preliminary injunctive relief is warranted.

IT IS THEREFORE ORDERED that Defendants and their officers, agents, employees, and attorneys, and any persons in active concert or participation with them, are TEMPORARILY and/or PRELIMINARILY ENJOINED from enforcing or requiring compliance with Tenn. Code Ann. § 39-15-218. This injunction is effective upon entry and shall expire on [DATE] unless extended by the Court for good cause shown or by agreement of the parties.

IT IS FURTHER ORDERED that the security requirement of Fed. R. Civ. P. 65(c) is waived, and that this injunctive relief is effective upon service.

Entered this ____ day of _____, 2020.

_____

U.S. DISTRICT JUDGE