UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*, Plaintiff, v. JOSHUA STEIN, *et al.*, Defendants, and PHILIP E. BERGER and TIMOTHY K. MOORE, Intervenor-Defendants.	**Case No. 1:23-cv-480** **DEFENDANT-INTERVENORS' RESPONSE IN OPPOSITION TO PLAINTIFFS' AMENDED MOTION FOR PRELIMINARY INJUNCTION**

INTRODUCTION

The Supreme Court held in *Dobbs v. Jackson Women's Health Organization* that "[i]t is time to heed the Constitution and return the issue of abortion to the people's elected representatives." 142 S. Ct. 2228, 2243 (2022). Ignoring that instruction, Plaintiffs are abortion providers who disagree with the policy choices behind North Carolina's new abortion laws and seek to constitutionalize their preferences for what North Carolina's laws should be. In doing so, Plaintiffs ask this Court to do what it cannot: "substitute [its] social and economic beliefs for the judgment of" North Carolina's elected

representatives by enjoining two common-sense "health and welfare laws." *Id.* at 2283–84. Because those laws implicate no fundamental right or protected class, are rationally related to North Carolina's legitimate interest in protecting maternal health and safety, and are not unconstitutionally vague, and because Plaintiffs have failed to satisfy the requirements for extraordinary relief, this Court should reject that invitation and deny Plaintiffs' Motion for Preliminary Injunction.

STATEMENT OF FACTS

I. Abortion Safety and Complications

Abortion is dangerous for both a pregnant mother and her unborn child. Dr. Monique Chireau Wubbenhorst is an obstetrician-gynecologist with over twenty years' experience and a researcher at Duke University School of Medicine. She testified in her declaration that abortion safety data is "incomplete" and the complication rate is not low. Decl. of Dr. Wubbenhorst ¶¶ 64, 96, attached as Ex. 1. Each method of abortion performed by Plaintiffs—chemical abortion, aspiration abortion, and dilation and evacuation (D&E) abortion, Farris Decl. ¶¶ 2, 14, ECF No. 49-1—can cause serious, even life-threatening, complications for women. Ex. 1, ¶¶ 7, 9–10, 37, 64, 80.

A. Chemical Abortion

The FDA has approved chemical abortion "for the medical termination of intrauterine pregnancy through 70 days [10 weeks] gestation." FDA Approved Label for Mifepristone (Mifeprex) (Jan. 2023) at 1, attached as Ex. 2 ("FDA Label"). The gestational limitation is based on overwhelming evidence that the risks of chemical abortion to the pregnant mother increase with gestational age. *Id.* at 13. Yet Plaintiffs admit that they provide the drugs off-label "through *11 weeks*" gestation. ECF No. 49-1, ¶ 16. Complications from chemical abortion include incomplete or failed abortion, hemorrhage, "serious and sometimes fatal infections," and even death. Ex. 2, 1–2, 8–9. According to the current FDA label, between 2.9% and 4.6% of women end up in the emergency room due to complications from chemical abortion. *Id.* at 8.

Chemical abortion is contraindicated for women with ectopic pregnancies. *Id.* at 6. An ectopic pregnancy is a pregnancy that occurs outside the uterine cavity. Decl. of Dr. Bane ¶ 58, attached as Ex. 3. Ectopic pregnancies occur in "approximately 2% of all pregnancies," and if left untreated and rupture "can be a life-threatening situation." *Id.* An ectopic pregnancy can only be ruled out by an ultrasound that confirms a pregnancy is inside the uterine cavity, which can be seen beginning around 5 or 6 weeks gestational age. *Id.* ¶¶ 55–58.

B. Aspiration Abortion

Aspiration abortion is a type of surgical abortion that "entails using suction to empty the uterus" and destroy the unborn child. ECF No. 49-1, ¶ 21. Planned Parenthood "provides aspiration abortion up to approximately 14 weeks LMP." *Id.* During an aspiration abortion, the physician inserts a hollow plastic tube into the uterus through the cervix, and sucks the unborn child, placenta, umbilical cord, and gestational sac out with a pump or syringe. *Id.*

Complications include "bleeding, infection, damage to the uterus, possible damage to other organs including bowel and bladder, . . . possible need for further surgery," and even death. Ex. 1, ¶¶ 80, 136. Planned Parenthood expert Dr. Christy M. Boraas Alsleben acknowledges, "[t]he risks associated with abortion increase with gestational age." Boraas Decl. ¶ 27, ECF No. 49-2. While it is impossible to eliminate the risk of complications from aspiration abortion, hospitals are better equipped to treat serious complications. Ex. 3, ¶ 51 ("Hospitals have more resources to manage . . . complications, including intensive care units.").

C. D&E Abortion

Dilation and evacuation abortion is a surgical abortion procedure Plaintiffs use beginning around 14 or 15 weeks LMP ("Last Menstrual Period"). ECF No. 49-1, ¶ 25. During a D&E abortion, the physician first "dilate[] the

patient's cervix," *id.* ¶ 26, and "inserts grasping forceps through the woman's cervix and into the uterus to grab the fetus." *Gonzales v. Carhart*, 550 U.S. 124, 135 (2007). Then, "[t]he doctor grips a fetal part with the forceps and pulls it back through the cervix and the vagina," causing the unborn baby to tear apart. *Id.* This "process of evacuating the fetus piece by piece continues until it has been completely removed." *Id.* at 135–36.

Due to the late gestational age at which D&E abortions are normally performed and the passing of medical instruments multiple times through the patient's cervix, it has a particularly high rate of complications. Ex. 1, ¶ 41 ("Many studies have quantified the association between increasing gestational age and increasing risk for maternal mortality."). Possible complications of D&E abortion include cervical laceration, uterine perforation, hemorrhaging, infection, and even death. *Id.* ¶¶ 152 & Table 3, 188. As with aspiration abortion, performing a D&E abortion in a hospital can reduce, but not eliminate, complications and ensure faster emergency care if they arise. Ex. 3, ¶ 51.

II. Procedural History

Senate Bill 20, "An Act to Make Various Changes to Health Care Laws and to Appropriate Funds for Health Care Programs" ("the Act"), as amended by House Bill 190, provides that "[i]t shall be unlawful after the twelfth week

of a woman's pregnancy to procure or cause a miscarriage or abortion in the State of North Carolina." N.C. Gen. Stat. § 90-21.81A(a). "Abortion" is defined to include surgical and chemical abortion. *Id.* § 90-21.81(1). The Act also provides: "[I]t shall not be unlawful to procure or cause an miscarriage or an abortion in the State of North Carolina" (1) "when . . . there exists a medical emergency"; (2) "[d]uring the first 12 weeks of a woman's pregnancy"; (3) "[a]fter the twelfth and through the twentieth week of a woman's pregnancy . . . when the woman's pregnancy is a result of rape or incest"; and (4) "[d]uring the first 24 weeks of a woman's pregnancy, if . . . there exists a life-limiting anomaly." *Id.* § 90-21.81B.

Plaintiffs ask this Court to enjoin two provisions—the hospitalization and IUP documentation requirements. Pls.' Am. Mot. for Prelim. Inj. 1, ECF No. 48. First, the Act provides that "[a]fter the twelfth week of pregnancy, a physician licensed to practice medicine . . . may not perform a surgical abortion as permitted under North Carolina law in any facility other than a hospital." *Id.* § 90-21.82A(b) (eff. Oct. 1, 2023) ("the hospitalization requirement"). Second, the Act provides that "[a] physician prescribing, administering, or dispensing an abortion-inducing drug must . . . [d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy." *Id.* § 90-21.83B(a) (eff. July 1, 2023) ("IUP documentation requirement").

ARGUMENT

A preliminary injunction is "an extraordinary remedy [that is] never awarded as of right." *In re Search Warrant Issued June 13, 2019*, 942 F.3d 159, 170 (4th Cir. 2019), *as amended* (Oct. 31, 2019) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008)). To prevail on their preliminary injunction motion, "[P]laintiff[s] must establish that (1) [they are] likely to succeed on the merits, (2) [they are] likely to suffer irreparable harm absent the requested preliminary relief, (3) the balance of the equities weighs in [their] favor, and (4) a preliminary injunction is in the public interest." *Id.* at 170–71. Plaintiffs do not meet any of those requirements here.

I. Plaintiffs cannot prove that the hospitalization requirement and IUP documentation requirement are unconstitutional.

To succeed on a motion for a preliminary injunction, Plaintiffs must make "*a clear showing* that [they are] likely to succeed at trial." *Roe v. Dep't of Def.*, 947 F.3d 207, 219 (4th Cir. 2020), *as amended* (Jan. 14, 2020) (cleaned up) (emphasis added). Plaintiffs failed to make that showing as to either the hospitalization or the IUP documentation requirements.

A. The hospitalization requirement is a legitimate and rational exercise of the State's authority to regulate abortion.

1. The hospitalization requirement satisfies rational basis review.

In *Dobbs*, the Supreme Court held that "rational-basis review is the appropriate standard" for "constitutional challenge[s]" to "state abortion regulations." 142 S. Ct. at 2283. Under rational-basis review, "[a] law regulating abortion . . . is entitled to a 'strong presumption of validity'" and "must be sustained if there is a rational basis on which the legislature could have thought it would serve legitimate state interests." *Id.* at 2284. Plaintiffs concede the Court must evaluate their claims using rational basis review, ECF No. 49, 11, and that the State has a legitimate interest in "the protection of maternal health and safety," *Dobbs*, 142 S. Ct. at 2284; ECF No. 49, 11–12.

Instead, Plaintiffs attempt to skirt *Dobbs* and argue that "the Hospitalization Requirement is not rationally related to any government interest in patient safety." ECF No. 49, 11. In determining whether an abortion regulation is rationally related to a legitimate state interest, "courts cannot 'substitute their social and economic beliefs for the judgment of legislative bodies.'" *Dobbs*, 142. S. Ct. at 2283–84. The pre-*Dobbs* cases cited by Plaintiffs do not say otherwise. ECF No. 49, 11–12. And Plaintiffs wrongfully suggest

that this Court not only can but must defer to "the factual findings" regarding hospital requirements from *overruled* cases. ECF No. 49, 12.

Under rational-basis review, "it is for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement." *Williamson v. Lee Optical of Okla. Inc.*, 348 U.S. 483, 487 (1955). Here, the General Assembly rationally concluded that requiring surgical abortions to be performed in a hospital after 12 weeks would make the procedure safer because hospitals are better equipped to address complications that everyone, including Plaintiffs and their expert witness, agrees arise. Ex. 3, ¶¶ 49, 50, 51, 52; Ex. 1, ¶ 225; ECF No. 49-1, ¶ 41; ECF No. 49-2, ¶¶ 49–52. Surgical abortions can have serious complications, including hemorrhage, infection, cervical laceration, uterine perforation, sepsis, and even death. Ex. 1, ¶ 152 & Table 3.

When these complications occur, hospitals, unlike abortion clinics, have sufficient staffing, systems, equipment, and space to treat complications. *Id.* at ¶ 225. Indeed, patients who suffer any of these complications are typically *transferred* to a hospital. *Id.* at ¶¶ 189, 191. The General Assembly reasonably concluded that it is safer for the patient to start at the hospital where necessary staff and equipment are already on hand.

Plaintiffs argue that the hospitalization requirement is irrational because "[s]erious complications . . . are vanishingly rare." ECF No. 49, 13; ECF No. 49-1, ¶ 31. But they admit that "serious complications do arise" that require them "to safely transfer the patient a hospital." *Id.* That confession alone satisfies rational-basis review. That Plaintiffs disagree with the General Assembly's safeguards does not make them irrational. To articulate Plaintiffs argument is to defeat it—the Constitution does not prohibit second-trimester surgical abortions to be performed in a hospital.

Plaintiffs next argue that the hospitalization requirement is irrational because data establishes "beyond any doubt the safety of outpatient abortions." ECF No. 49, 13. That is simply untrue, and Plaintiffs admit that some patients end up in the hospital due to serious, even life-threatening, complications ECF No. 49, 6, 13; ECF No. 49-1, ¶ 43. Again, there is no dispute that hospitalization will be necessary for at least *some* women who suffer complications during surgical abortions. It is not irrational to require safety precautions to protect these women who suffer serious complications during a surgical abortion.

Further, data on the safety of abortion is "severely flawed." Ex. 1, ¶¶ 96, 98, 101. The General Assembly has "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales*, 550 U.S. at 163. Plaintiffs may dislike the way elected officials interpreted the entirety of the

evidence and reached a result different from the one Plaintiffs advocate, but that does not make the General Assembly's different policy choices constitutionally irrational.

Nor does it matter that "major medical associations" disagree with North Carolina's conclusion that hospitalization makes second-trimester abortions safer. ECF No. 49, 13. It is squarely within the State's traditional power to protect the pregnant women that Plaintiffs admit *will* require hospitalization. Indeed, the Supreme Court has twice rejected the claim that a state must defer to differing policy choices advocated by voluntary medical associations. First, in *Gonzales*. 550 U.S. at 170–71 (Ginsburg, J., dissenting) (criticizing the majority for "tolerat[ing] . . . federal intervention to ban a nationwide procedure found necessary and proper in certain cases by the American College of Obstetricians and Gynecologists").

And second in *Dobbs*. *See* Brief for Am. Coll. of Obstetricians and Gynecologists, et al. as Amici Curiae Supporting Respondents 22–23, *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022) (No. 19-1392), 2021 WL 4312120 at * 21–23 (citing "medical consensus" to argue the State's conclusion that its law promoted the health and safety of women was without "legitimate scientific basis")."The day is gone when" courts "use[d] the Due Process Clause of the Fourteenth Amendment to strike down state laws" regulating abortion

because the challenger believes them to be "unwise, improvident, or out of harmony with a particular school of thought." *Lee Optical*, 348 U.S. at 488. The Court should not be persuaded by any argument to the contrary.

Plaintiffs also told the Court that "fewer complications from abortion are seen in settings that perform higher volumes of those procedures." ECF No. 49, 13 (citing ECF No. 49-1, ¶¶ 38, 74). But Dr. Farris cites no scientific studies for this point. ECF No. 49-1, ¶ 38 & n.29. Instead, she cites an article from U.S. News and World Report, Steve Sternberg & Geoff Dougherty, *Risks are High at Low-Volume Hospitals*, U.S. News & World Rep. (May 18, 2015, 12:01 A.M.), https://www.usnews.com/news/articles/2015/05/18/risks-are-high-at-low-volume-hospitals, that does not even *mention* abortion. Instead, it compares high volume hospitals to low volume hospitals—not hospitals to outpatient clinics. And here, Plaintiffs admit "serious complications do arise" that require them "to safely transfer the patient a hospital." ECF No. 49, 13; ECF No. 49-1, ¶ 31. When such complications occur, hospitals have the necessary staff and equipment to treat them. Ex. 1, ¶ 225. It is not irrational for the General Assembly to conclude that it is safer for a patient to start at the hospital where life-saving staff and equipment are already on hand.

Under the Constitution, state legislation must be upheld if it is rationally related to a legitimate state interest. At day's end, Plaintiffs utterly fail to meet

their burden of establishing that the hospitalization requirement is not rationally related to North Carolina's legitimate interest in women's health and safety. It is hardly irrational for the General Assembly to determine that a hospital is the best place for a procedure that causes life-threatening emergencies that require Plaintiffs to transfer patients to those very same hospitals. At most, Plaintiffs could accuse the law of being safer than they think it needs to be, but that is not irrational. For these reasons, the hospitalization requirement passes muster under rational basis review, and the Court should reject Plaintiffs' arguments.

2. The hospitalization requirement does not violate the Equal Protection Clause.

The Supreme Court held in *Dobbs* that "laws regulating or prohibiting abortion are not subject to heightened scrutiny" under the Equal Protection Clause. *Dobbs*, 142 S. Ct. at 2246. "Rather, they are governed by the same standard of review as other health and safety measures": the rational-basis test. *Id.* at 2246, 2283; *see also In re Premier Auto. Servs., Inc.*, 492 F.3d 274, 283 (4th Cir. 2007) (same).

Plaintiffs argue that the hospitalization requirement violates equal protection for two reasons: (1) "[i]t irrationally singles out physicians who provide and patients who seek abortion . . . as compared to those providing and seeking medical procedures of equal or greater risk," ECF No. 49, 9; and (2) it

applies "only to survivors of rape or incest and patients with grave fetal diagnoses," *id.* at 14. But the hospitalization requirement turns on gestational age, N.C. Gen. Stat. § 90-21-82A (C), a factor which even Plaintiffs admit increases risk. ECF No. 49-2, ¶ 27. Nothing in the law distinguishes between a particular class of *patients* (who may seek medical services aside from second-trimester abortion outside a hospital) or a class of *physicians* (who may perform gynecological procedures aside from second-trimester abortion outside a hospital). *See* ECF No. 49-1, ¶ 3 (listing non-abortion medical services that Dr. Farris performs).

Nothing in the law prevents abortion providers from obtaining privileges to perform abortions in hospitals after 12 weeks. Indeed, Plaintiff Dr. Gray does this. Because any provider may seek to perform abortions in a hospital and there is no disparate treatment.

Nor does the hospitalization requirement distinguish as to classes of patients: it applies to surgical abortions from 12–20 (or 24) weeks' gestational age. N.C. Gen. Stat. § 90-21-82A (C). North Carolina law does not violate the Equal Protection Clause because it distinguishes between "suitable facilit[ies]" based on the gestational age of the fetus and attendant risks, not a class of provider or patient. *See id.* §§ 90-21.81B, 90-21.82A.

Even before *Dobbs*, the Fourth Circuit upheld a South Carolina law distinguishing between performing an abortion at different types of facilities against an equal protection challenge, explaining that "[t]he rationality of distinguishing between abortion services and other medical services when regulating physicians or women's healthcare has long been acknowledged by Supreme Court precedent." *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 173 (4th Cir. 2000). Plaintiffs do not even mention *Bryant*, relying instead on pre-*Dobbs* out-of-circuit cases. *See* ECF No. 49, 9–10. But *Bryant* controls.

Plaintiffs next argue that the Act violates the Equal Protection Clause because miscarriage management using the same procedures can sometimes occur outside the hospital. ECF No. 49, 10–11. Again, that has no bearing on equal protection because the law regulates medical procedures, not protected classes of people. And it is well established that the legislature need not deal with every conceivable risk at once. *Lee Optical*, 348 U.S. at 489. Further, the Supreme Court has long held that "[a]bortion is inherently different from other medical procedures, because no other procedure involves the purposeful termination of a potential life." *Harris v. McRae*, 448 U.S. 297, 325 (1980); *see also Dobbs*, 142 S. Ct. at 2258.

In a last-ditch effort to wrench this law into a heightened scrutiny analysis, Plaintiffs claim that second-trimester surgical abortion "is as safe as"

other medical procedures that are performed outside of hospitals—procedures like "vasectomies, colonoscopies, wisdom tooth extraction, and tonsillectomies." ECF No. 49, 10. That claim is simply untrue. Ex. 1, ¶¶ 153–66. Regardless, the legislature "may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind." *Lee Optical*, 348 U.S. at 489. So even if Plaintiffs' claim is accepted on its face, it still fails—the Constitution doesn't require the General Assembly to make medical procedures safer all at once just because it chooses to make abortion safer.

Finally, Plaintiffs argue that the hospitalization requirement "makes accessing abortion even more challenging for people already facing personal hardship due to the circumstances of their pregnancies." ECF No. 49, 14. Even if Plaintiffs offered admissible opinions on this and were qualified to do so (they do not and are not) that does not state an Equal Protection violation. Under *Dobbs*, any alleged "burden" is a policy issue for the legislature to assess. 142 S. Ct. at 2272–73. Further, the hospitalization requirement is rationally designed to *protect* women who are at increased risk because of the gestational age of their unborn child. Plaintiffs provide no evidence that the requirement is motivated by "a bare desire to harm" such patients. ECF No. 49, 15. For these reasons, the hospitalization requirement passes muster under the Equal Protection Clause, and the Court should reject Plaintiffs' contrary arguments.

B. The IUP documentation requirement satisfies rational basis review.

The IUP documentation requirement provides that "[a] physician prescribing, administering, or dispensing an abortion-inducing drug must . . . [d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy." N.C. Gen. Stat § 90-21.83B(a). Plaintiffs argue that this requirement is "unconstitutionally vague" and "irrational in violation of the Due Process Clause." ECF No. 49, 9. Plaintiffs fail to show a likelihood of success on the merits of either claim.

1. The IUP documentation requirement is not vague.

A statute is unconstitutionally vague only if it fails to "give a person of ordinary intelligence adequate notice of what conduct is prohibited." *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019) (en banc). So long as a statute includes "sufficient standards to prevent arbitrary and discriminatory enforcement," it survives a vagueness challenge. *Id.*; *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) (adequate notice where terms are "clearly defined").

Where, as here, the challenged law does not implicate a fundamental right, "speculation about possible vagueness in hypothetical situations . . . will not support a facial attack on a statute when it is surely valid 'in the vast majority of its intended applications.'" *Hill v. Colorado*, 530 U.S. 703, 733

(2000) (citing *United States v. Raines*, 362 U.S. 17, 23 (1960)). And while "the standard of certainty is higher" "where a challenged statute 'imposes criminal penalties,'" *Carolina Youth Action Project v. Wilson*, 60 F.4th 770, 781 (4th Cir. 2023), the State still need not show that the challenged statute is written with "mathematical precision," *Greenville Women's Clinic v. Comm'r, S.C. Dep't of Health & Env't*, 317 F.3d 357, 366 (4th Cir. 2002).

Here, the IUP documentation requirement does not implicate a fundamental right. *See Dobbs*, 142 S. Ct. at 2242 ("The Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision."); *see also Planned Parenthood of Ind. & Ky., Inc. v. Marion Cnty. Prosecutor*, 7 F.4th 594, 603 (7th Cir. 2021) ("[C]ourts have looked with disfavor on facial vagueness challenges to statutes that do not implicate fundamental rights."). And while the IUP documentation requirement gives rise to both civil and criminal penalties, N.C. Gen. Stat. §§ 14-44, 14-45, 14-23.2, 90-21.88, 90-21.88A, each of the possible criminal penalties include a scienter requirement, *id.* §§ 14-23.2 (a)(1) ("willfully and maliciously"), 14-44 ("willfully"), 14-45 ("with intent"). These scienter requirements help "ameliorate[]" any heightened concerns due to the requirement's criminal prohibitions. *Hill*, 530 U.S. at 732.

The Act is not ambiguous: it provides that chemical abortion within the first 12 weeks of a woman's pregnancy are lawful only if the "physician prescribing, administering, or dispensing an abortion-inducing drug" first "document in the woman's medical chart the . . . existence of an intrauterine pregnancy." N.C. Gen. Stat. § 90-21.83B(a). This requirement is not subject to misinterpretation: it provides that a doctor can perform a chemical abortion through twelve weeks LMP, but only if they first document IUP. To read the statute otherwise would render the requirements of section 90-21.83B superfluous. *See United States v. Simms*, 914 F.3d 229, 241 (4th Cir. 2019) ("[W]e cannot adopt a reading of [a statute] that renders part of the statute superfluous over one that gives effect to its 'every clause and word.'").

Plaintiffs' vagueness challenge fails because the IUP documentation requirement "give[s] a person of ordinary intelligence adequate notice of what conduct is prohibited." *Manning*, 930 F.3d at 272. Its terms are "clearly defined." *Grayned*, 408 U.S. at 108. In fact, Plaintiffs do not even argue they cannot understand any specific term, but instead that the IUP documentation requirement "is ambiguous as to whether a provider who cannot comply with the documentation requirement" because "an intrauterine embryo cannot yet be detected by an ultrasound" is "prohibited" from performing a chemical

abortion. ECF No. 49, 17–18. Plaintiffs elide disagreement with vagueness, but the two are not equivalent.

A physician must use ultrasound to determine whether a pregnancy is intrauterine. Ex. 1, ¶ 254; Ex. 3, ¶ 60. Plaintiffs know this. *See* ECF No. 49, 17 (admitting that "document[ing] . . . the . . . existence of an intrauterine pregnancy" is "an impossibility . . . in the early weeks of pregnancy, where an intrauterine embryo cannot yet be detected by ultrasound"). This is not vague. Plaintiffs' dislike of the documentation requirement cannot provide grounds for this Court to hold an unambiguous statute unconstitutional.

Similarly, the IUP documentation requirement leaves no room for "arbitrary and discriminatory enforcement." *Manning*, 930 F.3d at 272. All a state official need do to determine whether the statute has been violated is check the "woman's medical chart" to see whether the physician "[d]ocument[ed] . . . the existence of an intrauterine pregnancy." N.C. Gen. Stat § 90-21.83. This is hardly a situation where a statute "specifies no standard of conduct." ECF No. 49, 18. Plaintiffs understand exactly what conduct is prohibited: performing a chemical abortion without documenting an intrauterine pregnancy. For these reasons, Plaintiffs have not shown a likelihood of success on the merits of their vagueness claim.

2. The IUP documentation requirement is rational.

Like the hospitalization requirement, the IUP documentation requirement is rationally related to the State's interest in "the protection of maternal health and safety," *Dobbs*, 142 S. Ct. at 2284. The IUP documentation requirement protects women's health by ensuring that physicians do not prescribe chemical abortion drugs to a woman suffering from an ectopic pregnancy. Ex. 3, ¶ 58. Critically, the FDA's warning label for mifepristone—the first drug in the chemical abortion regimen—states that the "[a]dministration of [mifepristone] and misoprostol for the termination of pregnancy . . . is contraindicated in patients with . . . [c]onfirmed or suspected ectopic pregnancy." *See* Ex. 2, 4.

The label also instructs that Mifepristone "is not effective for terminating ectopic pregnancies." *Id.* at 6. Untreated ectopic pregnancy can cause serious injury and even death if left untreated. Ex. 1, ¶¶ 246, 255 ("Ectopic pregnancy is the leading cause of first trimester maternal death . . . ectopic pregnancy . . . causes substantial morbidity and mortality."); Ex. 3, ¶ 58. Thus, "[h]ealthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a

medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy." Ex. 2, 6.

The only way to definitively diagnose ectopic pregnancy is by ultrasound, which can effectively show this beginning at about five or six weeks LMP. Ex. 1, ¶ 254 ("No determination that is not based on ultrasound and quantitative (blood) pregnancy testing can rule out ectopic pregnancy"); Ex. 3, ¶¶ 55, 58. Ectopic pregnancy is contraindicated for chemical abortion. The General Assembly rationally concluded that requiring documentation of an intrauterine pregnancy would prevent serious health consequences to women with undiagnosed ectopic pregnancies. The State has a longstanding, well-founded right to legislate for safety purposes and ensure that no woman who has an ectopic pregnancy (even those early in pregnancy) receive unapproved and dangerous drugs that could hurt her.

Plaintiffs suggest that their screening process—merely "asking questions about the patient's medical history and current symptoms," ECF No. 49, 19—adequately mitigates this risk. But some women suffering from ectopic pregnancies are asymptomatic for a long portion of the disease progression. Ex. 1, ¶ 352. This means that some women Plaintiffs screen and consider low risk for ectopic pregnancy suffer from the condition. Plaintiffs admit they would give chemical abortion drugs to such women. That is dangerous.

Nor is it safe to "*simultaneously* provide[] the medication abortion *and* conduct further testing using serial blood draws," ECF No. 49, 19 (emphasis added), because that protocol fails to rule out contraindications *before* prescribing dangerous abortion drugs, Ex. 1, ¶¶ 248–76. Dr. Farris admits that the test results can take up to 24 hours. That means that Dr. Farris has already administered the chemical abortion drugs to the patient and sent her home before any lab test suggesting an ectopic pregnancy is possibly available. And even if the lab results show a higher risk of ectopic pregnancy, Plaintiffs have no way to guarantee she will return to the clinic for additional lab testing or surgical abortion. Leaving aside the inconsistency of Plaintiffs' position that making an additional visit for follow up care is "prohibitive for some patients," ECF No. 49-1, ¶¶ 42, 54–55, such patients face serious injury and even death.

Indeed, the FDA medication label for mifepristone notes, "some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy," Ex. 2, 6. This means a woman may misinterpret her hemorrhaging due to a ruptured ectopic pregnancy as a normal side effect of the chemical abortion drugs. S.H. Jayanth, *et al.*, *Fatal Ruptured Ectopic Pregnancy—A Case Report*, 87 Medico-Legal J. 38, 38–41 (2019). Starting October 1, women in North

Carolina suffering from ectopic pregnancy will benefit from the law's protections.

Plaintiffs complain that "[r]eferring a patient for ectopic evaluation instead of providing a medication abortion . . . does not lead to earlier or more accurate diagnosis of ectopic pregnancy." ECF No. 49, 20. Even if that were true, which it is not, this has no bearing on the law. The IUP documentation requirement neither commands nor prevents a physician from "referring a patient for ectopic evaluation." Instead, it quite simply requires a physician to conduct an evaluation to identify the presence of an intrauterine pregnancy themselves *before* prescribing dangerous chemical abortion drugs that are contraindicated when a patient is suffering from an ectopic pregnancy. *See* N.C. Gen. Stat § 90-21.83B(a)(7). The point is this: no patient should get chemical abortion drugs before a physician has ensured the patient is not suffering from an ectopic pregnancy.

Plaintiffs further argue that the requirement is irrational because "any patient who is denied a medication abortion under [the IUP documentation requirement] could still. . . obtain a procedural abortion." ECF No. 49, 20. But the fact that very few surgical abortions occur before five or six weeks LMP is a sufficient rational basis for that distinction. Further, the legislature "may take one step at a time, addressing itself to the phase of the problem which

seems most acute to the legislative mind." *Lee Optical*, 348 U.S. at 489. Indeed, the legislature had the unfettered ability to outright ban all abortion under *Dobbs*, so anything less than that is certainly within its purview.

For these reasons, the IUP documentation requirement satisfies rational basis review.

II. Planned Parenthood has not shown it will suffer irreparable harm absent an injunction.

To obtain a preliminary injunction, "a plaintiff must demonstrate more than just a 'possibility' of irreparable harm." *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017). Rather, the "plaintiff must make a clear showing of irreparable harm, and the required irreparable harm must be neither remote nor speculative, but actual and imminent." *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 283 (4th Cir. 2002) (cleaned up).

Plaintiffs have not made that showing here: the Act does not irreparably harm Dr. Gray, Planned Parenthood, its physicians, or its patients because the Act does not deprive them of any constitutional rights as discussed above. Moreover, the supposed "burdens" imposed are both overstated and irrelevant under *Dobbs* because Plaintiffs' patients have no constitutional right to abortion. *Dobbs*, 142 S. Ct. at 2242. If North Carolina may constitutionally serve its interests in protecting fetal life and women's health by prohibiting

abortion entirely, it may constitutionally govern the circumstances under which an abortion can be performed.

Plaintiffs argue the Act will "harm Plaintiffs and their patients by delaying . . . and even, at times, denying—necessary health care." ECF No. 49, 21. But the challenged requirements do not deny women abortions; abortions in North Carolina are lawful before twelve weeks, including chemical abortions, so long as the physician follow the safety rules about ectopic pregnancy and after twelve weeks so long as the abortion fits into one of the statutory exceptions and occurs in a hospital. *See* N.C. Gen. Stat. §§ 90-21.81B, 90-21.82A, 90-21.83B. Further, most abortions are performed after five or six weeks (when the pregnancy is first visible by ultrasound). Ex. 1, ¶ 241. As Dr. Farris admits, many women do not even know that they are pregnant until around six weeks. ECF No. 49-1, ¶ 80.

Second, the Act recognizes the difficulty and heartbreak involved for survivors of sexual violence and patients with life-limiting fetal diagnoses by specifically *allowing* abortion up to 20 weeks LMP in cases of "rape or incest" and up to 24 weeks LMP in cases of "lethal fetal anomaly." N.C. Gen. Stat. § 90-21.81B. "Hospitals and emergency departments are trained" to provide the "intense medical and psychological support" that rape or incest victims need and to "ensure the forensic chain of evidence is followed," so that the

rapist may face justice. Ex. 3, ¶ 52. It is not irrational for the General Assembly to think that a hospital is the safest place for second-trimester surgical abortions.

Nor is the Act "an attack on families with low incomes, North Carolinians of color, and rural North Carolinians." ECF No. 49, 22. On the contrary, these groups deserve safe health care as do all North Carolinians. The General Assembly has determined that abortion is lawful within the first 12 weeks LMP (and longer for certain exceptions) and instituted modest and rational safety regulations. Moreover, the Act specifically addresses concerns of low-income North Carolinians by appropriating "$3,500,000[] in recurring funds for each year . . . to be used to award grants to local health departments and nonprofit community health centers" and "2,800,000[] in recurring funds" to Medicaid benefits relating to pregnancy and prenatal care. Ex. 4, SB 20 §§ 4.1, 4.2(a)–(c).

For these reasons, neither Dr. Gray, Planned Parenthood, its physicians, nor its patients will suffer irreparable harm absent an injunction.

III. The balance of the equities and the public interest weigh against enjoining the challenged provisions.

When balancing the equities, a court should "focus[] specifically on the concrete burdens that would fall on the party seeking the injunction [and] pay particular regard for the public consequences in employing the extraordinary

remedy of injunction." *Dep't of Defense*, 947 F.3d at 231. Here, both the balance of the equities and the public interest weigh against Plaintiff's proposed preliminary injunction.

At the outset, North Carolina will "suffer[] a form of irreparable injury" if this Court "enjoin[s]" it "from effectuating" the challenged provisions, which were "enacted by representatives of its people." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (citing *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)). Moreover, "the public interest is . . . served by permitting legitimate and duly enacted legislation," including the challenged provisions, "to be enacted." *N.C. State Conf., of the NAACP v. McCrory*, 156 F. Supp. 3d 683, 708 (M.D.N.C. 2016); *see also Priorities USA v. Nessel,* 860 F. App'x 419, 423 (6th Cir. 2021) (holding the public interest necessarily weighs against enjoining a duly enacted statute); *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (holding "[t]he public interest is likewise served by maintaining the ability to enforce the law adopted by the . . . Legislature and in upholding the exclusive authority vested in the . . . Legislature").

A preliminary injunction would not "preserve North Carolinians' health and safety." ECF No. 49, 23. Quite conversely, as detailed above and in the attached declarations, the challenged provisions serve to make abortion *safer* for the mother. For example, they ensure that abortion providers do not provide

contraindicated chemical abortion drugs to a woman suffering from an ectopic pregnancy without first determining whether she suffers from an ectopic pregnancy. And they ensure that admittedly higher-risk later-term abortions take place in a hospital where even Plaintiffs agree they send patients when certain complications arise. Regardless, the Constitution "give[s] state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales*, 550 U.S. at 163. Thus, the balance of the equities and the public interest support the State, and the Court should deny Plaintiffs' Motion.

CONCLUSION

This Court should deny Plaintiffs' Motion for Preliminary Injunction.

RESPECTFULLY SUBMITTED THIS 7th day of August 2023.

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*** *Notice of Special Appearance Filed*

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to all counsel of record.

s/ W. Ellis Boyle
W. Ellis Boyle

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing document complies with L.R. 7.3(d) and contains less than 6,250 words. I also certify that this document uses 13-point Century Schoolbook and has a top margin of 1.25" on each page in compliance with L.R. 7.1(a).

s/ W. Ellis Boyle
W. Ellis Boyle

Exhibit 1

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC and BEVERLY GRAY, MD, Plaintiff, v. JOSHUA STEIN, TODD M. WILLIAMS, JIM O'NEILL, SPENCER MERRIWEATHER, AVERY CRUMP, JEFF NIEMAN, SATANA DEBERRY, WILLIAM WEST, LORRIN FREEMAN, BENJAMIN R. DAVID, KODY H. KINSLEY, MICHAUX R. KILPATRICK, MD, PHD, and RACQUEL INGRAM, PHD, RN, all in their official capacities Defendants. and PHILIP E. BERGER and TIMOTHY K. MOORE Intervenor-Defendants.	)	**Case No. 1:23-cv-480**

DECLARATION OF MONIQUE CHIREAU WUBBENHORST, M.D., M.P.H.

I, Monique Chireau Wubbenhorst, MD, PhD, pursuant to the provision of 28 U.S.C. § 1746, do hereby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions I express in this declaration are based on my education, training, and experience in the fields of medicine (specifically obstetrics and gynecology), public health, epidemiology, and statistical analysis, and ongoing familiarity with the medical literature. These opinions are my own, and do not represent any group with which I am affiliated.

Introduction and Professional Background

2. I am a practicing board-certified obstetrician-gynecologist with over 30 years' experience in patient care, teaching, research, health policy, public health, global health, and bioethics. I graduated from Mount Holyoke College and received my medical degree from Brown University concurrently with a master's degree in public health from Harvard University. I completed my residency in obstetrics and gynecology at Yale-New Haven Hospital and my postdoctoral fellowship in health services research at the Sheps Center for Health Services Research at the University of North Carolina-Chapel Hill. I was on the faculty of the Duke University School of Medicine from 2003–18. Subsequently, I served as Senior Deputy Assistant Administrator in the Bureau for Global Health at the United States Agency for International Development. Currently, I am a Senior Research Associate at the Center for Ethics and Culture, University of Notre Dame.

3. My clinical career has focused on caring for women in underserved and disadvantaged populations, especially African American and Native American communities, with a focus on women with medical, social, and psychiatric comorbidities. I have worked in multiple domestic and international contexts, including inner city Boston, rural North Carolina, the Veterans Administration, and Native American reservations in the United States; and in India, the Philippines, Kazakhstan, Ghana, South Sudan, Nepal, Cameroon, and Kenya.

4. I chaired the Women and Special Populations Committee for the American Heart Association and worked as a senior consultant to the United States Veteran's Administration. I am a fellow of the American College of Obstetricians and Gynecologists and a fellow of the American Heart Association. I have authored over twenty peer-reviewed publications and have been a reviewer for peer-reviewed journals including The British Journal of Obstetrics and Gynecology, Public Health, The Journal of Medical Ethics, PLOS 1, Journal of General Internal Medicine, Public Health, Issues in Law and Medicine, and The North Carolina Medical Journal. My research interests include the epidemiology and molecular biology of adverse pregnancy outcomes and reproductive health, health services research, racial-ethnic disparities in women's health, adverse pregnancy outcomes and long-term cardiovascular health, maternal mortality, women veteran's health, and ethics in epidemiology and reproductive health.

5. My experience and qualifications are set forth in further detail in my curriculum vitae, attached hereto as Exhibit A.

II. Expert Opinion

A. Farris Declaration

A.1. There are significant safety problems associated with induced abortion.

i) Paragraph 9

6. Dr. Farris alleges that "Not only is it safe and evidence-based to provide medical abortion to patients whose pregnancies are too early to see by ultrasound and who are at low risk for ectopic pregnancy…."

7. There are significant safety efficacy concerns with medication abortion.

8. The integrity of some of the literature on medication abortion in early pregnancy and abortion in general can come into question.

9. AAPLOG says "In examining the peer-reviewed literature on medication abortion, the alert reader will notice two disparate trends. A study of over 42,000 women receiving abortions at <7 weeks gestational age documented that adverse events occurred in one in five women who had medication abortions and almost 6% required surgery. The rate of complications was four times higher in medical than in surgical abortions (Niinimäki M, Pouta A, MD, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate Complications After Medical Compared With Surgical Termination of Pregnancy. Obstet. Gynecol. 2009; 114:795–804. Another Finnish study of 18,000 women found an 8% rate of surgery for medication abortion failures in the first trimester, and almost 40% surgery rate in the second trimester. (Mentula M, Maarit Niinimaki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo1 O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Human Reproduction, Vol.26, No.4 pp. 927–932, 201.)

10. AAPLOG: "Studies performed internationally or by non-biased researchers often find that failures and complications after medication abortion are common. Meanwhile, studies performed by vocal abortion advocates tend to find much lower incidences of adverse outcomes. These trends merit examination. Many of the studies which conclude that medication abortion is extremely safe are published in journals published by abortion advocates."

11. As will be shown below, evidence purporting to show that abortion in the setting of pregnancy of unknown location suffers from methodological and other weaknesses.

A.2. Most abortions in North Carolina are performed before the second trimester.

12. Dr. Farris alleges that "…preserving patients' access to this very early abortion care is all the more important given North Carolina's 12 week ban."

13. The current epidemiology of abortion in NC indicates that women are readily accessing abortion in the first trimester.

14. Dr. Farris presents no evidence to indicate the percentage of women in NC who undergo abortion before a pregnancy can be visualized. Dr. Farris alleges that "…preserving patients' access to this very early abortion care is all the more important given North Carolina's 12-week ban."

15. Dr. Farris' allegation is difficult to understand given that in North Carolina, 90.7% of all abortions in 2020 were performed at 13 weeks or less (56.9% medical abortions, 33.8% surgical abortions), while only 2.6% of abortions were performed at > 9 weeks for medical abortion, and 6.3% at >13 weeks for surgical abortion (CDC abortion surveillance).

A.3. The Act is not an attack on low-income families or North Carolinians of color.

i) Paragraph 10

16. In paragraph 10, Dr. Farris alleges that "In particular, the Act is an attack on families with low incomes, North Carolinians of color, and rural North Carolinians, who already face inequities in access to medical care…forced pregnancy carries health risks for everyone…Black women, who in NC are more than 3 times as likely to as white women to die during pregnancy, will acutely feel the Act's harms." The allegation that "the Act is an attack on families with low incomes" is false.

17. In North Carolina, the majority of abortions are performed in women with 13 years of education or more. Since education is linked to earning potential and income, this suggests that most abortions are not performed in women with low incomes, but rather in college-educated women.

18. If anything, abortion has been an attack on women of color, especially black women, and the black community.

19. Any discussion of "attacks on North Carolinians of color" must mention the reproductive injustice inherent in the deliberate targeting and destruction of 17 million African American lives through abortion since Roe.

20. There are substantial racial disparities in abortion rates, abortion mortality and non-abortion-related maternal mortality between black women and white women.

21. Nationally black women have the highest percentage of abortions, the highest abortion rate, and the highest abortion ratio of any racial ethnic group in the United States. The abortion ratio and abortion rate for black women are 4 times higher than for white women. This is true even though African Americans (population 42,000,000) comprise only 12-14% of the total U.S. population.

22. Black women also have the highest rates of poverty and maternal mortality, suggesting that the purported benefits of abortion not only do not accrue to them, but that abortion has negative effects on black individuals and communities.

23. Of the 28,206 reported abortions performed in North Carolina in 2020, 7,871 (27.9%) were performed in white women, and 14,738 (52%) were performed in black women (CDC data). This striking racial disparity is all the more concerning since African Americans comprise 22% of the North Carolina population, while European Americans comprise 70% of the population.

24. The percentage of black women undergoing abortion in North Carolina is higher than the national average.

25. These facts suggest that abortion is a eugenic tool of injustice which fits into North Carolina's shameful (but acknowledged and apologized for) history of eugenic sterilization targeting black women.

26. Rather than attacking North Carolinians of color, the Act serves to protect them. Dr. Farris' speculation that abortion restrictions will harm black women has no basis in fact and does not accord with data.

A.4. Induced abortion is not health care.

i) "Abortion is common, safe and critical healthcare"

27. The statement that "abortion is healthcare" appears throughout the document, including in the phrases "abortion care" and "desperately needed healthcare."

28. Abortion is not health care. It does not prevent, treat, or palliate any disease and it always causes the death of a human being, an unborn child.

29. The term "abortion care" is an oxymoron. The killing of the fetus, an unborn child who is a human being, is not care, it is intentional feticide.

30. To say that abortion is health care implies that pregnancy is a disease.

31. Abortion is associated with significant risks to the mother and is always lethal to a developing child.

32. First trimester medication abortion carries substantial risks to the mother. A study by Niinimaki et al used data from Finland's health service administrative database, which included all women in Finland undergoing abortion from 2000 to 2006 (42,619 women) and collected follow up data for 42 days post abortion. This study design captured all outcomes for all women undergoing abortion in an entire country over a longer period of time than most studies of abortion complications. As a result, it is free of methodological problems and bias that plague other studies of abortion, including those conducted in the United States.

33. In the study by Niinimaki et al, 20% of women underwent medical abortion, and 5.6% underwent surgical abortion. The authors note that "The overall incidence of adverse events was fourfold higher in the medical compared with the surgical abortion cohort. The risk of hemorrhage with medical abortion was 15.6%, and 2.1% with surgical abortion. The risk of incomplete abortion with medical abortion was 6.7%, and 1.6% with surgical abortion. The risk of emergency surgery with medical abortion was 5.9% with medical abortion, and 1.8% with surgical abortion."

34. Therefore, in this study, women undergoing medical abortion had 8 times the risk for hemorrhage compared to those undergoing surgical abortion. They had 5 times the risk of needing a curettage to remove retained placenta or fetal parts, and 4.2 times the risk for an adverse event compared to those undergoing surgical abortion. These findings have significant implications given the increased use of medical abortion.

35. As noted, the strength of this study was its ability to completely ascertain all abortions and all associated complications.

36. In contrast, other studies attempting to answer questions about the safety of abortion have methodological issues related to the study design. For example, a study by Upadhyay et al (Ushma D. Upadhyay, Sheila Desai, Vera Zlidar, Tracy A. Weitz, Daniel Grossman, Patricia Anderson, Diana Taylor. Incidence of Emergency Department Visits and Complications After Abortion. Obstet Gynecol 2015;125:175–83) has many limitations, similar to other retrospective administrative database research studies. These include potential confounding associated with inaccurate coding; the absence of clinical data, especially on gestational age at the time of abortion and method of abortion; and the likelihood that patients with complications did not engage with the medical system. As with many studies of this type, no charts were reviewed. There was very limited follow up. The authors acknowledge some of these issues and note as well that, for example, second trimester abortion complications in their study are lower than in other studies, suggesting that

their population may not be representative, or that cases were incompletely ascertained.

37. First trimester surgical abortion carries immediate risks of hemorrhage, infection, continuing pregnancy, death, perforation of the uterus, damage to organs including hysterectomy. These complications, and the need to discuss them in counseling for informed consent, are described in the National Abortion Federation 2020 Clinical Policy Guidelines for Abortion Care.

38. The risks of abortion increase with gestational age. As Turok et al (2008) note, "The risk of death from abortion increases with gestational age, and these procedures are potentially more morbid because of the increased size of fetal and placental tissue, increased blood volumes and a distended uterus…'.

39. Cates and Grimes (1981) used data from approximately 243,000 D&E procedures from 1972-1978 and noted that for women undergoing D&E the mortality rate was 5.6 per 100,000 at 13-15 weeks' gestation and 14.0 per 100,000 at > 16 weeks.

40. The mortality rate for dilation and curettage procedures at < 12 weeks' was 1 per 100,000; for instillation procedures at > 13 weeks' it was 13.9 per 100,000 for saline and 9 per 100,000 for prostaglandin and other agents; and for hysterectomy and hysterotomy 42.8 per 100,000. The authors note that "because the risk of death from D&E is directly related to gestational age, the death: case rate [or ratio of deaths per 100,00 procedures] in the 13-15 week interval (5.6/100,000) is significantly…less than at 16 weeks' or later (14/100,000)."

41. Many studies have quantified the association between increasing gestational age and increasing risk for maternal mortality, specifically in second trimester abortions. A study by Cates and Grimes using abortion data from 1972-1978 shows that D&E procedures performed at 16 weeks gestation were nearly 3 times more dangerous than those performed from 13-15 weeks, with the risk of a woman dying from a second trimester abortion increasing 50% for each additional gestational week.

42. Similarly, Zane et al reported using CDC and AGI abortion data from 1998-2010 that the mortality rate for women having second trimester abortions increases with gestational age, from 2.4 deaths per 100,000 abortions at 14-17 weeks' gestation to 6.7 deaths per 100,000 at or after 18 weeks gestation.

43. Rates of complications associated with second trimester abortion are higher than for first trimester abortion. For example, Turok et al (Turok D, Gurtcheff SE, Esplina MS, Shahb M, Simonsena SE, Trausch-Van Horn J, Silvera RM. Second trimester termination of pregnancy: a review by site and procedure type. Contraception 77 (2008), pp. 155–161) studied differences in complications between second trimester abortions performed in 475 women, in hospitals vs. free-standing clinics. The authors found that major complications (defined as death, uterine

perforation, hysterectomy, transfusion, clotting disorders, deep venous thrombosis, pulmonary embolus, stroke or heart attack, need for exploratory surgery, and prolonged hospitalization) occurred in 1-11% of women undergoing D&E.

44. Other complications included: need for readmission, need for curettage after abortion for retained placenta and/or fetal parts, infection of the fetal membranes after initiation of the procedure, and uterine infection. The authors also note that complications may have been underreported due to loss to follow-up.

45. Edlow et al. (Edlow AG, Hour MY, Maurer R, Benson C, Delli-Bovi L, Goldberg A. Uterine evacuation for second-trimester fetal death and maternal morbidity. Obstetrics and Gynecology 2011;117:307–16) noted that "[higher] gestational age was significantly associated with maternal morbidity", with women undergoing abortion at > 20 weeks' being 2 ½ times more likely to suffer a complication than women undergoing abortion at < 20 weeks' gestation.

46. Lederle et al. (Lederle L, Steinauer JE, Montgomery A, Aksel S, Drey E, Kerns JL. Obesity as a Risk Factor for Complication After Second-Trimester Abortion by Dilation and Evacuation. Obstetrics and Gynecology 2015 September; 126(3): 585–592) found a 30% increased risk for complications with each additional week of gestation.

47. African American women also have 2-3 times higher mortality rate from abortion compared with white women. Bartlett et al found that "The second most significant risk factor for death [from abortion, after gestational age] overall was race. Women of black and other races were 2.4 times as likely as white women to die of complications of abortion…At all gestational ages, women of black and other races had higher case mortality rates than white women."

48. Zane et al (2015) also reported that the abortion "mortality rate was 0.4 for non-Hispanic white women, 0.5 for Hispanic women, 1.1 for black women and 0.7 for women of all other races…Black women have a risk of abortion-related death that is three times greater than that for white women."

49. Large records-based studies show that women who have undergone abortion have an increased death rate due to accidents, compared to women who were not pregnant and compared to women who carried a pregnancy to term (Reardon DC, Ney PG, Scheuren FJ, Cougle JR, Coleman, PK, Strahan T. Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women. Southern Medical Journal. 2002; 95: 834).

50. In this study women who gave birth had the lowest death rate and women who had abortions, the highest, compared to the non-pregnant group.

51. In Gissler's study, post-abortive women had more than four times the accidental death rate of women who gave birth. Gissler M, Kauppila R, Merilainen J,

Toukomaa H, Hemminki E Pregnancy-Associated Deaths in Finland 1987-1994—Definition Problems and Benefits of Record Linkage, Acta Obstetricia et Gynecologica Scandinavica. 1997;76: 651.

52. One study suggests that some of the increase in the accidental death rate may be due to suicidal behavior that is not recognized as such (passive vs active suicide) (Reardon et al, 2002). "Reports of post-abortive women deliberately crashing their automobiles, often in a drunken state, in an attempt to kill themselves have been reported by post-abortion counselors and in the published literature." Reardon DC, Strahan TW, Thorp Jr. JM, Shuping MW. Deaths associated with abortion compared to childbirth—a review of new and old data and the medical and legal implications. Journal of Contemporary Health Law and Policy. H2004; 20(2):279-327.

53. "One post-abortive woman reported intentionally going out and sitting in a puddle during a thunderstorm. Another said, "'I cracked up my car three times, driving recklessly at extreme speeds. In one wreck, I broke four ribs and punctured my lung. My life became a series of … accidents and self-destructive benders.'" Burke T and Reardon DC. Forbidden Grief: The Unspoken Pain of Abortion.2002; Springfield, IL: Acorn Books.

54. Rates of accidental death may be affected by drug and alcohol abuse which are increased after abortion (Coleman, PK. Induced Abortion and Increased Risk of Substance Abuse: A Review of the Evidence. Current Women's Health Reviews. 2005;1:21-34; Coleman P K, Reardon DC, Cougle J. Substance use among pregnant women in the context of previous reproductive loss and desire for current pregnancy. Br J Health Psychol 10, 255–268).

55. It appears that post-abortive women have a higher rate of accidental death compared to women who give birth. This may be due to suicidal behavior resulting in outcomes that are interpreted are accidental, or substance abuse causing accidents, or a mix of both.

56. In another study, women who had an abortion were found to have a 60% higher risk of death from natural causes during the year after their abortion compared to women who gave birth. (Thorp, JM. Jr., Hartmann, KE, Shadigian E. Long-Term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence. Obstetrical & Gynecological Survey. 2003; 58(1):67-79).

57. In a 2002 California Medicaid study spanning 8 years, women who aborted had a 44% higher risk of death from natural causes over eight years of the study than women who gave birth as well as a 62% increase in all cause deaths and a 154% increased risk in suicide (Reardon DC, Cougle J, Ney PG, Scheuren F, Coleman PK, Strahan T. Deaths associated with delivery and abortion among California Medicaid patients: A record linkage study. Southern Medical Journal 2002;95:834-41).

58. Abortion is associated with increased drug and alcohol abuse which in turn are associated with multiple health problems and high-risk behaviors (as well as contributing to accidents as noted above). Numerous studies show a strong association between abortion and substance abuse (including alcohol).

59. Fergusson et al. in a 2006 study found higher rates of illicit drug dependence (but not alcohol dependence) in post-abortive women compared to women who had been pregnant but non-abortive, and also compared to never pregnant women. This association persisted after controlling for confounding factors. (Fergusson DM, Horwood LJ, Ridder EM. Abortion in young women and subsequent mental health. Journal of Child Psychology & Psychiatry 47:1 (2006), pp 16–24.)

60. Abortion is associated with increased risk for cigarette smoking which in turn is associated with established health risks (cardiovascular, cerebrovascular, and respiratory diseases). Women who abort are twice as likely to become heavy smokers and suffer the associated health risks. This is especially problematic in women who smoke and use hormonal contraception, since the latter combination increases the risk for cardiovascular disease such as stroke and heart attack.

61. In the 2002 California Medicaid study, among women with only one pregnancy during the 8 years of the study, those who had abortions were nearly three times more likely to die of circulatory disease (OR 2.87) and over five times more likely to die from cerebrovascular disease (OR 5.46). This study also found that abortion was significantly associated with risk of death from HIV/AIDS. Pelvic inflammatory disease (PID) is a relatively common complication of abortion and PID may increase the risk of HIV transmission. (Heisterberg L. Pelvic Inflammatory Disease Following Induced First-Trimester Abortion. Danish Medical Bulletin.1988; 64; Sørensen JL, Thranov I, Hoff G. & Dirach J. Early- and Late-Onset Pelvic Inflammatory Disease Among Women with Cervical Chlamydia Trachomatis Infection at the Time of Induced Abortion—A Follow Up Study. Infection. 1994; 22: 242; Hillis S. D. et al. Delayed Care of Pelvic Inflammatory Disease as a Risk Factor for Impaired Fertility. Obstetrics & Gynecology 1993; 1503).

62. Since abortion is associated with increased risk for substance abuse, this can increase the likelihood of HIV infection via IV drug abuse and other high-risk behaviors.

63. In my opinion, the above data support the assertion that the safety of abortion, especially in the second trimester, is overestimated.

A.5. Induced abortion is not always simple or straightforward, and is surgery.

i) Paragraph 14: "All methods of abortion provided at PPSAT…are simple, straightforward medical treatments…that have an extremely low complication rate"

64. As noted above in multiple references, abortion does not have a low complication rate.

A.6. Surgical abortion is surgery

i) Paragraph 15: "Although aspiration abortion and D&E are both sometimes referred to as "surgical", they are not what is commonly understood to be surgery."

65. This statement is medically inaccurate.

66. "Aspiration abortion" is more accurately described as suction abortion with curettage. In fact, Dr. Farris states in her own declaration, in Paragraph 21, that "Aspiration abortion" is "also known as suction curettage or dilation & curettage."

67. Both suction abortion with curettage and D&E are types of surgical abortion. Such abortions are understood to be surgery; they are coded, billed, and reimbursed as such, and listed everywhere in the medical literature as surgical procedures.

68. Surgical abortion requires surgical training distinct from other types of training.

69. It requires standard surgical operative sterile technique.

70. Surgical abortion at any gestational age requires the forcible dilation of the cervix with instruments +/- Laminaria, removal by suction of the living fetus, placenta, and membranes (resulting in his or her death), and curettage of the uterine cavity.

71. Curettage is essentially a linear incision through the lining of the uterus.

72. These incisions are associated with surgical complications.

73. "Asherman's Syndrome (AS) is an acquired condition defined by the presence of intrauterine adhesions (IUA) that cause symptoms such as menstrual abnormalities, pelvic pain, infertility, recurrent miscarriage, abnormal placentation,

and attendant psychological distress. Classically, AS is considered an iatrogenic disease triggered by trauma to the pregnant uterus." (Santamaria et al, 2018).

74. Per Santamaria et al (2018), "15–20% of patients receiving curettage due to an induced or spontaneous abortion…develop IUA [intrauterine adhesions]." Xavier Santamaria, Keith Isaacson, and Carlos Simón Asherman's Syndrome: it may not be all our fault. Human Reproduction, Vol.33, No.8 pp. 1374–1380, 2018.

75. Abnormal placental attachment occurs as a result of damage to the lining of the uterus with curettage.

76. Such damage may lead to premature separation of the placenta (abruption) or invasion (accreta).

77. Abnormal placental attachment is a significant cause of maternal morbidity and mortality. It occurs when the normal process of placental invasion goes awry and is associated with catastrophic hemorrhage at delivery.

78. Baldwin et al (2018) found that uterine curettage (as occurs with surgical abortion) doubled the risk of abnormal placental attachment (Heather J. Baldwin, Jillian A. Patterson, Tanya A. Nippita, Siranda Torvaldsen, Ibinabo Ibiebele, Judy M. Simpson, Jane B. Ford. Antecedents of Abnormally Invasive Placenta in Primiparous Women (Obstet Gynecol 2018; 131:227–33)).

79. Interestingly, in 1950, pre-Roe, abnormal placental attachment occurred in 1:30,000 deliveries. In 2016 it occurred in 1:272 deliveries, a 110-fold increase.

80. Abortion is associated with surgical complications such as bleeding, infection, damage to the uterus, possible damage to other organs including bowel and bladder, and possible need for further surgery.

81. It also is incontrovertible that D&E involves the cutting up, tearing apart and crushing of the fetus, and is, therefore, a destructive feticidal surgical procedure.

82. Other procedures, such as those performed in the oropharynx, nose and other locations are considered surgery.

A.7. Medication abortion is not the same as miscarriage management

i) Paragraph 17: "Indeed, the process of medication abortion very closely approximates the process of miscarriage."

83. This is a medically and ethically inaccurate statement.

84. Abortion and miscarriage are quite different, and abortion is neither ethically nor medical identical to miscarriage.

85. In a miscarriage, the fetus or embryo, the unborn child has died on his or her own. Clinicians then use either medications (misoprostol) or surgery to remove the fetus, placenta and membranes, and their role is to provide healing.

86. In an abortion, intentional feticide occurs. Clinicians use mifepristone to kill the fetus or embryo, then add misoprostol to effect the expulsion of its dead body, and their role is to assist in the killing of the unborn child.

87. Research has shown that the risk of complications following medical abortion is higher than for miscarriage. In a randomized controlled trial by Trinder et al (the MIST trial), only 3% of patients who received medical management of their miscarriage with misoprostol experienced excessive bleeding and 3% of patients were diagnosed with infection (J Trinder, P Brocklehurst, R Porter, M Read, S Vyas, L Smith. Management of miscarriage: expectant, medical, or surgical? Results of randomized controlled trial (miscarriage treatment (MIST) trial). BMJ, doi:10.1136/bmj.38828.593125.55).

88. This is in contrast to Niinimaki's study, in which 15.6% of women undergoing medical abortion experienced hemorrhage.

89. A prospective cohort study comparing complication rates for women following medical or surgical abortion, which had 100% patient follow-up for 2 weeks, found that among women who underwent surgical abortion, 10.9% were treated for infection Jeffrey T. Jensen, Susan J. Astley, Elizabeth Morgan, and Mark D. Nichols. Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study. Contraception 1999;59:153–159.

90. In comparison with miscarriage, medical abortion is intentional feticide and is associated with higher risks for infection and hemorrhage.

A.8. Mifepristone carries risks and is not safer than Tylenol or Viagra

i) Paragraph 18: "Mifepristone and misoprostol are safe – substantially safer than Tylenol and Viagra, for example."

91. The report cited by Dr. Farris to support this allegation, "Analysis of Medication Abortion Risk and the FDA report, by Advancing New Standards in Reproductive Health, does not accurately report the data from the FDA report on post-marketing events in women who had taken mifepristone. The FDA report is shown below.

92. The report also states inaccurately that "13 cases appear to be unrelated to the abortion…." This is not only false, it also implies that FDA came to this conclusion, when such a conclusion appears nowhere in the FDA report.

93. The report also states that "Because it is mandatory to report any death among someone who used mifepristone and because the US Centers for Disease Control and Prevention has an active surveillance program to monitor abortion related deaths…these reports capture information about all possible deaths related to medication abortion…"

94. This statement is demonstrably false. Only drug manufacturers are mandated to report adverse events associated with their product, and as a consequence only deaths and complications that were reported to manufacturers must be reported. Deaths and complications not reported are not included in FDA's reports, and it is almost certain that many deaths and complications have not been reported for a variety of reasons.

95. FDA and CDC reports do not capture information about all possible deaths related to mifepristone.

A.9. US abortion data are incomplete.

96. U.S. abortion data are incomplete. The collection of abortion statistics is widely acknowledged to be severely flawed. CDC's collection of data is voluntary, not mandatory. Starting in 1998, multiple states did not report their abortion data or provided incomplete data. Per CDC's 2019 Abortion Surveillance, "Data from 24 reporting areas excludes 17 states that did not report, did not report by race/ethnicity or did not meet reporting standards," including Alabama, Arizona, California, Delaware, District of Columbia, Florida, Hawaii, Illinois, Louisiana, Maine, Maryland, New Hampshire, New Mexico, Tennessee, Vermont, Wisconsin, and Wyoming Abortion Surveillance — United States, 2019, MMWR (cdc.gov).

97. California, Maryland, and New Hampshire do not report any official data, and many states submit incomplete data which lack information on gestational age, race-ethnicity, and gestational age. The lack of abortion reporting from some of the most populous states makes it difficult to arrive at accurate estimates of the number of abortions performed in the United States.

98. Abortion statistics and abortion mortality statistics are widely acknowledged to be inaccurate. There is no federal reporting requirement for either the number of abortions performed in the United States of the number of women who dies from abortion. Only 26 states require providers to report. The data provided are estimates: "Many state health departments are able to obtain only incomplete data from abortion providers, and in some states, only 40-50% of abortions are reported." (Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991-1999. Am J Obstet Gynecol 2006;194:92-93; Saul R. Abortion

reporting in the United States. Fam Planning Perspect 1998;30:244-47; Guttmacher Institute. Abortion reporting requirements. State Policies in Brief. 2009; 12 September; Jones RK, Zolna MRS, Henshaw SK, Finer LB. Abortion in the United States: Incidence and access to services. Perspect on Sexual and Repro Health 2005;40(1):6-16).

99. Abortion-related deaths, not including the unborn child, are maternal deaths. CDC collects maternal mortality data in 2 separate systems, the National Vital Statistics System (NVSS), and the Pregnancy Mortality Surveillance System (PMSS). From 1995-97 NVSS reported 898 maternal deaths while PMSS reported 1,387 deaths.

100. Only 54% of deaths were reported in both systems (MacKay A, Berg CJ, Duran C, Chang J, Rosen berg H. An assessment of pregnancy-related mortality in the U.S. Pediatric & Perinatal Epidemiology 2005; 19:206-14).

101. CDC's 2020 Abortion Surveillance report stated that "because reporting to CDC is voluntary and reporting requirements vary by the individual reporting areas…***CDC is unable to report the total number of abortions performed in the United States***." [emphasis added]. Data collected by the Alan Guttmacher Institute (AGI) are also limited because AGI relies on surveys rather than collection of case data (for a description of their methodology, see https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017).

102. Both CDC and AGI data acknowledge the limitations of their data and their quality. Their reports are estimates and cannot be used to precisely assess the total number of abortions performed in the United States. Without even a precise estimate of the number of abortions performed in the United States, accurate estimates of deaths and complications from abortion cannot be made.

103. Estimates of abortion-related mortality are likewise inaccurate because deaths from abortion appear to be underreported (see David C. Reardon, Thomas W. Strahan, John M. Thorp, Jr. & Martha W. Shuping, Deaths Associated with Abortion Compared with Childbirth – A Review of New and Old Data and the Medical and Legal Implications, 20 J. Contemp. Health Law & Policy 279, 286-91 (2004); Byron Calhoun, Systematic Review: The maternal mortality myth in the context of legalized abortion, The Linacre Quarterly, 264 (2013).

104. The problem of inadequate data collection and analysis is not limited to abortion mortality. It is far greater for abortion complications. CDC does not systematically collect and report data on abortion complications, nor do many abortion providers. In some states, abortion providers are required to report immediate complications.

105. However, there are very few studies on longer-term follow up. The American College of Obstetrician-Gynecologists Current Commentary: Routine

Follow up Visits After First-Trimester Induced Abortion (2004) noted that "In practice, attendance at abortion follow up visits is usually low, generally about 50%. Studies of first trimester aspiration abortion complications observing consecutive series of patients show follow-up proportions from 35% to 60%, although a few series report proportions as high as 80-90%."

106. For example, Summit Medical Centers, which operate abortion clinics in Atlanta and Detroit, explicitly state on their website that "You do not need to return to Summit Medical for a follow-up visit after your abortion." (https://www.summitcenters.com/after-your-abortion/).

107. It is a principle of medical practice that physicians must follow up with their patients after treatment, or arrange such follow up.

108. Most women with complications from abortion seek help at emergency departments. This is especially true of abortions performed by non-physicians, who by definition cannot manage abortion complications.

109. Therefore, the true risks of abortion to women and the frequency of abortion-related complications remain unknown. The need for accurate statistics on abortion is a public safety issue, not a pro-life or pro-abortion issue.

110. As will be seen, this inadequate ascertainment of complications and deaths related to abortion is a fatal flaw in most of the studies cited by Drs. Farris and Alsleben.

111. Women experiencing life-threatening health complications from abortion go to hospital emergency rooms and are not usually seen by abortionists.

112. Deaths from abortion complications are often not counted. In addition, abortion-related deaths from (from physician complications of the procedure) are usually reported as maternal deaths.

113. The FDA report states that 26 women have been reported to have died in the United States and 12 women in foreign countries following the use of mifepristone for first trimester abortion.

Table 1. Cumulative Post-Marketing Fatal and Ectopic Pregnancy Reports in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy	
Date range of cumulative reports	09/28/00[†] - 06/30/21
Died [‡]	26
*Ectopic pregnancies [||]	97

[†] U.S. approval date

[‡] The fatal cases are included regardless of causal attribution to mifepristone. Deaths were associated with sepsis in eight of the 26 reported fatalities (seven cases tested positive for *Clostridium sordellii*, and one case tested positive for *Clostridium perfringens*). Seven of the eight fatal sepsis cases reported vaginal misoprostol use; one case reported buccal misoprostol use. Seventeen of the 18 remaining U.S. deaths involved two cases of homicide, two cases of combined drug intoxication/overdose, two cases of ruptured ectopic pregnancy, two cases of drug intoxication, and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; delayed onset toxic shock-like syndrome; hemorrhage; bilateral pulmonary thromboemboli; unintentional overdose resulting in liver failure; and a case of natural death due to severe pulmonary emphysema. In the eighteenth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *C. sordellii*. There were 12 additional reported deaths in women in foreign countries who used mifepristone for medical termination of pregnancy. These fatal cases were associated with the following: sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial; sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure;" thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; thromboembolism; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes, a jejunostomy feeding tube, and severe cystic fibrosis; and a case of *Clostridium septicum* sepsis (from a published literature report).

114. The report also notes that 97 ectopic pregnancies were reported.

115. The cited report by Advancing New Science in Reproductive Health omitted data on severe complications and adverse events from FDA. It also misrepresents FDA's conclusions regarding severe complications and hospitalizations associated with mifepristone use (see FDA report below).

Table 2. Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Medical Termination of Pregnancy

Date ranges of reports received	09/28/00[†] - 10/31/12	11/01/12 - 06/30/21[‡]
Cases with any adverse event	2740	1467
Hospitalized, excluding deaths	768	277
*Experienced blood loss requiring transfusions [§]	416	187
Infections [||] (*Severe infections [¶])	308 (57)	105 (13)

[†] U.S. approval date

[‡] FDA implemented the FDA Adverse Event Reporting System (FAERS) on September 10, 2012, and migrated all the data from the previous reporting system (AERS) to FAERS. Differences may exist when comparing case counts in AERS and FAERS. FDA validated and recoded product information as the AERS reports were migrated to FAERS. As a result of this change, it is not recommended to calculate a cumulative number when reviewing the data provided in Table 2.

* The majority of these women are included in the hospitalized category in Table 2.

[§] As stated in the approved labeling for Mifeprex (mifepristone) and its approved generic version, bleeding or spotting can be expected for an average of 9-16 days, and may last for up to 30 days. Excessive vaginal bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

[||] This category includes endometritis (inflammation resulting from an infection involving the lining of the womb), pelvic inflammatory disease (involving the nearby reproductive organs such as the fallopian tubes or ovaries), and pelvic infections with sepsis (a serious systemic infection that has spread beyond the reproductive organs). Not included are women with reported sexually transmitted infections such as chlamydia and gonorrhea, cystitis, and toxic shock syndrome not associated with a pelvic infection.

[¶] This subset of infections includes cases that were determined to be severe based on medical review of the available case details. Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have other physical or clinical findings, laboratory data, or surgery that suggest a severe infection.

116. "The FDA also published the number of cases of hospitalization and other complications (some already counted in the hospitalization cases) reported to them among women using medication abortion. However, unlike for deaths, there is no active surveillance program, so this report should not be considered as conclusive. We do know that serious complications are rare with medication abortion…"

117. Contrary to what is stated in the ANSIRH report, there is no active surveillance program for either deaths or complications from mifepristone use. FDA relies on reports made to manufacturers for these data.

118. As can be seen from the table, FDA received reports of 4,207 adverse events, 1045 hospitalization, 603 patients who required transfusion, and 413 infections, 70 of which were severe. According to the table, "Severe infections generally result in death or hospitalization for at least 2-3 days, require intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, or have

other physical or clinical findings, laboratory data, or surgery that suggest a severe infection."

119. It is demonstrably scientifically inaccurate to state that mifepristone is safer than Tylenol and Viagra.

120. Unlike Tylenol and Viagra, mifepristone carries a black box warning, which notifies clinicians and patients of serious and even fatal complications from taking a medication. FDA's black box warning process involves assessment of post-marketing experience.

121. As noted by Drugwatch (https://www.drugwatch.com/fda/black-box-warnings/), "A black box warning is the FDA's most stringent warning for drugs and medical devices on the market. ***Black box warnings, or boxed warnings, alert the public and health care providers to serious side effects, such as injury or death.*** The FDA requires drug companies to add a warning label to medications that have a black box warning…Before adding a boxed warning to a medication or medical device, the FDA must have evidence that the drug poses a significant risk. This evidence comes from observations and studies conducted after a drug has been on the market. ***After determining a drug needs a black box warning, the FDA contacts the drug company to add a warning to its labeling. The drug company then submits its language for FDA approval. Once the FDA approves the language, it is printed on the drug or device's package and on the medication insert***" [emphasis added].

122. Below is the black box warning for mifepristone, which warns of "serious and sometimes fatal infections or bleeding."

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)**

MIFEPREX is only available through a restricted program called the mifepristone REMS Program (5.3).
Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.
Advise the patient to take the MEDICATION GUIDE with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider knows that she is undergoing a medical abortion. (5.1, 5.2)

123. Below is the prescribing information for sildenafil (Viagra), which does not have a black box warning.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VIAGRA safely and effectively. See full prescribing information for VIAGRA.

VIAGRA® (sildenafil citrate) tablets, for oral use
Initial U.S. Approval: 1998

----------RECENT MAJOR CHANGES----------
Warnings and Precautions, Effects on the Eye (5.3) 08/2017

----------INDICATIONS AND USAGE----------
VIAGRA is a phosphodiesterase-5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED) (1)

----------DOSAGE AND ADMINISTRATION----------
- For most patients, the recommended dose is 50 mg taken, as needed, approximately 1 hour before sexual activity. However, VIAGRA may be taken anywhere from 30 minutes to 4 hours before sexual activity (2.1)
- Based on effectiveness and toleration, may increase to a maximum of 100 mg or decrease to 25 mg (2.1)
- Maximum recommended dosing frequency is once per day (2.1)

with caution, and only when the anticipated benefits outweigh the risks, in patients with a history of NAION. Patients with a "crowded" optic disc may also be at an increased risk of NAION. (5.3)
- Patients should stop VIAGRA and seek prompt medical attention in the event of sudden decrease or loss of hearing (5.4)
- Caution is advised when VIAGRA is co-administered with alpha-blockers or anti-hypertensives. Concomitant use may lead to hypotension (5.5)
- Decreased blood pressure, syncope, and prolonged erection may occur at higher sildenafil exposures. In patients taking strong CYP inhibitors, such as ritonavir, sildenafil exposure is increased. Decrease in VIAGRA dosage is recommended (2.4, 5.6)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥ 2%) include headache, flushing, dyspepsia, abnormal vision, nasal congestion, back pain, myalgia, nausea, dizziness and rash (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer at 1-800-438-1985 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- VIAGRA can potentiate the hypotensive effects of nitrates, alpha blockers, and anti-hypertensives (4.1, 5.5, 7.1, 7.2, 7.3, 12.2)
- With concomitant use of alpha-blockers, initiate VIAGRA at 25 mg dose

124. Acetaminophen (Tylenol) is an over the counter (OTC) medication.

125. Per Dailymed's data on acetaminophen (https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=511536b2-6cbd-463e-b2db-6feec474cf6b) "Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies."

126. It is therefore erroneous to state that mifepristone is as safe as or safer than Viagra or Tylenol. Mifepristone can and has caused serious complications and death. It is also clear that there are significant risks associated with the use of mifepristone which require close monitoring, like the REMS to prevent harms to women.

127. An updated 2022 FDA complete post-marketing report for mifepristone is shown below.

TTT # 2022-2468
NDA 020687
ANDA 091178
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022

The following information is from United States (U.S.) post-marketing reports received by FDA of adverse events that occurred among patients who had taken mifepristone for medical termination of pregnancy. Because FDA has eliminated duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided here may differ from the numbers of the reports that may be obtained through Freedom of Information Act requests. These events cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions. The estimated number of women who have used mifepristone in the U.S. for medical termination of pregnancy through the end of June 2022 is approximately 5.6 million women.

For informational purposes, fatal foreign cases that were reported after U.S. approval of mifepristone for medical termination of pregnancy are also included in a footnote in Table 1.

128. Given that the United States lacks comprehensive data on abortion morbidity and mortality, these statistics likely represent a small minority of deaths and complications from mifepristone. Also, given that medical abortion is for the most part an elective procedure, deaths and serious complications from mifepristone represent an unacceptable level of risk.

i) Paragraph 19: "In the rare event that a medication abortion is unsuccessful, the patient may require follow-up care with procedural abortion, but in the vast majority of cases a patient who prefers medication abortion will be able to use that method, saving them from an unwanted procedure or a hospital referral."

129. In a study cited by Dr. Alsleben, Barnhart et al noted that 15% of patients undergoing medical abortion required subsequent surgical abortion to complete the procedure.

A.10. Dilation and evacuation (D&E) is a brutal procedure with maternal risks.

i) Paragraph 25: "Dilation and evacuation…uses a combination of gentle suction and additional instruments…to evacuate the pregnancy contents from the uterus."

130. This statement is medically and ethically inaccurate.

131. Even by abortionists' accounts, D&E is anything but gentle.

132. In fact, it is a demonstrably brutal procedure that kills an unborn child in a way that would not be countenanced for an animal.

133. The "pregnancy contents" are not tissue or "a clump of cells." In addition to placenta and membranes they include fetus, a living human being, an unborn child, with human DNA and human parents, and that human being is killed by intentional feticide.

A.11. Abortion is not one of the safest procedures in medicine – it carries risks for the mother and is always lethal to a developing fetus, an unborn child.

i) Paragraph 30: "Abortion is one of the safest procedures in medicine."

134. As described above, maternal abortion safety is not accurately ascertainable using current data collection methods.

135. As a result of these flaws, it is not possible to accurately estimate the risks of abortion, including abortion mortality.

136. It is known that young and healthy women have died following a first trimester abortion. For example, in 2016, following an elective first trimester surgical abortion at 6 weeks performed at Carolina Center for Women in Greensboro, NC, an 18 year old woman from Charlotte died from probable disseminated intravascular

coagulation (D&C), a known complication of abortion, with retained products of conception (see https://www.operationrescue.org/wp-content/uploads/2018/07/Autopsy-Report-DiamondWilliams.pdf).

137. Dr. Farris cites the study by the National Academies of Science. Nat'l Acads. Scis., Eng'g & Med., *The Safety and Quality of Abortion Care in the United States* 1, 77 (2018), *available at* http://nap.edu/24950.

138. The NAS report has very significant flaws.

139. Per AAPLOG Practice Guideline Number 8 (February 2020), the study "was funded by the Packard, Buffet, and Hewlett foundations, which are leading funders of international abortion advocacy." While the study authors performed an extensive literature review, they excluded hundreds of studies, and primarily used those written by abortion advocates.

140. Not surprisingly, by primarily utilizing studies performed by fellow abortion advocates, they concluded that serious complications or long term physical or mental health effects are virtually non-existent. In fact, they reported abortion is so safe that the only deterrent to its safety is legislative restrictions enacted by the states that may prevent a woman from accessing an abortion immediately, "creating barriers to safe and effective care."

141. However, when one examines the research studies they used for their conclusions, the poor quality of the literature regarding long-term complications becomes apparent. For many questions, there were very few or no studies that met their inclusion criteria, and they disqualified many studies due to perceived study defects. Thus, in all cases, there were less than five studies on which they based their definitive conclusion of "no long-term impact." To make this determination, however, they rejected hundreds of other published peer-reviewed studies.

142. A closer glance at some of the large studies the NAS referenced show that they also contain many flaws. One study reported a very small percentage of emergency room visits for abortion complications but ignored the reality that documentation specifying medication abortion complications is very difficult in the ICD-10 system. Another study documented a very low incidence of serious abortion complications by reviewing Planned Parenthood's database, ignoring the fact that most abortionists do not maintain hospital admitting privileges or care for their own complications."

143. The studies cited by Dr. Farris by Upadhyay et al. have many limitations. The 2015 study has been discussed above. For the 2018 study, a national sample was used, but this study also had issues. For example, it included only about 15.7% of hospitals. It under-sampled some regions (West and South) and oversampled others. Significantly, the authors note that "Most visits were to non-trauma or

trauma level III hospitals (62.8%) and most were to hospitals in urban locations (92.3%)".

144. Similar to other retrospective administrative database research studies, this study had issues including potential confounding associated with inaccurate coding; the absence of clinical data, especially on gestational age at the time of abortion and method of abortion; and the likelihood that patients with complications may have been distributed differently in different regions and hospitals.

145. Gestational age at the time of abortion, race-ethnicity and abortion method were not ascertained for this study. As with many studies of this type, no charts were reviewed.

146. However, it is noteworthy that one-third of patients in the study required suction curettage for bleeding and presumed retained fetal parts, placenta and membranes. 15 patients in the sample had ED visits that ended in the patient's death.

147. The authors state that "…the major incident rate may have been slightly underestimated…using billing codes to understand the nature of the ED visit can be imprecise and incomplete…The lack of full clinical data to determine abortion relatedness could cause errors. For example, the visits in this study could include cases of miscarriage. Likewise, this study may miss abortion-related incidents that were inaccurately coded as a miscarriage."

A.12. Abortion is not comparable to the other surgical procedures listed.

i) Paragraph 33: "Abortion compares favorably with a markedly lower complication rate, to other procedures routinely performed outside of a hospital setting…."

148. First, Dr. Farris has conflated first- and second-trimester abortion. As noted, they are very different in terms of morbidity, mortality, and complications.

149. Per CDC, in 2020 81% of abortions (496,261) were performed at less than or equal to 9 weeks, 93% (576,904) were performed at less than or equal to 13 weeks, and 7% (55,829) were performed at > 13 weeks. But it is an established fact that deaths and complications from abortion mostly occur in the smaller number of abortions performed at later gestational ages. Most abortion advocates report abortion complication and death rates as averages across all gestational ages. As a result, estimates of deaths and complications are skewed toward the lower mortality rates at lower gestational ages, due to the much larger number of abortions done at lower gestational ages. This "needle in a haystack" effect, along with inadequate data collection for abortion complications and deaths, obscures the true risks associated with abortion, especially at higher gestational ages.

150. Second, Dr. Farris' allegation overlooks the fact that the frequency of complications associated with a procedure is not the same as the magnitude and severity of complications. All of the procedures to which she compares abortion are minimally invasive. Abortion in either the first or second trimester is an invasive procedure. Not only is the cervix forcibly dilated, the amniotic membranes are penetrated, the fetus is crushed and suctioned out (first trimester abortion), or dismembered and removed piece by piece (second trimester abortion), and the uterine cavity is scraped.

151. First trimester surgical abortion carries immediate risks of hemorrhage, infection, continuing pregnancy, death, perforation of the uterus, and damage to organs including hysterectomy. These complications, and the need to discuss them in counseling for informed consent, are described in the National Abortion Federation *2020 Clinical Policy Guidelines for Abortion Care*.

152. Listed risks for second trimester abortion appear in Table 3. These are probably underestimates of morbidity given that in the United States there is no mandatory reporting for abortion, abortion complications, or abortion deaths.

Table 3. Complications associated with second trimester abortion (medical and surgical)

Complication	**Incidence and estimated cases per year***	**Studies**
Bleeding and hemorrhage†	0.09-11.6% (35-4637)	Peterson 1983, Altman 1985, Autry 2002, Jacot 1993, Ashok 2004, Castleman 2006, Patel 2006, Mentula 2011, Lederle 2016, Sonalkar et al 2017
Infection†	1.3-3% (520-1199)	Peterson 1983, Altman 1985, Jacot 1993, Autry 2002, Ashok 2004, Patel 2006, Castleman 2006, Mentula 2011
Uterine perforation	0.45-3.7% (180-1479)	Peterson 1983, Grimes 1984, Altman 1985, Jacot 1993, Pridmore and Chambers 1999, Ashok 2004, Patel 2006, Castleman 2006, Nucatola 2008
Uterine rupture	0-4.8% (0-1919)	Peterson 1983, Altman 1985, Jacot 1993, Herabutya 2003, Ashok 2004, Dashalakis 2005, Dickinson 2005, Castleman 2006,

		Daponte 2006, Mazouni 2006, Patel 2006, Cayrac 2011
Cervical laceration	1.3-3.8% (520-1519)	Peterson 1983, Altman 1985, Jacot 1993, Autry 2002, Ashok 2004, Castleman 2006, Patel 2006, Lederle 2016
Embolus Pulmonary embolus Amniotic fluid embolus‡	 0.1-0.2% (39-800) 0.000125 - 0.001% (<1-<1)	*ACOG Practice Bulletin #135*, 2013
Coagulopathy	0.17-0.2 (67-80)	York 2012, Frick 2010, Lederle 2016
Exploratory surgery Repair of bowel injury Hysterectomy	 0.53% (2119) 0.00005-2.4% (<1-959)	 Darney 1990 Mentula 2011, Garofalo 2017
Retained fetal parts and/or placenta requiring D&C	0.2-21% (80-8396)	Autry 2002, Mentula 2011, Lederle 2016, Peterson 1983, Jacot 1993 Ashok 2004, Altman 1985, Patel 2006, Castleman 2006

153. The papers cited by Dr. Farris either do not focus on the magnitude of procedural complications, are not indicative of uncomplicated procedures, or indicate that the risks of the procedure in question are lower than for abortion.

154. Vasectomy: the incisions made during vasectomy are superficial. Bleeding is usually minimal. Moderate sedation or general anesthesia are not used.

155. In fact, the paper cited by Dr. Farris, by Adams and Farris, states the following: "Complications from vasectomy are rare and minor in nature. Immediate risks include infection, hematoma, and pain. Complications seldom lead to hospitalization or aggressive medical management." It does not mention damage to bowel or bladder, sepsis, embolism, or other complications that are associated with abortion.

156. Colonoscopy: colonoscopy involves no forcible dilation or scraping of viscera. Deeper levels of sedation or general anesthesia are not used.

157. The paper cited by Dr. Farris does not focus on colonoscopy complications. Instead, the authors state that the goal of the paper was to develop "an outcome measure to profile outpatient facilities by estimating risk-standardized rates of unplanned hospital visits within 7 days of colonoscopy", not to estimate the overall incidence of complications. This paper cannot answer the question of whether colonoscopy is associated with fewer complications than abortion.

158. Wisdom tooth extraction: wisdom tooth extraction involves no entry into viscera. Moderate sedation or general anesthesia are not used.

159. The study cited by Dr. Farris focuses on impacted wisdom teeth, not non-impacted wisdom teeth. The management of impacted wisdom teeth is more complicated than for non-impacted wisdom teeth. Patients with impacted wisdom teeth are referred from general dentists to oral surgeons. It is inaccurate to imply, as Dr. Farris does, that the stated complication rate for removal of impacted wisdom teeth is the same as for removal of all wisdom teeth.

160. For example, the authors state "The extraction of impacted mandibular third molars is a common procedure in oral and maxillofacial surgery. The reasons for extracting these teeth include acute or chronic pericoronitis, presence of cysts or a tumour, periodontal problems and presence of a carious lesion on the second or third mandibular molar." This is entirely different from unimpacted wisdom tooth extraction.

161. Further, the complication rate quoted by Dr. Farris comes from the below table. It lists complications described by the authors as temporary. They include numbness, superficial infection and alveolitis (inflammation of the tooth socket). These complications are minor and not comparable to abortion complications.

Table 4. Complications according to patient's sex for removal of impacted third molars

Complication	Males *n* = 225 teeth (%)	Females *n* = 325 teeth (%)	Total *n* = 550 teeth (%)
Alveolitis	4 (1.8)	16 (4.9)	20 (3.6)
Infection	1 (0.4)	11 (3.4)	12 (2.2)
Paresthesia of the IAN	0	6 (1.8)	6 (1.1)
Lingual paresthesia	0	0	0
None	220 (97.8)	292 (89.8)	512 (93.1)
Total	5 (2.2)	33 (10.2)	38 (6.9)

IAN = inferior alveolar nerve

162. Tonsillectomy: tonsillectomy involves no entry into viscera.

163. The paper cited by Dr. Farris is a randomized controlled trial to assess whether tonsillectomy, adenotonsillectomy or nonsurgical management is better in

children. Its goal was to assess whether surgery offers benefit over nonsurgical management of children with repeated episodes of throat infection.

164. The authors concluded, that "Nonetheless, the degree of benefit conferred by either operation in these children was modest, and appears [to] not justify the inherent risks…morbidity, and cost of the operations. Accordingly, we conclude that, under ordinary circumstances, neither eligibility criteria such as those we used for the present trials nor the criterion for surgery in the above-cited official guidelines are sufficiently stringent for use in clinical practice.

165. In other words, the authors argue that the observed complication rate of 6.9% was not acceptable and that this approach should not be used in general clinical practice. This is very different from reporting that a complication rate of 6.9% is usual and acceptable in clinical practice.

166. The comparison highlights the differences because for all of these procedures, accurate epidemiologic data are available, in contrast to abortion.

ii) Paragraph 33: "Abortion is significantly safer than the alternative of carrying a pregnancy to term and giving birth."

167. Abortion is not safer than childbirth. This claim does not acknowledge flaws in abortion data collection and data from multiple studies and ignores differences in the biology and physiology of pregnancy at different stages.

168. In paragraph 24 Dr. Alsaden quotes the National Academies of Sciences report on abortion (which as noted is flawed) as stating that the "risk of death from childbirth is 12.57 times higher than that from abortion." The assertion that "abortion is safer than childbirth" has been repeated multiple times in multiple publications. However, it is not supported by scientific evidence.

169. In evaluating the risks of childbirth vs abortion, the NAS report compared mortality from abortion to mortality from childbirth and several surgical procedures. There are multiple problems with the data sets used, as well as mortality data which were not evaluated in the report.

170. Studies focusing on abortion mortality mix different types of data, from different sources, with different denominators and definitions. A widely reported study by Raymond and Grimes asserted that abortion is 14 times safer than childbirth by using four disparate and difficult to calculate numbers, with non-comparable denominators. The Comparative Safety of Legal Induced Abortion and Childbirth in the United States Elizabeth G. Raymond, MD, MPH, and David A. Grimes, MD Obstet Gynecol 2012;119:215–9). Abortion-related deaths were compared to the number of legal abortions. Maternal deaths were compared to the number of live births. Only live births can be accurately measured in the U.S. due to birth certificates being mandated.

171. U.S. maternal mortality data are also incomplete. Only 2/3 of maternal deaths occur in association with a live birth. It is well documented in the U.S. that at least 50% of maternal deaths are not reported as pregnancy related on death certificates. This is because many reported deaths occur while a woman is pregnant, but not near term. Reliable records-linkage studies from Finland document that 94% of abortion-related deaths are not documented as such on the maternal death certificate (Gissler M, Kauppila R, Merilainen J, Toukomaa H, Hemminki E. Pregnancy associated deaths in Finland 1987-1994: Definition problems and benefits of record linkage. Acta Obstetricia et Gynecologia Scandinavica 1997;76:651-57; Gissler M, Ber C, Bouvier-Coll M, Buekins P.. Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland 1987-2000; Gissler M, Berg C, Bouvier-Colle MH, Buekens P. Injury deaths, suicides, and homicides associated with pregnancy, Finland 1987-2000. European J of Public Health 2005;15:459-63).

172. As noted above, U.S. abortion data are incomplete.

173. Maternal death reporting associated with early losses is even more compromised, *with international records-linkage studies documenting that less than a quarter of deaths following induced abortion are reported on death certificates*. Because of these severe data deficiencies, the U.S. did not report a maternal mortality ratio to the world from 2007-2016.

174. Even now, researchers are aware that U.S. statistics continue to be flawed and many deaths go underreported. Calculations of abortion related mortality and maternal mortality not only overlap, they also use different denominators. Some studies use the number of maternal deaths per 100,000 abortions. Some use the number of deaths per 100,000 live births.

175. Many pregnancy outcomes are never reported. For these reasons it would be impossible to count all pregnancies occurring in all women in a given year (the denominator for estimates of maternal mortality).

176. The numbers of miscarriages and induced abortions occurring annually in the United States is not known, nor is there mandated reporting of their complications and deaths, so we lack knowledge about the adverse outcomes of most early pregnancy events. (Stuart M. Berman, H. Trent MacKay, David A. Grimes, Nancy J. Binkin. Deaths From Spontaneous Abortion in the United States. JAMA 1985;253:3119-3123); Hani K. Atrash, H. Trent MacKay, Nancy J. Binkin, Carol J. R. Hogue. Legal abortion mortality in the United States: 1972 to 1982. Am J Obstet Gynecol 1987;156:605-12; Herschel W. Lawson, Alice Frye, Hani K. Atrash, Jack C. Smith, Holly B. Shulman, Merrell Ramick. Abortion mortality, United States, 1972 through 1987. Am J Obstet Gynecol 1994; 171:1365-72; Mona Saraiya, Clarice A. Green, Cynthia J. Berg, Frederick W. Hopkins, Lisa M. Koonin, Hani K. Atrash. Spontaneous Abortion–Related Deaths Among Women in the United States—1981–

1991. Obstet Gynecol 1999;94:172– 6; Suzanne Zane, Andreea A. Creanga, Cynthia J. Berg, Karen Pazol, Danielle B. Suchdev, Denise J. Jamieson, William M. Callaghan. Obstet Gynecol. 2015 August ; 126(2): 258–265. doi:10.1097/AOG.0000000000000945; CDC Abortion Surveillance 2018 available at https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm).

177. In 2004, Dr. Julie Gerberding, then head of the CDC, noted that maternal mortality rates and abortion mortality rates "are conceptually different and are used by the CDC for different public health purposes." Julie Louise Gerberding, M.D., to Walter Weber, American Center for Law & Justice, July 20, 2004, http://afterabortion.org/pdf/CDCResponsetoWeberReAbortionStats-Gerberding%20Reply.pdf, responding to Weber's April 30, 2004, letter to Tommy G. Thompson, U.S. Department of Health and Human Services, requesting a reassessment of pertinent statistical measures of mortality rates associated with pregnancy outcome, http://afterabortion.org/pdf/WeberLettertoThompson&CDCReAbortionStats.pdf.

178. Assertions that abortion is safer than childbirth also do not take into consideration the biology of pregnancy. At 8 weeks, the fetus is 1.22 inches long and weighs 0.71 ounces. At 20 weeks, the fetus is 12.7 inches long and weighs 11.7 ounces. At term the average fetus is 21 inches long and weighs 8 lbs. Uterine size increases from approximately the size of an orange late in the first trimester to almost the size of a watermelon in the late third trimester. Uterine blood flow increases fivefold.. An abortion done in the first trimester is therefore vastly different from childbirth. It is my opinion, supported by scientific evidence, that the two procedures (first trimester abortion and childbirth) are not comparable due to these changes.

A.13. Data show that abortion is riskier at equivalent gestational ages compared with miscarriage or birth.

179. The death statistics tabulated for abortion focus on "uncomplicated" abortion, whereas statistics for childbirth incorporate complicated deliveries (cesarean deliveries). Comparing uncomplicated delivery to uncomplicated abortion shows the risk of dying from abortion is twice that of uncomplicated vaginal delivery. (Lanska J, Lanska A, Rimm A. Mortality from abortion and childbirth. J of American Medical Association 1983;250:361)

180. Comparisons without regard to gestational age are flawed. Deaths during the first 6 weeks of pregnancy (when maternal morbidity and mortality are highest) are classified as maternal deaths and placed together with deaths due to birth and delivery. This is inappropriate since the intended outcomes are unknown. Women who reach the common point of awareness of pregnancy and make a decision to abort (approximately 6-8 weeks) have already survived beyond the period of pregnancy's greatest risk. Abortions do not typically occur very early (before 6 weeks)

or > 9 months of gestation when most of the maternal deaths in the maternal mortality statistics occur.

181. Bartlett et al (2004) used abortion mortality data to estimate abortion mortality as gestational age increases. They noted that "currently, the risk of death [from abortion] increases exponentially at all gestational ages…the risk of death at later gestational ages may be less amenable to reduction because of the inherently greater technical complexity of later abortions related to the anatomical and physiologic changes that occur as pregnancy advances [emphasis added]." Bartlett L, Berg C, Shulman H, Zane S, Green X, Whitehead S, Atrash H. Risk Factors for Legal Induced Abortion–Related Mortality in the United States. Obstet Gynecol 2004;103:729 –37. These authors found that the risk of a woman dying from abortion increased 38% for each week of gestational age. Abortions performed past 21 weeks had a mortality rate 76 times greater than abortions done in the first trimester. Based on their data, during the 2nd and 3rd trimesters, the abortion related mortality equals and then exceeds that of childbirth (Bartlett, 2004).

182. Available statistics do not address the long-term and less direct causes of death associated with abortion and childbirth, as noted above. Risk of death associated with abortion increases over time (due to substance abuse, cancer, pregnancy complications, suicide) while risk of death following term pregnancy is lower.

183. A Finnish study in 1997 as noted found death rates 4 times higher after abortion compared to childbirth up to 1 year. (Gissler M, Kauppila R, Merilainen J, Toukomaa H, Hemminki E. Pregnancy associated deaths in Finland 1987-1994: Definition problems and benefits of record linkage. Acta Obstetricia et Gynecologia Scandinavica 1997;76:651-57). Subsequent studies in Finland showed maternal mortality-childbirth 28.2/100,000, while abortion mortality was 83.1/100,000 or 3 times higher (Gissler M, Ber C, Bouvier-Coll M, Buekins P. Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland 1987-2000). The risk of suicide was 6 times higher following abortion.

184. Chang et al. in 2003 found 3 most common causes of maternal mortality in abortion were infection (33.9%), hemorrhage (21.8%) and embolism (13.9%) and that deaths from hemorrhage were 8 times higher and from infection 9 times higher in abortion compared to live-birth. (Chang J, Elam-Evans LD, Berg CJ, Herndon J, Flowers L, See KA, Syverson CJ. Pregnancy-related mortality surveillance-United States 1991-1999. MMWR 2003;52:1-8).

185. It can be concluded from the above that abortion at comparable gestational ages is more dangerous than carrying to term.

A.14. Second trimester abortion is better performed in a hospital.

i) Paragraph 36: "There is no medical reason to require that all abortions after twelve weeks take place in hospitals and not abortion clinics...Procedural abortions are almost always performed in an outpatient setting; nationwide, only 3% of abortions are performed in hospitals"

186. There are very limited data on whether it is safer to perform 2nd trimester abortion in hospitals vs. clinics.

187. However, available data as well as patient experience and my personal experience suggest that not only is the safety of 2nd trimester abortions performed in clinics overrated, but there are also excellent reasons for these abortions to be performed in hospitals.

188. Multiple women's deaths from abortions performed in clinics have been documented. Some of their names appear below.

i. 2010: Alexandra Nunez (NYC), 37 years old, at 16 weeks' gestation, died from hemorrhage (https://www.nydailynews.com/news/queens-clinic-a1-medicine-probed-alexandra-nunez-fatally-injured-undergoing-abortion-article-1.460728)

ii. 2010: Rebecca Charland (DC), at 16 weeks' gestation, died from hemorrhage (https://abortiondocs.org/wp-content/uploads/2018/01/2011-Washington-Surgi-Clinic.pdf)

iii. 2012: Tonya Reaves (IL), 24 years old, at 16 weeks, died from hemorrhage (Deposition of Mandy Gittler, M.D.)

iv. 2013: Jennifer Morbelli (MD), 29 years old, at 33 weeks, died from amniotic fluid embolism (MorbelliDeathCertificate-Redacted.pdf).

v. 2013: Maria Santiago (MD), 38 years old, 12 weeks, died from hypoxia (EMS report)

vi. 2014: Lakisha Wilson (OH), 22 years old, 23 weeks, died from hypoxia, hemorrhage (autopsy report)

vii. 2016: Jamie Lee Morales (NY), 30 years old, 25 weeks, died from uterine perforation, internal hemorrhage, https://www.nytimes.com/2016/10/12/nyregion/queens-doctor-is-charged-for-womans-death-after-abortion-procedure.html

2016: Cree Erwin Sheperd, 24 years old, died from uterine perforation, pulmonary embolus, hemorrhage (autopsy report).

viii. 2017: Keisha Marie Atkins (NM), 23 years old, 24 weeks, died from septic abortion, pulmonary embolus (autopsy report).

ix. 2019: Tia Archeiva Parks (OH), 26 years old, died from ruptured undetected ectopic pregnancy after first trimester abortion (autopsy report).

x. 2020: April Lowry (AL), 29 years old, gestational age of baby unknown, died from internal hemorrhage with a retained fetus (autopsy report).

189. In addition, between February 2022 and May 2023 PPSAT Chapel Hill transferred multiple patients emergently by ambulance to UNC Hospital with complications from abortion, based on from documented 911 calls:

i. 2/26/2022 – 911 call for severe bleeding and pain, patient transferred to hospital (https://www.youtube.com/watch?v=tDwBL9tlzzU)

ii. 1/28/2023 – 911 call for bleeding, patient transferred to hospital (see transcript)

iii. 3/24/2023 – 911 call for bleeding, patient transferred to hospital (https://www.operationrescue.org/archives/abortion-injuries-on-the-rise-at-chapel-hill-planned-parenthood/)

iv. 4/1/2023 – 911 call for uncontrolled hemorrhage, patient transferred to hospital (https://www.operationrescue.org/archives/abortion-injuries-on-the-rise-at-chapel-hill-planned-parenthood/)

v. 5/5/2023 – 911 all for uncontrolled hemorrhage, patient transferred to hospital (see transcript)

190. These are only the ambulance calls that were documented. Other women have likely experienced complications days after their abortion and gone to hospital emergency departments for treatment.

191. These facts demonstrate that despite statements about "safe abortion care," PPSAT's abortionists have transferred multiple women with hemorrhage to the hospital multiple times in the past 1 ½ years alone, indicating that they do not have the capacity to manage emergency situations, and that they rely on hospitals to back up these frequent complications.

192. Dr. Farris alleges (based on the paper by Jones et al) that 3% (total 2810) of abortions are performed in hospitals. (Rachel K. Jones, Marielle Kirstein, Jesse Philbin. Abortion incidence and service availability in the United States, 2020. Perspect Sex Reprod Health. 2022;54:128–141).

193. There are methodological problems inherent in this Guttmacher Institute abortion report, which include:

194. The use of surveys rather than patient-level data (47% response rate)

195. Estimation of "caseloads at facilities that accounted for 12% of abortions and used state health department data for the remaining 4% of abortions. This problem was particularly pronounced in six states, including larger ones such as New York (30%), Florida (33%), and New Jersey (40%)."

196. Use of "health department data to determine the abortion caseloads of 17% of facilities and we estimated caseloads for 31%. We adopted a variety of strategies and information sources to make caseload estimates, including responses to prior surveys, key informants, media stories, on-line reviews, and other tools. Some 80% of the facilities for which we had to make estimates were either hospitals (49%) or physicians' offices (31%) (not shown); both of these facility types typically have small abortion caseloads". In other words, the authors made estimates for a substantial number of caseloads, using sources such as media stories, which weakens the validity of their study.

197. The study did not appear to collect, or did not report data on race/ethnicity.

198. The study did not appear to collect or did not report data on gestational age at the time of abortion.

199. Dr. Farris' allegation also does not address the fact that most abortions in this sample, 492,210 (53%) were medication abortions, performed in the first trimester, which at the present time are not done in hospitals.

200. Recalculating the true percent of abortions done in hospitals as a fraction of non-medication abortions provides an estimate of 6.4%.

201. In any event, by performing second trimester abortions in clinics, abortionists have (1) Shifted responsibility for their complications to the emergency rooms of local hospitals, and covering gynecologists, and (2) Enabled complications to evade the review, scrutiny and accountability that would occur if these procedures were performed in hospitals. Abortion clinics in NC are required to report complications, but abortionists practicing in clinics do not manage their own complications.

202. Many OB/GYN physicians, including myself, have cared for critically ill patients with serious complications from abortion because abortionists refuse to manage their complications.

203. For example, I have personally cared for a patient who was brought to the emergency room a few days after a second trimester abortion with high fever and severe pain. She had sepsis and her uterus had been perforated, with damage to her large bowel. She was hospitalized for 10 days and required 2 procedures.

204. Rather than performing abortions in hospitals, where complications can be immediately managed, abortionists inappropriately choose to perform procedures in clinic settings under the guise of improved safety when evidence suggests otherwise.

205. It is an axiom in medicine that physicians should not perform procedures if they are not able to manage their complications.

206. It is not appropriate for emergency rooms and hospitals to backstop for clinicians who do not wish to manage their own complications.

207. In addition, patients suffering complications post-abortion have been told to lie and to tell emergency department staff that they are miscarrying.

a. "If a woman seeks medical attention, she does not have to say she used medicines. She can say she is having a miscarriage. The symptoms and treatment of a complication of miscarriage is exactly the same as treatment for abortion"(https://consult.womenhelp.org/en/page/417/what-to-do-in-case-of-emergency).

b. An online article quotes physicians staffing the Miscarriage and Abortion Hotline. "…in those uncommon cases where they do think a visit to a hospital is necessary, Dr. Prine says they suggest that callers tell their doctors they've had a miscarriage. "There's no way to tell if a person has self-induced their abortion or if they are just having a spontaneous miscarriage," notes Dr. Prine. "So as long as the person doesn't divulge they've taken pills, they can't be charged with anything." (The Miscarriage And Abortion Hotline Will Walk You Through A Self-Managed Abortion (cosmopolitan.com)

c. This is medically inaccurate. As noted above, following medical abortion, women are at higher risk for bleeding, infection, and retained products of conceptions than women suffering miscarriage.

d. Encouraging patients to not give accurate history of their illness is not only unethical, it can have significant implications for women suffering complications from abortion. Since abortion clinic records are not available to hospitals, the physicians caring for the patient cannot verify the patient's medical history. A failure to disclose abortion has significant impact on potential complications.

e. In Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization (J. Studnicki1 , T. Longbons, D. J. Harrison, I. Skop, C. Cirucci, D. C. Reardon, C. Craver, J. W. Fisher, M. Tsulukidze. Health Services Research and Managerial Epidemiology 92 Volume 9:1-4), the authors found that nondisclosure of a woman's post-abortion status was associated with significantly increased risks for complications, including retained fetal and placental tissue (retained products of conception) and hospitalization.

f. The authors state that "Chemical abortion patients whose abortions are misclassified as miscarriages during an ER visit subsequently experience on average 3.2 hospital admissions within 30 days. 86% of the patients ultimately have surgical removal of retained products of conception. Chemical abortions are more likely than surgical abortions result in an admission, and chemical abortions concealed are more likely to result…in a subsequent admission [for retained products of conception… Surgical abortions [that are concealed] are similarly twice as likely to result in hospital admission than those without miscoding."

g. They conclude that "Patient concealment and/or physician failure to identify a prior abortion during an ER visit is a significant risk factor for a subsequent hospital admission. Patients and ER personnel should be made aware of this risk."

h. Failure to disclose an abortion to emergency medicine and OB/GYN physicians when seen for complications post-abortion also impedes the collection of data on abortion complications, with significant negative public health consequences.

ii) Paragraph 38: **"…there is no scientific evidence indicating that abortions performed in a hospital are safer than those performed in an appropriate outpatient clinic…"**

208. As noted above, there is limited evidence comparing the safety of abortions performed in hospitals vs. clinics.

209. In fact, the sources cited by Dr. Farris do not address the scientific evidence on the safety of abortions performed in hospitals vs. clinics.

210. The ACOG paper cited does not discuss the question of whether abortions should be performed in hospitals vs clinics (See Comm. on Health Care for Underserved Women, ACOG Committee Opinion No. 815: Increasing Access to Abortion, 136 Obstetrics & Gynecology e107, e109 (2020)).

211. The APHA citation is a 2008 policy statement that does not discuss the question of whether abortions should be performed in hospitals vs clinics. (Am. Pub. Health Ass'n, Policy Statement No. 20083—Need for State Legislation Protecting and Enhancing Women's Ability to Obtain Safe, Legal Abortion Services Without Delay or Government Interference (Oct. 2008), http://www.apha.org/ policiesand-advocacy/public-healthpolicy-statements/policy database/2014/07/23/09/30/needforstate-legislation-protecting-and-enhancing-womensability-to-obtain-safe-legal-abortion).

212. The paper by Levy et al focused on office and clinic requirements for procedures including abortion. It did not discuss the question of whether abortions should be performed in hospitals vs clinics. (Barbara S. Levy et al., Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology, 133 Obstetrics & Gynecology 255 (2019).

213. The paper by Roberts *et al* compared outcomes for women with private insurance whose abortions were performed in ambulatory surgical centers vs. clinics. It did not address the question of whether abortions should be performed in hospitals vs clinics. (Sarah C. M. Roberts et al., Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions, 319 JAMA 2497, 2502 (2018)).

214. The US News and World Report article does not discuss abortion at all; it compared outcomes for 4 procedures and 2 medical conditions (elective hip replacement, knee replacement, cardiac bypass, cardiac valve surgery, heart failure and chronic obstructive pulmonary disease, COPD) for high vs low volume hospitals. (Steve Sternberg & Geoff Dougherty, Risks are High at Low-Volume Hospitals,U.S. News & World Rep. (May 18, 2015, 12:01 A.M.), https://www.usnews.com/news/articles/2015/05/18/risks-are-high-at-low-volumehospitals#:~:text=These%20large%20numbers%20of%20low,similar%20patients%20rather%20than%20by).

iii) "…licensed abortion clinics like PPSAT's [are safer] for most patients than most hospitals, many of which do not routinely provide abortion care."

215. Again Dr. Farris conflates organizations offering abortion with clinicians providing abortion.

216. Neither hospitals nor clinics provide abortions, clinicians do, and patients are better served when these procedures are performed by clinicians where complications can be immediately managed, as opposed to awaiting ambulance transfer for a critically ill patient.

217. Abortions which are felt to be higher risk are often performed in hospitals.

iv) "In fact, at least one study demonstrated that second-trimester terminations of pregnancy by D&E in appropriate patients in a dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor."

218. Dr. Farris alleges that "In fact, at least one study demonstrated that second-trimester terminations of pregnancy by D&E in appropriate patients in a dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor."

219. The study cited by Dr. Farris, by Turok et al (2008) was a retrospective cohort study of differences in complications between second trimester abortions performed in 475 women, in hospitals vs. free-standing clinics.

220. It should be noted that retrospective studies are very vulnerable to bias and confounding. The authors found that major complications (defined as death, uterine perforation, hysterectomy, transfusion, clotting disorders, deep venous thrombosis, pulmonary embolus, stroke or heart attack, need for exploratory surgery, and prolonged hospitalization) occurred in 11% of hospital D&E patients, 10% of hospital induction patients, and 1% of clinic patients (though there were no deaths in study participants).

221. Of note, the patients undergoing abortion or pregnancy termination (for an *in utero* demise) in-hospital had more medical problems, were further along in pregnancy (higher gestational ages) and were much more likely to be undergoing non-abortive pregnancy termination for fetal death *in utero* than those seen in the clinic.

222. The authors also note that complications may have been underreported due to loss to follow-up in the clinic patients. "In our cohort…It is noteworthy that the populations are not identical. Patients who received care at the university hospital were older, more likely to have maternal medical problems, have pregnancy-related complications, have undergone a prior cesarean section and have had prior early pregnancy failure.

223. "… As a tertiary care center, the university hospital is more likely to care for patients in whom pregnancy complications have occurred prior to arrival at the hospital. Thus, it is not surprising that this group of patients would have a greater rate of complications. For example, patients who have had an abruption or have severe anemia from end-stage renal disease are at increased risk to require a transfusion during or after the procedure. Similarly, patients with chorioamnionitis frequently begin their care with a complication."

224. This study is also weakened by the surprising lack of data on race-ethnicity and Medicaid status, the differences in populations, and the authors' decision to combine cases of cases D&E for abortion with cases of *in utero* fetal death.

It is highly possible that these issues were associated with residual confounding and bias of the results.

v) Paragraph 39: "The features that differentiate hospitals from abortion clinics include systems operations requirements, staffing requirements, and building construction requirements. Not only are these features irrelevant and unnecessary in the context of abortion care, they also provide no medical benefit."

225. Yet it is precisely these features, including wider hallways and doorways, emergency equipment, higher staffing levels, anesthesiologist support, well-maintained equipment, safety protocols, a blood bank, radiology, etc. that are not present in abortion clinics.

226. In fact, during one of the emergency calls by PPSAT Chapel Hill listed above, the physician requests that paramedics come in through a side door, stating "The side door is important. We would prefer that you come there…a broader doorway."

227. Abortion clinics are also not open 24 hours per day to address urgent complications.

228. While there are limited data comparing abortion safety in clinics vs. hospitals, there are data on abortion clinic safety. In 2016, Americans United for Life published data collected from 32 states over 8 years on abortion clinic health and safety violations (Unsafe: How the public health crisis in America's abortion clinics endangers women. Americans United for Life, 2016). More than 1400 clinic health and safety violations were documented in the report. The top 10 violations were:

(1) Failure to ensure a safe and sanitary environment and failure to follow infection control protocols;

(2) Failure to accurately document patient records and keep patient information confidential;

(3) Failure to ensure staff were properly trained for duties;

(4) Unlicensed/unqualified/untrained staff providing patient care;

(5) Expired medications and medical supplies;

(6) Failure to purchase and maintain required equipment;

(7) Failure to adopt, follow and/or periodically review health and safety protocols;

(8) Failure to properly handle medications:

(9) Failure to comply with physical plant standards;

(10) Failure to monitor patient vital signs.

229. A report on inspections of North Carolina abortion facilities shows that over the past 5 years, several clinics have been cited for similar deficiencies.

230. PPSAT clinics in Winston-Salem and Chapel Hill, A Woman's Choice clinics in Charlotte and Greensboro A Preferred Women's Health Clinic in Raleigh; and others (see NC DHSR AHCLCS: Reports of Surveys for Abortion Clinics, ncdhhs.gov) were cited for deficiencies.

231. These included instruments not being washed; vaginal ultrasound probes not being sterilized; autoclaving (sterilization) not being done properly; violations of patient privacy; no history or physical examination being done on patients; staff not using protective personal equipment; patients not being notified of physician admitting privileges as required by law; and other deficiencies.

232. The above data indicate a history of many health and safety problems at North Carolina abortion clinics. There is no universal accrediting body for abortion clinics mandating standards for health and safety. While the North Carolina Department of Health has carefully documented problems in abortion clinics (as noted above), there is no mechanism other than biannual inspection by the Department to help ensure that standards of health and safety are upheld in abortion clinics, and no accrediting body promulgating standards of care to which abortion clinics may be held accountable.

233. In contrast, hospitals are highly regulated by federal and state entities. The safety and quality of care offered in hospitals is evaluated by independent observers through three processes: state licensure, Medicare certification and voluntary accreditation.

234. In addition to state and federal inspections, many hospitals choose to go through voluntary accreditation by an independent accrediting organization. Hospitals must meet specific standards during on-site inspections by these organizations in order to be accredited. Hospitals also engage in external benchmarking, which allows the facility to compare its performance to the performance of other hospitals.

235. CMS requires hospitals to take steps to ensure that patients do not acquire infections during their care at these facilities. Hospitals have epidemiology committees, survey their facilities for specific bacteria and resistance patterns, and educate staff intensively on infection control.

236. Hospitals are required to maintain complete, comprehensive, and accurate medical records.

237. Hospitals have "crash carts" (equipment for patients suffering respiratory or cardiac arrest" on every patient care unit and dedicated teams covering critically ill patients. They are fully equipped to address emergencies.

vi) Paragraph 41: "…management can nearly always be safely and appropriately administered in the clinic where the abortion is being provided"

238. As the data above suggest, and in my personal experience, based on more than 30 years of clinical practice, experience suggests otherwise. Abortion complications, especially in the 2nd trimester, often cannot be managed in the clinic as demonstrated by the frequency of ambulance transfers by PPSAT Chapel Hill. Given that carrying a pregnancy to term is safer than an abortion, observed rates of morbidity and mortality from abortions performed in clinics are unacceptable.

A.15. Pregnancies of unknown location must be evaluated, diagnosed and treated appropriately.

i) Paragraph 50: "The act would therefore force patients with pregnancies of unknown location either to delay their abortion until an intrauterine pregnancy can be seen by ultrasound…even if they have been determined to be at low risk for ectopic pregnancy…"

239. According to *Radiopaedia*, "The gestational sac is the first sign of early pregnancy on ultrasound and can be seen with endovaginal ultrasound at approximately 3-5 weeks gestation when the mean sac diameter (MSD) would approximately measure 2-3 mm in diameter https://radiopaedia.org/articles/gestational-sac?lang=us. The yolk sac "is the first anatomical structure identified within the gestational sac. As the pregnancy advances, the yolk sac progressively increases from the 5th to end of the 10th gestational week, following which the yolk sac gradually disappears and is often sonographically undetectable after 14-20 weeks. Around 5-6 weeks' gestation, it may be possible to see the gestational sac via transvaginal ultrasound.

240. The "fetal pole" is the earliest sonographic manifestation of the developing embryo and refers to the body of the unborn child (*Radiopaedia*, https://radiopaedia.org/articles/fetal-pole).

241. Cardiac activity on ultrasound is present in the embryo before the pregnancy can even be detected by ultrasound imaging. In my experience, it is possible to detect cardiac activity as early as 5 weeks' gestation. On ultrasound at that stage, fetal cardiac activity looks like a faint twinkle within the embryo.

242. Since the widespread use of ultrasound began in the 1980s, these ultrasound findings have been used to visualize the developing child.

243. But contrary to Dr. Farris' allegations, there are two important reasons for the requirement that an intrauterine pregnancy be seen before abortion can be performed.

244. The first is that some proportion of women seeking abortion will be in the process of having a miscarriage. Using medication abortion in a woman with a miscarriage would unnecessarily expose her to medications and result in patients being charged a fee for no reason.

245. The second is that another proportion of women seeking abortion will have an ectopic pregnancy.

246. If a woman has no intrauterine pregnancy, but instead has an ectopic pregnancy, she might receive mifepristone/misoprostol, believe that she is no longer pregnant, and go on to have a ruptured ectopic pregnancy, which is associated with high rates of morbidity and mortality. Ectopic pregnancy is the leading cause of first trimester maternal death, and a 2020 study by Mann *et al* noted that its incidence is increasing.

247. Ectopic pregnancy is a <u>contraindication</u> to medical abortion, based on mifepristone product labeling (see above) and must be ruled out before using mifepristone in pregnancy.

248. Practitioners who do not rule out ectopic pregnancy before using mifepristone for medical abortion are ignoring clear warnings associated with the use of this drug. In fact, FDA's updated 2022 post-marketing report for mifepristone notes that 97 women have been diagnosed with ectopic pregnancies in the setting of medical abortion, with 2 deaths being reported from ruptured ectopic pregnancy.

249. Given that reporting of post-marketing events to FDA is voluntary, this is likely an underestimate.

250. Dr. Farris' allegation also ignores rational standards for the care of women with pregnancy of unknown location (PUL).

251. Ectopic pregnancy is a contraindication to medical abortion, based on mifepristone product labeling, below.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

----------**DOSAGE FORMS AND STRENGTHS**----------
Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card (3)

----------**CONTRAINDICATIONS**----------
- Confirmed/suspected ectopic pregnancy or undiagnosed adnexal mass (4)
- Chronic adrenal failure (4)

252. The same FDA document cited by Dr. Farris notes that 97 women were diagnosed with ectopic pregnancies in the setting of medical abortion. This is likely an underestimate.

253. An extensive literature on pregnancy indicates that there are significant safety concerns related to the potential for missing ectopic pregnancy in the setting of abortion.

254. Ectopic pregnancy can be difficult to diagnose. No determination that is not based on ultrasound and quantitative (blood, hCG) pregnancy testing (such as patient history, and/or physical examination) can rule out ectopic pregnancy. Even with hCG and ultrasound, ectopic pregnancies can be missed.

255. It is entirely inappropriate for the risks of ectopic pregnancy – which causes substantial morbidity and mortality – to be downplayed and even casually accepted simply because more screening takes more time, money, follow-up, and expertise.

256. It is also inappropriate to rely on a patient's memory to rule out a potentially life-threatening condition.

257. In addition, if the patient's hCG levels are low, she may be miscarrying. She would then have gone through the expense, risk, and stress of an abortion for a pregnancy that is non-viable. This is a serious concern.

258. It is also noteworthy that despite assurances that PPSAT's care is "patient-centered," they rely on a hospital for backup if a patient has an ectopic pregnancy.

259. For decades, since the availability of ultrasound and rapid quantitative hCG, the standard of care for patients with suspected ectopic pregnancy has been immediate evaluation with ultrasound and hCG, not provider subjective assessment, because as noted above ectopic pregnancy is notoriously difficult to diagnose.

260. A provider simply cannot rule out ectopic pregnancy based on patient history and symptoms alone.

261. The strategy presented is clinically deficient for several reasons.

262. First, the patient may be miscarrying. She would therefore have been subjected to an unnecessary procedure, for which she had to pay.

263. Second, the provider has not ruled out ectopic pregnancy.

264. Third, the patient may not return for follow up.

265. If she has an ectopic pregnancy that has not been ruled out, she is at risk for tubal rupture and death.

266. Because most abortions at this gestational age are elective, there must be a high bar for patient safety.

267. Missing any ectopic pregnancy that could have been reasonably diagnosed is a failed interaction with the medical system that puts patients' lives at risk.

268. Fourth, the protocol states in paragraph 55 that "If…the patient's hCG levels are sufficiently high…this may be evidence of ectopic pregnancy." Implicit in this statement is the fact that because appropriate diagnostic steps to rule out ectopic pregnancy were not taken at the time of the patient's initial visit, she must now undergo surgical abortion in addition to medical abortion. This is not only inappropriate medical practice, it implies a financial motivation, and one must ask whether the patient would be billed for both interventions.

269. Dr. Farris alleges that "If a low-ectopic-risk patient with a pregnancy of unknown location were referred to a hospital for ectopic evaluation instead of receiving a medication abortion…in most cases the hospital would perform the very same serial hCG testing that, under the protocol, PPSAT performs simultaneously with the medication abortion. Referring a low-ectopic-risk patient with a pregnancy of unknown location for ectopic evaluation instead of providing a medication abortion…does not lead to earlier or more accurate diagnosis of ectopic pregnancy. Instead, it only delays the patient's abortion."

270. Evidence has already been presented showing that this is not the case and that better diagnosis and treatment of PUL is associated with improved patient outcomes.

271. However, the real purpose for using a different protocol than what is used by PPSAT is evident in the last sentence of the paragraph. The expressed priority is that a patient's abortion should not be delayed.

272. In these paragraphs it is also worth noting the number of times that PPSAT's abortionists would rely on hospital staff to backstop their protocol.

273. Paragraph 52: "If we determine that the patient is at high risk of ectopic pregnancy, we refer the patient to another provider, typically an emergency department, for diagnosis and treatment."

274. Paragraph 55: If the patient with high hCG levels does not opt for aspiration, or if a gestational sac is not identifiable following aspiration, the provider may refer the patient for further ectopic evaluation, usually in an emergency department.

275. Paragraph 57: "Patients whose hCG levels have not decreased sufficiently are further evaluated for ectopic pregnancy, including, where medically indicated, through referral to a hospital provider."

276. The shortcomings of this protocol are evident.

ii) Paragraph 59: "If a low-ectopic-risk patient with a pregnancy of unknown location were referred to a hospital for ectopic evaluation instead of receiving a medication abortion according to this protocol, in most cases the hospital would perform the very same serial hCG testing that, under the protocol, PPSAT performs simultaneously with the medication abortion.

277. This statement is misleading. While it is true that a patient with PUL who is referred to a hospital for definitive diagnosis before medication abortion would likely receive serial hCG testing similar to what she would receive at PPSAT, she would also receive serial ultrasounds to check for the presence of a gestational sac or ectopic pregnancy.

278. The PPSAT protocol does not mention follow up ultrasound in paragraph 55; it states only that the provider would look for a "…gestational sac following aspiration…" It appears that PPSAT does not provide serial ultrasounds for these patients.

279. Clearly in this circumstance, the patient would receive better care at the hospital. She would also not have received a potentially unnecessary intervention prior to diagnosis. That is, if she were miscarrying or had an ectopic pregnancy, hospital evaluation would enable her to be properly diagnosed.

iii) Paragraph 60

280. The studies cited by Dr. Farris do not prove that medication abortion in the setting of PUL is safe.

281. The study by Bizjak et al defined efficacy as the successful completion of the TOP [termination of pregnancy] with no continuing pregnancy and without the need for vacuum aspiration for incomplete termination."

282. However, the study never defines how this was defined i.e., ultrasound or hCG. The authors note that "The lack of more specific definitions regarding outcomes…is troublesome".

283. The study also noted that "two patients presented with ruptured ectopic pregnancy. The first patient's initial hCG value was…[high] but did not trigger any further investigation. The second patient['s]…second follow up…measurement was not taken until day 9…the patient was admitted…and laparoscopy revealed intra-abdominal bleeding."

284. The study by Goldstone et al found that women with PUL who underwent medical abortion were "significantly more likely to have EMA [early medical abortion] failure or continuing pregnancy after EMA than women with a confirmed IUGS [intrauterine gestational sac…."

iv) Paragraph 61: "Furthermore, banning medication abortion, but not procedural abortion, for…patients with pregnancies of unknown location is arbitrary and unnecessary."

285. This is not true. If an abortionist finds no tissue consistent with fetal parts, placenta and membranes after performing a surgical abortion, they would immediately contact the patient for follow-up and evaluation for ectopic pregnancy.

286. This is in contrast to medical abortion, where such evaluation is not provided. As noted, known or suspected ectopic pregnancy is a contraindication to medical abortion.

v) Paragraph 62: "Further, PPSAT sometimes has clinic days on which, for staffing reasons, it is able to offer medication abortion but not procedural abortion."

287. This statement also confirms the need for second trimester abortions to be performed in hospitals, as it is an implicit admission that PPSAT is unable to provide follow up care for patients with complications. If they cannot provide surgical abortions every day, they lack the capacity to manage complications and cannot provide care, including D&C, for a patient with hemorrhage or retained products of conception post-abortion. If these abortions were performed in a hospital, there would be 24-hour availability of care for patients with complications.

A.16. Women in crisis relationships need compassion, appropriate evaluation and care

i) Paragraph 65: "Because of the non-consensual nature of rape and incest, these survivors are at heightened risk of unwanted pregnancy…the traumatic circumstances of the pregnancy may increase the urgency of access to abortion."

288. Evidence suggests that many women victimized by rape or incest choose to carry their children to term. In Dr. Sandra Makhorn's 2013 study of rape survivors, one of the few studies on this subject, 75-85% of women who became pregnant as a result of rape chose to carry their children to term (Mahkorn Sandra (1979) Pregnancy and Sexual Assault. In: Mall, Watts, The Psychological Aspects of Abortion. University Publications of America,Washington, D.C, 55-69).

ii) "…For these survivors, pregnancy can trigger flashbacks, dissociative episodes and other symptoms of re-traumatization."

289. The paper by L.G. Ward *et al*, cited by Dr. Farris, does not use any of these terms. In fact, it notes positively the possible benefits of trauma-informed care for patients who carry to term. For example, it states that "For survivors of sexual violence (SV), the perinatal period can be especially stressful due to the overlap between bodily sensations experienced in SV and pregnancy, childbirth, and perinatal care … However, the perinatal period can also be a time of remarkable growth and resilience for those survivors who are able to experience childbirth as life-affirming, empowering, and healing. In some cases, the difference between a birthing experience that is re-traumatizing and one that is healing could be determined by the sensitivity and awareness of perinatal care providers… Nowhere in this paper is abortion mentioned as a positive alternative to carrying a baby to term.

iii) Paragraph 66: "Research has indicated that women who are denied a wanted abortion…face a greater likelihood of continued physical violence from the man involved in the pregnancy."

290. The study cited by Dr. Farris (Roberts et al) is problematic for 2 reasons.

291. Many abortions are coerced. This question was not addressed in the study. In a study in the journal *Cureus*, 24% of women stated that their abortions were "unwanted or coerced" and only 33% stated that their abortions were wanted; 60% of women would have chosen to give birth if they had emotional or financial support (Reardon D, Rafferty K, Longbons T. The Effects of Abortion Decision Rightness and Decision Type on Women's Satisfaction and Mental Health. Cureus May 11, 2023).

292. Guttmacher researchers Moore et al (2009) also document coerced abortion in their study of men, women and reproductive control (Moore A, Frohwirth L, Miller E. Male reproductive control of women who have experienced intimate partner violence in the United States. Soc Sci Med 2010 Jun;70(11):1737-44).

293. The percentage of participants reporting violence in the study was very low. Regardless of the percentage of women who experience violence, it is always to be condemned.

294. For physical violence 3% of women reported violence before pregnancy, 3% during pregnancy and 2% before and during pregnancy.

295. For psychological violence, 3% of women reported violence before pregnancy, 3% during and 1% before and during pregnancy.

296. Since 3% of the 848 participants reported psychological violence, the total number of women in all groups who experienced psychological violence was 25.

297. The very small numbers also suggest that their results are not generalizable to the population of women seeking abortion who are exposed to violence during pregnancy.

298. It is also intuitively obvious that if a woman aborted in the first or second trimester, she had fewer months of pregnancy during which she experienced violence (12 weeks for women with first trimester abortion vs. 24 weeks maximum for women with second trimester abortion vs. 40 weeks for women who carried to term).

299. For comparison, a systematic review and meta-analysis of worldwide data on intimate partner violence by Román-Gálvez *et al* noted that "Due to the high prevalence of this serious problem, estimated violence during pregnancy ranges from 15 to 40.5% for any type of violence" against women in pregnancy.

300. A more important problem is that Dr. Farris has set up a false equivalence.

301. Her statement implies that the intentional feticide of a woman's unborn child, with its attendant risks, is preferable to carrying to term if a woman is in a violent relationship.

302. The solution to violence against a pregnant woman (including those being trafficked) is not abortion. It is to assist her in safely exiting the violent relationship and ensuring she and her child are protected from the perpetrator.

303. Dr. Farris presents no evidence that PPSAT works to help women safely exit abusive relationships (including trafficking). If anything, her report suggests that after an abortion a woman (or girl) simply returns to the abuser or perpetrator.

304. In contrast, hospitals have devoted substantial resources to training staff to detect abuse and trafficking and help survivors. They have social workers and specialized nurses, and can provide resources to assist women in crisis while engaging law enforcement. To the best of my knowledge, such resources are not available at abortion clinics.

305. It can be concluded that the Hospitalization Requirement offers needed protection to vulnerable women and children.

> **iv) Paragraph 67**: **"If the Hospitalization Requirement applies to patients seeking abortion due to rape or incest, those patients would have to be referred to a hospital provider, despite the clinic being able to safely provide the care, forcing the patient who has already experienced trauma to present to and share their story with an additional provider."**

306. Implicit in Dr. Farris' statement is that rape and incest should be hidden. This is precisely what rapists, traffickers and childhood sexual abusers want – that their crimes should be shrouded in secrecy and shame.

307. Another concern is forensics. Establishing paternity can assist with conviction of perpetrators. Hospitals routinely preserve all specimens taken from a patient's body, including fetal parts, membranes and placenta from those who undergo abortion after rape or child sexual abuse, and these specimens are available for DNA analysis.

A.17. Parents of unborn children with anomalies have other options besides abortion.

> **i) Paragraphs 68-69: "…patients who are diagnosed with a fetal anomaly usually receive this diagnosis after the twelfth week of pregnancy…Requiring abortion after twelve weeks to be provided in hospitals will reduce these patients' access to care."**

308. As noted, abortion is not health care.

309. A large body of literature indicates that most parents prefer to carry their affected children to term, and that their psychological outcomes are better than those of parents who choose to abort.

310. There is significant evidence that even in the case of a lethal fetal diagnosis (which is the indication for less than 5% of abortions), neonatal palliative and other care can improve both the quality and length of life for the newborn as well as psychological outcomes for the parents.

311. For many families, there are other options than abortion for unborn children with disabilities. Advancements in science and medicine, especially over the past 50 years, have paved the way for the significant growth in maternal fetal medicine (MFM) and fetal care centers in the U.S., and for perinatal hospice.

312. For conditions that are currently untreatable before or after birth, there are 125 perinatal hospice programs, a subspecialty within MFM. Several studies show improved psychosocial outcomes for families who carried their affected children to term and then cared for them through the end of their children's lives in the neonatal and infant period.

313. Multiple studies indicate that women who undergo abortion for fetal anomalies experience significant negative mental health outcomes. Calhoun et al (1997) noted that a disproportionate number of adverse mental health outcomes occurred following abortion for fetal abnormalities, citing a study by Zolese et al (1992) (Byron C. Calhoun, James S. Reitman & Nathan J. Hoeldtke, Perinatal Hospice: A Response to Partial Birth Abortion for Infants with Congenital Defects, 13 Issues L. & MED. 125 1997). The authors of that study stated that "Those requiring therapeutic abortion on medical grounds because of foetal abnormalities or serious medical complications are consistently found to be associated with poorer psychological outcome…."

314. In a review of published research, Sullivan and Faoite (2017) noted that "Data from the studies examined indicate that many women, having aborted due to serious anomaly, suffer from PTSD [post-traumatic stress disorder], a mental health problem." (Nora Sullivan & Eoghan de Faoite, Psychological Impact of Abortion due to Fetal Anomaly: A Review of Published Research, 32 Issues L. & MED. 19 2017).

315. Sullivan and Faoite continue by saying that "The disorder is shown in multiple studies to continue for months and even years in some women." While the percentage of women with PTSD appears to diminish over time, "…the number of women still dealing with PTSD a year or more after termination of pregnancy remained surprisingly high." The authors reported that "Kersting et al (2009) found that 45% of subjects were demonstrating signs of PTSD 14 days after the abortion. Korenromp et al (2009 and 2007) found that 44% and 46% of women, respectively, were suffering form PTSD four months after pregnancy termination. Davies et al (2005) found that 67% of participants screened positive for PTSD at six weeks, which fell to 50% at six months."

316. The mental health effects of pregnancy termination, including depression and PTSD, often lasted more than a year. Sullivan and Faoite concluded that "These articles repeatedly conclude that abortion for reason of potentially fatal anomalies can have a lasting and negative psychological impact."

317. Interestingly, they note that "experiences highlighted in the research suggest that induced termination did play a role in the psychological issues these mothers faced. Gammeltoft et al (2008) found: 'Even though their obstetrician had advised abortion, most felt that the ultimate decision to terminate the pregnancy had been their own, made in consultation with their relatives. The harshness of their loss seemed to be magnified by the fact it was 'chosen' by themselves.'"

318. Research has specifically examined the question of whether outcomes are better for women who undergo termination of pregnancy for an unborn child with anomalies vs. carrying to term. Rates of mental health problems for women who underwent induced abortion for a fetus with anomalies are higher than those for women carrying an affected child to term. Cope et al (2015) studied the impact of abortion vs carrying a pregnancy to term when the unborn child was affected by anencephaly, an abnormality which usually results in the death of a baby shortly after birth (Cope H, Garrett M, Gregory S, Ashley-Koch A. Pregnancy continuation and organizational religious activity following prenatal diagnosis of a lethal fetal defect are associated with improved psychological outcome. Prenatal Diagnosis 2015, 35, 761-768).

319. In this study, women who underwent abortion had much higher scores on a standard measure of perinatal grief than women who continued with their pregnancies (52% vs. 33%, respectively). Women who underwent abortion also had higher rates of depression than those who continued their pregnancies (48% vs. 27%). The authors note that "A significant number of women and men reported symptoms of grief, post-traumatic stress, and depression within the pathogenic range…psychiatric distress tended to decrease over time. However, it is important to note that there was tremendous individual variability…there were participants whose pregnancies ended over 10 years ago still scoring within the pathogenic range."

320. Of note, "Pregnancy continuation was also associated with less psychiatric distress in women. As a group, women who continued reported significantly less despair, avoidance, and depression than women who terminated. And "items related to guilt were significantly associated with termination in women. The active choice involved in termination does appear to increase the likelihood that guilt will be experienced, even in the case of lethal fetal anomalies…Termination at a later gestational age was associated with greater psychiatric distress in both men and women, although this was only statistically significant in men. Cope et al concluded that "There appears to be a psychological benefit to continue the pregnancy following prenatal diagnosis of a lethal fetal defect" 98.

321. Malloy *et al* stated "As Hoeldtke and Calhoun note, while the explosive growth of prenatal diagnostic technologies in particular has resulted in earlier diagnoses of life-limiting and life-threatening diagnoses, 'the ability to accurately diagnose a fetal condition often outstrips the ability to prevent or treat that condition. This is especially true for some specific fetal congenital defects' and would include anencephaly. "Infants carrying these diagnoses who are born alive may die in the neonatal period or experience long stays in intensive care units. Parents of these fetuses face significant emotional, logistical, and social challenges related to the outcome of their pregnancy. Recently, options for perinatal hospice have become more prevalent and established for those whose pregnancies are complicated by such diagnoses. Perinatal hospice care provides comprehensive prenatal, perinatal, and postnatal medical care and support to infants with life-threatening and life-limiting diagnoses, and their families, in order to improve their quality of life. Perinatal hospice is family centered and addresses the emotional, social, spiritual, and other needs of families within their cultural contexts. C. Malloy, M. Chireau Wubbenhorst, T. Sander Lee, The Perinatal Revolution, Issues in L. & Med. 26 Vol. 34 no. 1 (2019), page 15.

322. Between 40-85% of women will typically choose perinatal hospice or palliative care for a fatal fetal anomaly, if given the option (Flaig F, Lotz J, Knochel K, Borasio GD, Fuhrer M, Hein K. Perinatal palliative care: A qualitative study evaluating the perspectives of pregnancy counselors. Palliative Medicine 2019 vol 33(6), pages 704-711; Balaguer A, Martin-Ancel A, Ortigoza-Escobar D, The model of palliative care in the perinatal setting: a review of the literature. BMC Pediatrics 2012; Guon J, Wilfond BS, Farlow B, et al. Our children are not a diagnosis: the experience of parents who continue their pregnancy after a prenatal diagnosis of trisomy 13 or 18. Am J Med Genet 2014; 164A: 308–318; Calhoun BC, Napolitano P, Terry M, et al. Perinatal hospice—comprehensive care for the family of the fetus with a lethal condition. J Reprod Med 2003; 48(5): 343–348; Janvier A, Farlow B and Wilfond BS. The experience of families with children with trisomy 13 and 18 in social networks. Pediatrics 2012; 130(2): 293–298).

323. Malloy et al further noted that "Perinatal palliative care services can also help care for those parents who choose to terminate their pregnancy. Such families often experience significant loss and grief, without adequate support, which could be provided by a palliative care team…"

324. Similar to the goals of adult and oncologic hospice, the goals of perinatal hospice can be simply stated - to provide healing without cure for the patient. Palliative perinatal care, however, does not consist of comfort measures only, and may include cesarean delivery and newborn intensive care.

325. Another common theme was parents' "unanimous and strong need to acknowledge the personhood of their baby, and his/her role in the family," and their desire for "people to legitimize the baby's life and not to pretend the infant does not

exist (Malloy, supra, page 25; Cote-Arsenault, D. and E. Denrey-Koelsch, "My baby is a person": parents' experiences with life- threatening life- threatening fetal diagnosis. J Palliat Med, 2011. 14(12): p. 1302-8). Perinatal palliative care has helped parents with this process in the prenatal period by using the baby's name to reinforce the child's identity (Munson, D. and S.R. Leuthner, Palliative care for the family carrying a fetus with a life-limiting diagnosis. Pediatr Clin North Am, 2007. 54(5): p. 787-98, xii; Ryan, A., H. Bernhard, and B. Fahlberg, Best practices for perinatal palliative care. Nursing, 2015. 45(10): p. 14-5; Williams, C., et al., Supporting bereaved parents: practical steps in providing compassionate perinatal and neonatal end-of-life care. A North American perspective. Semin Fetal Neonatal Med, 2008. 13(5): p. 335-40).

326. Such options as perinatal hospice are not discussed or available at abortion clinics. It is only in a hospital setting that perinatal hospice can be provided for parents.

ii) Paragraph 72: "Patients who are able to get an appointment at a hospital may also face lengthy wait times, added stress, complicated paperwork and other logistical requirements, loss of confidentiality, and possibly increased medical risk from clinicians who provide abortion care infrequently."

327. No data are provided to support this statement and it is therefore speculative.

328. University of North Carolina Memorial Hospital has performed hundreds of abortions over the last few years. For example, according to https://www.thecollegefix.com/unc-med-school-has-aborted-more-than-500-babies-in-the-past-three-years/, "We performed 533 pregnancy terminations between 1/1/2019 and 10/1/2021," Phil Bridges, the communications director for UNC Health told The College Fix in response to a public records request. The number of abortions works out to 16 a month and almost two hundred per year… The abortions include "cases where the life of the mother was endangered if the unborn child were carried to term; the pregnancy was the result of rape or incest [and] issues concerning maternal and fetal health…. the abortions could be due to "fetal anomalies; emergency procedures due to hemorrhage or infection; and elective procedures, as well as procedures for pregnancies that resulted in miscarriage and fetal demise.""

> **iii) "Particularly when deep sedation or general anesthesia is used, as is done at some hospitals, but not at PPSAT's clinics, the total appointment time, clinics—the total appointment time, post procedure recovery time, staffing and facility requirements, costs, and procedure risks increase, without any medical benefit to the patient."**

329. This allegation indirectly supports the logic of performing second trimester abortions in the hospital.

330. In the hospital, anesthesiologists, who are specialists and often fellowship trained, have responsibility for overseeing the provision of anesthesia and use whichever modality is safest and best for the patient given her history, the procedure being performed and the level of pain control needed. They can provide optimum anesthesia care.

331. In contrast, in outpatient abortion clinics, anesthesia is administered by the abortionist performing the procedure, who is not an anesthesiologist.

> **iv) Paragraph 73: "Moreover, some hospitals may provide abortion using practices that are not patient-centered. Because only 3% of abortions nationwide are provided in hospitals, physicians who primarily practice in a hospital setting are likely less experienced in procedural abortion, particularly D&Es (given that most abortions occur before the point in pregnancy when D&Es are generally provided).**

332. No data are provided to support these statements and they are therefore speculative.

333. Dr. Farris states that "only 3% of abortions are performed in hospitals" However, given that there were approximately 600,000 to 700,000 abortions in the United States in 2020 (CDC Abortion Surveillance), this means that 18,000 to 21,000 abortions were performed in hospitals.

334. In North Carolina in 2020, an estimated 1894 abortions were performed after 14 weeks' gestation, out of a total of 29,636 abortions in the state, or about 6.3% of all abortions in NC.

335. As noted, UNC Hospital alone performs approximately 200 abortions per year, at least some of which are apparently second trimester abortions, and abortions are performed at Duke Hospital as well.

v) Paragraph 76: "While there are of course excellent physicians and staff providing compassionate, patient centered care in hospital settings, too, patients are more likely to encounter stigma and judgment at a hospital than at a licensed abortion clinic in North Carolina"

336. No data are provided to support this statement and it is therefore speculation.

337. In addition, both UNC Hospital and Duke Hospital not only employ abortionists who provide abortions, they also have full time faculty who teach residents and fellows to do them (see https://obgyn.duke.edu/education-training/fellowship-programs/complex-family-planning and Complex Family Planning Procedures Clinic - UNC Department of Obstetrics & Gynecology.

338. For example, Dr. Beverly Gray, one of the plaintiffs in the case, "provides abortion both in a hospital setting and in outpatient clinics."

B. The allegation that it would be "impossible" to provide medication abortion at early gestational age is not true. Plaintiffs may still provide medication abortion, they must simply document the location of the pregnancy.

i) Paragraph 62: "If the Act denies patients in this situation access to medication (but not procedural) abortion, it is irrational. And it will harm Plaintiffs' patients by forcing them to have a procedural abortion when they have important reasons for choosing a safe, noninvasive method of abortion, or to wait and potentially make additional visits to the health center and seek abortion later in pregnancy (but before 12 weeks) for no medical reason.

339. The Act is not irrational. It is ensuring that the highest standard of care is being met, where patient who have miscarried or who are miscarrying (and who therefore do not need an abortion) will be identified and given appropriate care.

340. It is also ensuring that women with ectopic pregnancies will also be identified and referred for appropriate care, rather than either inappropriately taking mifepristone and misoprostol, or not being diagnosed with ectopic pregnancy, putting them at risk for severe morbidity and mortality.

C. Alsleben declaration

C.1. Abortion does not prevent pregnancy complications

i) Paragraph 30: "Moreover, pregnancy carries risk, and delaying abortion forces a pregnant person to remain pregnant longer, experiencing the symptoms, risks, and potential complications of pregnancy."

341. Abortion does not prevent or treat pregnancy complications or maternal death. It ends a pregnancy during which a woman may or may not have had a complication.

342. A woman's individual risk for pregnancy complications can be estimated but not predicted with certainty, because there is no way to predict whether an individual woman will suffer a pregnancy complication.

343. Good maternal care during pregnancy markedly reduces the risk of complications from many diseases. There is no way to predict whether an individual woman will suffer a pregnancy complication.

344. No research using patient level data has shown that abortion reduced maternal mortality.

C.2. Women need adequate anesthesia during abortion

345. Paragraph 36: "General anesthesia or deep sedation are not necessary for most second trimester abortion patients, and moderate or minimal sedation with local anesthesia are sufficient…at the hospital, it is most often the anesthesiologist that recommends the level of sedation, and some anesthesiologists prefer general anesthesia."

346. Research suggests that for patients undergoing second trimester abortion, pain control is often suboptimal and problematic (Dzuba et al, 2022), and that such pain affects patients' experience of the procedure, undermining the argument that more sedation is not needed for second trimester abortion. (Ilana G. Dzuba, Sruthi Chandrasekaran, Laura Fix, Kelly Blanchard, and Erin King. Pain, Side Effects, and Abortion Experience Among People Seeking Abortion Care in the Second Trimester. Women's Health Reports Volume 3.1, 2022).

347. This statement, however, indirectly supports the logic of performing second trimester abortions in the hospital.

348. In the hospital, anesthesiologists, who are specialists and often fellowship trained, have responsibility for overseeing the provision of anesthesia and use whichever modality is safest and best for the patient and can provide optimum anesthesia care.

349. In contrast, in outpatient abortion clinics, anesthesia is administered by the abortionist performing the procedure, or an assistant, neither of whom is an anesthesiologist.

350. The ability to provide better pain control in an outpatient setting is limited by safety, that is, the need to avoid over-sedation and respiratory compromise.

i) Paragraph 44: "Administration of medication abortion for patients with pregnancies of unknown location, combined with simultaneous screening for ectopic pregnancies, has been shown to be both safe and effective."

351. The study by Barnhart at al, cited by Dr. Alsleben, is unequivocal in stating that ectopic pregnancy is common, and often difficult to diagnose.

352. "Ectopic pregnancy (EP) occurs in 1-2% of pregnant women and may compromise a woman's health and future fertility. The most common clinical complaints suggestive for EP are symptoms of abdominal pain and/or vaginal bleeding. Unfortunately, these symptoms are neither sensitive nor specific for the diagnosis of EP and some women remain asymptomatic for a long portion of the disease progression. Practice guidelines, derived from evidence-based literature, aim for an accurate and early diagnosis of EP to limit the morbidity and mortality resulting from this condition…There is worldwide consensus regarding the utility of transvaginal ultrasound (TVS) and (serial) quantitative serum hCG concentrations in the diagnosis of EP…However, the location of a gestation after TVS can be inconclusive in a substantial number of women…This situation is termed a pregnancy of unknown location (PUL), necessitating further diagnostic tests and follow up to achieve a final diagnosis."

353. Barnhart's study also notes that "As the diagnostic process continues, the aim is that all women with an initial ultrasound classification of a PUL should have an ultimate diagnosis of an IUP, an EP, or spontaneous resolution of a pregnancy that remains of unknown location."

354. Performing a medical abortion without identifying the location of the pregnancy goes against the recommendations in this paper and subjects patients to increased risk for adverse outcomes.

355. "I recently co-authored a study of pregnancy outcomes for patients presenting for abortion at Planned Parenthood in St. Paul, Minnesota…Our study found that this protocol – immediate medication abortion treatment with simultaneous serial testing of…hCG to further exclude ectopic pregnancy—was safe and effective."

356. The study by Borchert et al cited here has several limitations.

357. The median time to diagnose pregnancy location was 3 days in the delay-for-diagnosis group, 4 days for the immediate treatment medication abortion group, and 2 days in the immediate treatment surgical abortion group.

358. The initially undiagnosed ectopic pregnancy rates were high in all groups – 10 women in the first group (6.8%), 13 women in the second group (5.3%) and 8 in the third group (7.3%) respectively, as was the loss to follow up rate (39% in the first group, 25% in the second group, and 17% in the third group). This is higher than the national average (1-2% of pregnancies).

359. Rates of loss to follow up were very high in this study. With a high loss to follow up rate, no conclusions can be drawn related to risk for complications.

360. There were significant differences between groups which were likely to have affected the results of the study.

361. In the other groups, however, rates of miscarriage could not be assessed.

362. Of note, it took 4 days to diagnose ectopic pregnancies in the first group, 7.5 days to diagnose ectopic pregnancies in the medication abortion group, and 4.5 days to diagnose ectopic pregnancies in the surgical aspiration group.

363. Rates of failed treatment for medication abortion were 15% (patients required follow up surgical abortion) and 2.5% for the surgical abortion group.

364. What this study implies is that:

a. Patients with ectopic pregnancies were not evaluated and treated in a timely fashion

b. A high percentage of patients were lost to follow up, and their outcomes could not be ascertained

c. 15% of patients in the medication abortion group required surgical abortion

d. 5-7% of patients received unnecessary interventions (medication or surgical abortion) because they had ectopic pregnancies.

e. Some percentage of patients in the medical and surgical abortion groups probably received unnecessary interventions because they were miscarrying.

f. Significantly, if clinicians waited until pregnancy location was diagnosed, the efficacy of abortion was higher (100% in the delay-for-diagnosis group, 85.2% for the medication abortion group, and 97.6% for the surgical abortion group).

365. As a result, this study does not document that waiting for diagnosis of pregnancy is unsafe. Indeed, it suggests that waiting until a diagnosis of pregnancy location can be made is not only safer, it is associated with likely improved efficacy of abortion.

366. The study is concerning because a number of patients categorized as being at low risk ultimately were diagnosed with ectopic pregnancies, and multiple patients underwent unnecessary interventions.

367. The other study cited in paragraph 44, by Goldberg et al, also suggests that there are safety and efficacy concerns associated with medical abortion for patients with PUL.

368. This study enrolled patients with last menstrual period less than or equal to 42 days. The ectopic pregnancy incidence for women with PUL was 7%.

369. First, enrollment by group was very lopsided. There were 394 women in the delay for diagnosis group and 55 in the medication abortion group.

370. Similar to the previous study, the delay-for-diagnosis group differed in important ways from the immediate treatment (medication abortion) group.

371. Pregnancy gestational age for women in the delay-to-diagnosis group was statistically significantly greater than in other groups.

372. These women were more likely to have an uncertain last menstrual period date.

373. All 31 ectopic pregnancies were in this group.

374. As the authors note, "The difference in the ectopic pregnancy rate between management groups may be due to confounding, where certain…patient characteristics influence a clinician's decision to manage expectantly…." This is a serious weakness of the study.

375. 233 patients in this group (52% of total) never received medical abortion because they miscarried (69), were treated for ectopic pregnancy (31), switched to surgical abortion (62), chose to keep their baby (1) or were lost to follow up (66).

376. 9 patients in this group had a serious adverse event documented, as opposed to zero patients in the medical abortion group.

377. For each group, different methods were used to arrive at a pregnancy location diagnosis.

378. For the delay-to-diagnosis group, "the pregnancy location diagnosis was usually made by confirming pregnancy location on ultrasonogram…"

379. "…for patients in the same-day-start group, the diagnosis of pregnancy was usually made by…[a] decline in serial hCG levels."

380. The immediate treatment group did not receive follow up ultrasound. No assessment was performed to document whether the patient had a miscarriage rather than a viable intrauterine pregnancy.

381. Patients in each group were managed very differently insofar as the diagnosis of pregnancy location was concerned.

382. In the delay-to-diagnosis group, those women "with an initial hCG level les than 2,000, a doubling of their hCG level in 48-72 hours, and no ectopic pregnancy symptoms…were presumed to have a normal intrauterine pregnancy and were scheduled for a repeat ultrasonagram and abortion when their hCG levels were expected to be greater than 2000…Those whose hCG level did not rise as expected or who were symptomatic or at high risk were managed on a case-by-case basis."

383. The authors do not present data on what algorithm clinicians used to decide when patients would return for ultrasound and whether this algorithm was applied consistently.

384. They also do not explain what percent of patients were managed on a case-by-case basis, or how.

385. This introduces a degree of subjectivity into the study that seriously weakens its conclusions.

386. In the immediate treatment group, patients took mifepristone and had follow up hCG collected 48 to 72 hours after misoprostol. As noted, the diagnosis of pregnancy location was made by declining serial hCG levels.

387. It is obvious that in the delay-to-diagnosis group, patients' time to diagnosis of pregnancy location was more likely to be prolonged not only for logistical reasons, but also for reasons that are not described in the study.

388. In Figure 2, the median days to diagnosis of pregnancy location in a woman with PUL was 9 with a range of 5 to 40 days. Waiting 9 days to rule out an ectopic pregnancy in a patient with PUL is unacceptable and does not meet the standard of care for PULs.

389. In their conclusions, the authors noted that "initiating medication abortion with mifepristone was associated with…shorter time to rule out ectopic pregnancies and…shorter time to completed abortion." Given the issues noted above, these conclusions can be questioned.

390. They also noted that "…initiating medication abortion in the setting of pregnancy of unknown location was associated with an increased risk of ongoing pregnancy compared with initiating medication abortion with a gestational sac visualized…"

391. "Additionally, some patients who present with undesired pregnancies of unknown location may never require an abortion. We found that 18% of patients in the delay-for-diagnosis group were eventually diagnosed with early pregnancy loss and 8% with ectopic pregnancy; thus, collectively, 26% did not require abortion…delaying treatment to determine a diagnosis may enable these patients to avoid the out-of-pocket expenses of abortion…."

392. Goldberg et al concluded that there were risks and benefits to both approaches. However, (1) They acknowledge that confounding occurred in their study; (2) 26% of patients in the delay-for-diagnosis group did not require abortion; (3) Rates of miscarriage were not assessed in the immediate treatment group; (4) Rates of successful medication abortion were higher, and rates of ongoing pregnancy were lower, in the delay-for diagnosis group, and (5) Subjective decisions determined when women in the delay-for-diagnosis group would return for follow up ultrasound and abortion. This means that any comparison between groups is not objective. Differences in the diagnostic criteria for resolution of PUL and major differences in management between the two groups bring into question any comparisons of outcomes.

393. Medication abortion in women with PUL is only made possible because abortionists do not perform follow up ultrasound testing, and the responsibility for diagnosing ectopic pregnancy is shifted to hospital emergency departments. The protocols listed in the paper state that for "hCG less than 2,000, the abortion can proceed as planned; hCG between 2,000 and 2,900, a diagnostic ultrasound must be performed…If a diagnostic ultrasound cannot be performed that day…the patient must be referred to an ED for ectopic pregnancy evaluation…hCG of more than 3,000 or if diagnostic ultrasound does not confirm IUP, the patient must be referred to an ED…"

ii) Paragraph 50: "…use of an ultrasound to rule out an ectopic pregnancy is not medically indicated for most patients."

394. There are two problems with this statement. The first is that it implies that it is acceptable to miss some ectopic pregnancies. The study by Upadhyay et al (2002), cited by Dr Alsleben, actually states the following: "One of the major obstacles to expanded provision of medication abortion with history-based screening alone is clinician concern about the ability to identify an ectopic pregnancy. In this study, the ectopic pregnancy rate of 2 per 1000 suggests that the screening procedures used by the participating clinics will not triage all patients with ectopic risks to ultrasonography before the abortion. However, the potential benefits of expanded

access, increased convenience, and earlier treatment conferred by removing testing requirements may outweigh potential risks of delayed identification of ectopic pregnancies."

395. This statement acknowledges that some ectopic pregnancies will be missed but disregards their known high morbidity and mortality. It shows precisely why it is mandatory for women with a PUL to not undergo abortion until the location of their pregnancy has been diagnosed. The statement suggests that a higher emphasis should be put on "expanded access, increased convenience, and earlier treatment" than "delayed identification of ectopic pregnancies" .

396. The study by Upadhyay et al (2022) also has serious flaws related to ascertainment of outcomes, missing data and loss to follow up.

397. This was a "retrospective cohort study assessing the effectiveness and safety of using history -based screening alone for medication abortion." The study was designed to estimate the safety and effectiveness of no-test medication abortion (i.e., no hCG testing was performed, nor was ultrasound or Rh testing done). Medical abortion pills were dispensed through telemedicine and through the mail.

398. It is intuitively obvious that simply dispensing abortion pills without seeing a patient, assessing gestational age or Rh status, evaluating for ectopic pregnancy, or screening for abuse or trafficking is not clinically appropriate.

399. Abortions that were incomplete were those that "met any of the following 4 criteria": the patient had a surgical abortion, the patient received additional doses of mifepristone, misoprostol or other medications; the patient was treated for ectopic pregnancy; or the patient had a viable pregnancy and no intervention.

400. Abortions were classified as complete based on laboratory or ultrasound findings, or a symptom checklist or patient report. Some records were recoded as complete if notes in the chart indicated that "the reating clinician had no concern that the abortion was incomplete after phone, text, or email follow-up contact with the patient."

401. Some of these definitions were not consistent or objective.

402. There was a 25% loss to follow up rate, and of the 75% who provided any follow up data, 15% did not provide abortion outcome data.

403. In the final sample, slightly less than 2/3 (63%) of patients had abortion outcome data.

404. 4 patients were treated for ectopic pregnancy.

405. The authors note that "…we may have failed to identify some additional interventions and adverse events."

406. Without linkage to hospital or other databases to attempt to obtain complete data on complications following abortion, this rate of adverse events likely underestimates the true magnitude of complications, especially ectopic pregnancy.

407. If anything, Dr. Alsleben's citation of this study disproves her allegation that the IUP Documentation Requirement will not improve patient safety. Women deserve to undergo thorough evaluation before abortion and careful management during and after abortion, and the Hospitalization Requirement and the IUP Documentation Requirement improve patient safety by helping to achieve those goals.

D. Conclusion

408. In conclusion, the Act, including the Hospitalization Requirement and the IUP Documentation Requirement will have a favorable impact on the health of women in the state of North Carolina. They address some of the significant safety problems associated with induced abortion. Most abortions in North Carolina are performed before the second trimester. The Act, including the Hospitalization Requirement and the IUP Documentation, protect women especially since abortion is not health care, induced abortion is not always simple or straightforward, and surgical abortion is surgery. Mifepristone is not safer than Viagra or Tylenol. Abortion is not one of the safest procedures in medicine – it carries risks for the mother and is always lethal to a developing fetus, an unborn child, especially dilation and evacuation (D&E) a brutal feticidal procedure which has maternal risks. Abortion is an invasive procedure which differs from other procedures and is not comparable. Pregnancies of unknown location must be evaluated, diagnosed and treated appropriately. Abortion is not safer than childbirth, and abortion does not prevent pregnancy complications. Pregnant women in crisis relationships need compassion, appropriate evaluation and care.

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 7, 2023.

Monique Chireau Wubbenhorst

Monique Chireau Wubbenhorst, M.D., M.P.H.

Exhibit A

CURRICULUM VITAE

Updated: 5-25-2023

Name: Monique Chireau Wubbenhorst, MD, MPH, FACOG, FAHA
18420 Bulla Road
South Bend, IN 46637

Medical licensure: North Carolina, 05-21-2000 to present
Indiana, 8-26-2022 to present

Specialty certification(s) and dates: American Board of Obstetrics and Gynecology, 1997 - present

Date of birth: XX-XX-XXXX **Place:** New York, NY

Citizen of: United States

Languages spoken: English, French.

Education:

Institution	Degree	Date (Year)
Waterford High School	High school diploma	1974-1976
Mount Holyoke College	A.B., Biological Sciences	1976-1981
Oral Roberts Medical School	(None, transferred)	1986-1988
Brown University Medical School	M.D.	1988-1991
Harvard University	Master's in Public Health	1989-1991
University of North Carolina	Postdoctoral Fellowship	2001-2003

Scholarly societies (Alpha Omega Alpha, Sigma Xi, Phi Beta Kappa, etc.): Past member, Sigma Xi; Fellow, American College of Obstetricians and Gynecologists; Fellow, American Heart Association; member, American Association of Pro-Life Obstetricians & Gynecologists; member, North Carolina Medical Society; member, Massachusetts Medical Society.

Other organizations: Board member, Americans United for Life.

Professional training and academic career (chronologically commencing with first postdoctoral position):

Institution	Position/Title	Dates
Yale-New Haven Hospital New Haven, CT	Resident, Obstetrics and Gynecology	1991-1995
Beth Israel-Deaconess Medical Center Boston, MA	Faculty, Division of Epidemiology and Public Health Department of Obstetrics and Gynecology	1995-1998
Harvard Medical School Boston, MA	Instructor, Obstetrics-Gynecology	1995-2000
University of North Carolina-Chapel Hill, Chapel Hill, NC	Postdoctoral Fellow, North Carolina Program for Women's Health Research, Sheps Center for Health Services Research	2001-2003
	Adjunct Clinical Assistant Professor, Division of Women's Health, Department of OB/GYN	2001-2003
Center for Health Services Research Durham VA Medical Center Durham, NC	Women's Health Fellow	2003-2004
Duke University Medical Center Durham, NC	Assistant Professor, Division of Reproductive Sciences Department of Obstetrics and Gynecology	2003-2018
United States Agency for International Development Washington, DC	Senior Advisor, Office of Population and Reproductive Health, Bureau for Global Health	2018-2019
	Deputy Assistant Administrator, Bureau for Global Health	2019
	Senior Deputy Assistant Administrator Global Health	2020-2021
University of Notre Dame	Senior Research Associate, de Nicola Center for Ethics and Culture	2021 - 2023

Past and Present Hospital and Clinical Affiliations:

Institution	Position/Title	Dates
Beth Israel-Deaconess Medical Center, Boston, MA	Staff Gynecologist	1995-1998

Dimock Community Health Center Roxbury, MA	Staff obstetrician-gynecologist	1995-1996
Dimock Community Health Center Roxbury, MA	Director, Obstetrics and Gynecology Service Dimock Community Health Center	1996-1998
Harvard Vanguard Medical Associates Watertown, MA	Staff obstetrician-gynecologist (*locum tenens*)	1998-1999
Mt. Auburn Hospital Cambridge, MA	Staff obstetrician-gynecologist *(locum tenens)*	1999-2000
Somerville Community Health Center Somerville, MA	Staff obstetrician-gynecologist	1998-2000
St. Elizabeth Medical Center Boston, MA	Staff obstetrician-gynecologist	1999-2000
Hugh Chatham Hospital Elkin, NC	Staff obstetrician-gynecologist *(locum tenens)*	2000-2017
Chinle Indian Hospital Chinle, AZ	Staff obstetrician-gynecologist *(locum tenens)*	2000
Fallon Clinic Leominster, MA	Staff obstetrician-gynecologist (*locum tenens)*	2000-2001
WW Hastings Indian Hospital Tahlequah, OK	Staff obstetrician-gynecologist *(locum tenens)*	2001-2002
Alamance Regional Hospital Burlington, NC	Staff obstetrician-gynecologist *(locum tenens)*	2003
Pine Ridge Indian Hospital Pine Ridge, SD	Staff obstetrician-gynecologist (locum tenens)	2003
Rosebud Indian Hospital Rosebud, SD	Staff obstetrician-gynecologist *(locum tenens)*	2003-2009
Durham VA Medical Center Durham, NC	Staff Gynecologist, Departments of Surgery and Ambulatory Care	2003-2018
Roy Lester Schneider Hospital St. Thomas, US Virgin Islands	Staff obstetrician-gynecologist (locum tenens)	2005-2014
Chowan Hospital Edenton, NC	Staff obstetrician-gynecologist (locum tenens)	2005-2014

Roanoke-Chowan Hospital Ahoskie, NC	Staff obstetrician-gynecologist (locum tenens)	2007-2008
The Outer Banks Hospital Nags Head, NC	Staff obstetrician-gynecologist (locum tenens)	2012-2016
Carteret General Hospital Morehead City, NC	Staff obstetrician-gynecologist (locum tenens)	2010-2014
Vidant Beaufort Hospital Washington, NC	Staff obstetrician-gynecologist (locum tenens)	2011-2016
Vidant-Duplin Hospital Kenansville, NC	Staff obstetrician-gynecologist (locum tenens)	2014
Vidant Edgecombe Hospital Tarboro, NC	Staff obstetrician-gynecologist (locum tenens)	2016-2017
Maria Parham Hospital Henderson, NC	Staff obstetrician-gynecologist (locum tenens)	2017
Tenwek Mission Hospital Bomet, Kenya	Visiting consultant, Obstetrics and Gynecology	2022-2023
Saint Joseph's Regional Medical Center Mishawaka, IN	Obstetrician-gynecologist hospitalist	2023-

Publications:

1. **Refereed journals:**

    1. Harrison D, Buskmiller C, **Chireau M**, Ruppersberger L, Yeung P. Systematic review of ovarian activity and potential for embryo formation and loss during the use of hormonal contraception. *Linacre Q.* 2018 Nov; 85(4): 453–469.

    2. Malloy C, **Chireau M**, Sander Lee T. The perinatal revolution. *Issues in Law and Medicine*, Spring 2019.

    3. **Chireau Wubbenhorst M**, Wubbenhorst J. Evangelical international organizations and family planning. *Dignitas* Summer 2017; 24(2):11-21.

    4. **Chireau Wubbenhorst M**, Wubbenhorst J. Should Evangelical Christian organizations support international family planning? *Christian Journal of Global Health* fall, 2017.

    5. **Chireau Wubbenhorst, M**. Is misoprostol equivalent to oxytocin for postpartum hemorrhage? *Issues Law Med*. 2015 Autumn; 30(2):217-25.

6. Koch E, **Chireau M**, Pliego F, Stanford J, Haddad S, Calhoun B, Arecena P, Bravo M, Gatica S, Thorp J. Abortion legislation, maternal healthcare, fertility, female literacy, sanitation, violence against women, and maternal deaths: a natural experiment in 32 Mexican states. *BMJ Open* 2015 Feb 23;5(2):e006013.

7. **Chireau, M**. Gestational diabetes is a significant cardiovascular disease risk factor. *BJOG* 2014 Nov;121(12):1537.

8. Bushnell Cheryl, McCullough Louise D, Awad Issam A, **Chireau Monique** V, Fedder Wende N, Howard Virginia J, Lichtman Judith H, Lisabeth Lynda D, Piña Ileana L, Reeves Mathew J, Rexrode Kathryn M., Saposnik Gustavo, Singh Vineeta, Towfighi Amytis, Vaccarino Viola, Walters Matthew R. Guidelines for the Prevention of Stroke in Women: A Statement for Healthcare Professionals from the American Heart Association/American Stroke Association Council on Stroke. *Circulation* 2014 May.

9. Crochet J, Bastian L, **Chireau M**. Does this woman have an ectopic pregnancy? *JAMA* 2013 Apr 24;309(16):1722-9.

10. **Chireau M.** More than an ounce: Editorial commentary on: The 2011 Effectiveness-Based Guidelines for the Prevention of Cardiovascular Disease in Women. Available in: American Heart Association Learning Library.

11. Bushnell C, and **M. Chireau**. Preeclampsia and stroke: risks during and after pregnancy. *Stroke Research and Treatment* 2011 Jan 20;2011:858134.

12. Brown HL, Small M, Taylor YJ, **Chireau M,** Howard DL. Near miss maternal mortality in a multiethnic population. *Ann Epidemiol.* 2011 Feb;21(2):73-7.

13. Schwartz E, Borrero S, **Chireau M**. Safe Prescribing for women of reproductive age; treatment recommendations for the VA. *Federal Practitioner*, 2009;26(2).

14. Brown H, **Chireau M,** Jallah Y, Howard D. The "Hispanic Paradox": An investigation of racial disparity in perinatal outcomes at a tertiary care center medical center. *Am J Obstet Gynecol 2007* Aug; 197(2) e1-7.

15. Fowler C, Gavin N, Adams EK, Tao G, **Chireau M**. Racial and ethnic disparities in prenatal syphilis screening among women with Medicaid-covered deliveries in Florida. *Matern Child Health J* 2007 Jul 18**.**

16. Wilson EK, Adams EK, Gavin NI, **Chireau M**. Patterns in prenatal syphilis screening among Florida Medicaid enrollees. *Sex Transm Dis*, 2006 Nov 6.

17. **Chireau M,** Salz T, Bastian L. Pregnant veterans' outcomes, cost and utilization of care. *Federal Practitioner*, September 2006, 23:9.

18. **Chireau M**, Benedict MB, Gavin NI, Adams EK. Gestational diabetes testing among pregnant Medicaid recipients: implications for clinical care. *Journal of Clinical Outcomes Management*, 2006; Jun; 13(6):315-332.

19. Gavin NI, Adams EK, Hartmann KE, **Chireau M.** Racial and ethnic disparities in the use of pregnancy-related health care among Medicaid pregnant women. *Matern Child Health J*. 2004; Sep;8(3):113-26.

20. Hirschhorn LR, Miller L, **Chireau M**. Papanicolaou smear and follow-up in women with HIV infection receiving primary care in an inner-city community health center (CHC): a role for continuous quality improvement and quality care. *National Center for Women's Health Archive*, 1997.

21. Kresina TF, Cheever LW, **Chireau M,** Johnson J, Ramirez B, Peters P, Olds GR. Human Epstein-Barr virus transformed lymphocytes of patients with *Schistosoma japonicum* infection secrete idiotypically related immunoregulatory antibodies. *Clinical Immunology* 1992; 65(3):325-9.

2. Non-refereed publications:

Chireau Wubbenhorst, M. and Baugus B. Does abortion improve economic outcomes for women? A review of the evidence. Accessible at https://lozierinstitute.org/does-abortion-improve-economic-outcomes-for-women-a-review-of-the-evidence/

Chireau Wubbenhorst, M. Midtrimester abortion epidemiology, indications and mortality. Accessible at https://lozierinstitute.org/midtrimester-abortion-epidemiology-indications-and-mortality/

Environmental Health Risks and Your Pregnancy. Public health pamphlet for American Association on Intellectual and Developmental Disabilities, July 2009.

Primary Care of Women with HIV/AIDS, in *Care of HIV-infected Patients in VA*, 2008.

3. Selected abstracts

Chireau M, Crosslin D, Hauser B, Olshan A, Zheng S, Salafia C, Thorp J. Endothelial function gene polymorphisms are associated with pregnancy outcomes, independent of placental vascular disease. Society for Maternal-Fetal Medicine Annual Meeting, 2008.

Chireau M, Crosslin D, Hauser B, Olshan A, Zheng S, Salafia C, Thorp J. Polymorphisms in endothelial function genes are associated with pregnancy outcome in a multi-ethnic North Carolina sample. Society for Maternal-Fetal Medicine Annual Meeting, 2008.

Chireau M, Bushnell CB, Goldstein L, Brown H, Bastian L. Adverse pregnancy outcomes are associated with stroke risk later in life. Society for Gynecologic Investigation Annual Meeting, 2006.

Chireau M, Biswas M, Newby K, Brown H, Bastian L. Adverse pregnancy outcomes are associated with increased risk for mortality. American College of Obstetricians & Gynecologists Annual Meeting, 2006.

Chireau M, Biswas M, Newby K, Brown H, Bastian L. Adverse pregnancy outcomes are associated with coronary artery and cardiovascular disease risk. American College of Obstetricians & Gynecologists Annual Meeting, 2006.

Chireau M, Bushnell CB, Goldstein L, Brown H, Bastian L. Adverse pregnancy outcomes are associated with stroke risk later in life. American Neurological Association Annual Meeting, 2005.

Consultant appointments:

2001-2003 Consultant to RTI International Maternal-Child Health Division

2007-2009 Consultant to Chief Consultant, Women Veterans Health Strategic Healthcare Working Group, Veterans Administration Central Office, Washington DC.

Invited Presentations

2005 Panelist, "Thinking outside the box: Designing an effective health care delivery system", 2nd Annual Healthcare Symposium on Patient Satisfaction, Winston-Salem State University School of Health Sciences, Winston-Salem, NC.

"Preeclampsia – the long and the short of it." Presentation at Stroke Division of Neurology, Duke University Medical Center, Durham, NC.

"Adverse pregnancy outcomes and the risk of stroke." Presentation at American Society for the Study of Stroke in Women, Second Annual Symposium, Durham, NC.

2006 "Adverse pregnancy outcomes and the risk of cardiovascular disease." Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Improving outcomes for African American women and children". Presentation at Shaw University Institute for Health, Social and Community Research Annual Conference, Raleigh, NC.

"Endothelial function gene polymorphisms and the risk of adverse pregnancy outcomes". Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

2007 "Teratogenicity of commonly prescribed drugs in the Veterans Administration". Presentation at the National Reproductive Health Working Group, for the Women Veterans Health Strategic Healthcare Group. Washington, DC.

"Neurologic diseases in women's health" Grand Rounds presentation, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Adverse pregnancy outcomes and the risk of cardiovascular disease" Presentation to the Carter Society, Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC.

"Urgent Problems in Women's Health". Presentation at the Veterans Administration National Primary Care Conference, Washington, DC July 2008.

2009 "Pregnancy and Long-term Health Risk". Clinical Seminar at the American College of Obstetrics and Gynecology Annual Clinical Meeting, Chicago, May 2009.

"Contraception Issues for Women Veterans". Presentation at the Veterans Integrated Service Network 6 Primary Care Conference, Roanoke Rapids, VA, March 2009.

2010 "Adolescent Pregnancy As a Development Issue". Presentation at the United Nations Conference on the Status of Women, New York, NY, February 2010.

2011 "Women's Reproductive Health as a Gender, Development, and Human Rights Issue". Presentation at the United Nations Beijing + 15 Conference, New York, NY, February 2011.

"Sexual Dysfunction in Women". Live webinar presentation at the VISN Primary Health Conference, March 2011.

"Women's Reproductive Health as a Gender, Development, and Human Rights Issue: Regaining Perspective". Presentation for the Center for Bioethics and Human Dignity, Washington, DC, June 2011.

"Short and Long-term Effects of Pregnancy Termination". Presentation at Healing Visions conference, Milwaukee, WI, October 2011.

2012 "The Future of Roe". Presentation at The Conference on Reproductive Health and the Law, National Press Club, Washington DC, January 2012.

"Adolescent Health". Plenary speaker at AXIOS Misión Mujer Conference, Simposium Adolescentes en las Políticas Públicas, Guadelajara, México, March, 2012.

"Women and the Health of Families, Community and Society: Cause or Effect?" Plenary speaker, Center for Bioethics and Human Dignity Bioethics Conference, Deerfield, IL, July, 2012.

"Management of High Risk Pregnancy". Presentation at the International Conference on Maternal Mortality, Dublin, Ireland, September 2012.

"Management of High Risk Pregnancy in Developing Countries". Presentation at Pathan Hospital, Kathmandu, Nepal, September 2012.

2013 "Contemporary Management of High Risk Pregnancy". Presentation at the United Nations 56th Commission on the Status of Women, New York, NY, March 2013.

"*Roe* at 40: What we have learned". Presentation, Roe at 40 Conference, Stanford Law School, Stanford, CA, March 2013.

2014 "Medical and surgical complications of induced abortion". Presentation at Americans United for Life Annual Conference, National Press Club, Washington, DC.

"Contraception Update". Presentation at Women Veterans Health Provider Retreat, Raleigh, NC, May 2014.

2015 “Is Misoprostol Equivalent to Oxytocin for Postpartum Hemorrhage?”. Presentation at the Matthew Bulfinch Educational Conference, Annual Meeting of the American Association of Pro-Life Obstetrician-Gynecologists, February 2015.

“Medical vs. surgical abortion”. Presentation at the World Congress on Families, Salt Lake City, Utah, October 2015.

2016 “The Transformation of Reproductive Health”, Clarke Family Keynote Lecture, Notre Dame Institute for Ethics and Culture Medical Ethics Conference, Notre Dame University, South Bend, IN.

“Abortion and Childbirth”, presentation at the Vita Institute, Notre Dame Institute for Ethics and Culture, Notre Dame University, South Bend, IN.

“Maternal Health, the Millennium Development Goals and the Sustainable Development Goals: Where are we going and how do we get there?” Presentation at the Coloquio Integral en Salud 2016, Leon City, Guanajuato, Mexico.

2017 “Safety of Childbirth vs. Abortion”, presentation at the Vita Institute, Notre Dame Institute for Ethics and Culture, Notre Dame University, South Bend, IN.

“Should Evangelical Christian organizations support international family planning?” Presentation at the Trent Center for Bioethics & Humanities Series, Duke University, Durham, NC.

2018 “Women Speak: Health Implications of Lower Abortion Rates”. Presentation at the Women Speak conference, June 13, 2018, Heritage Foundation, Washington DC.

“The #MeToo Moment: Second Thoughts on the Sexual Revolution”. Presentation at the Ethics and Public Policy Center, Washington, DC.

“Let Every Soul Be Subject to the Higher Powers: Romans 13, Subsidiarity, and International Aid”. Presentation at the Notre Dame Center for Ethics and Culture 2018 Fall Conference, South Bend, IN.

“Partnering with USAID and the Journey to Self-Reliance”. Presentation at the Global Missions Health Conference, Louisville, KY.

2021 Response to Opening Keynote: "In Pursuit of Dignity and Freedom: One Perspective on the American Experience", de Nicola Center for Ethics and Culture, Notre Dame University.

2022 “Is abortion safer than childbirth?” Presentation at Vita Institute Annual Conference, Notre Dame University.

2023 “Challenges and opportunities in building a civilization of love”. Panel presentation for the Center for Ethics and Culture’s Women and Children First Initiative, at the National Press Club, Washington DC.

Professional awards and special recognitions:

1995-2000	National Health Service Corps Award for clinical practice in health shortage areas
2001	National Research Service Award from the Agency for Health Care Policy and Research for Post-Doctoral Training in Health Services Research, Cecil G. Sheps Center
2008	"Best Poster", Poster Session V, Society for Maternal-Fetal Medicine Annual Meeting 2008

Organizations and participation:

1/91 – 3/91	Clinical and laboratory field work with the Schistosomiasis Control Project in Palo Leyte and Metro Manila, the Philippines; a collaboration between the World Health Organization, the Philippines Ministry of Health, Brown University and the University of the Philippines.
4/91	Internal medicine and medical-surgical intensive care at Apollo Hospital, Madras, South India.
10/94	Expanded Training Program in Obstetrics-Gynecology, Alma-Ata Regional Hospital, Kazakhstan, the Commonwealth of Independent States. Intersectoral collaboration between the Kazakhstan Ministry of Health, Merck and Company, World Vision, and Project MotherCare-Hospital of St. Raphael, New Haven, CT.
4/99	Maternal-child health officer with International Health Services Foundation, as part of assessment mission to Kosovar refugee camps and clinics in Macedonia during the Kosovo War.
2000	Field work in primary care and maternal-child health, Hope for Africa Ministries, Ghana, West Africa.
2001	Jackson Laboratories Summer Statistical Genetics Course
2001, 2002	Member, 2001 and 2002 Objective Review Committees, Expanded Medical Capacity for Community Health Centers, Bureau of Primary Health Care, Health Research and Services Administration, Washington D.C.
2004 – 2018	Reviewer for the *Journal of General Internal Medicine*
2004-2016	Duke University Medical Center IRB member
2004 – 2018	Reviewer for *The North Carolina Medical Journal*
2006 – 2018	Reviewer for *The British Journal of Obstetrics and Gynecology*
2007	Study section, Centers for Medicare and Medicaid Services grant program, Baltimore, MD

2007	National Reproductive Health Working Group member, Women Veterans Health Strategic Healthcare Group, Veterans Administration Central Office, Washington, DC
2007-2009	Member, Project Access of Durham Steering Committee, Durham, NC
2007-2010	Member, Duke University Medical School Admissions Committee
2007-2009	Consultant to Acting Chief Consultant, Women Veterans Health Strategic Healthcare Working Group, Veterans Administration Central Office, Washington DC.
2008-2009	Member, National Surgical Quality Improvement Program Committee, GYN Surgery Subspecialty, for Women Veterans Health Strategic Healthcare Working Group, and Duke University Medical Center
2008-2010	Summer Institute Program to Increase Diversity in Genetic Research on Complex Heart, Lung and Blood Diseases, sponsored by NHLBI
2009-2018	Member, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2009-2014	Board Member, Project Access of Durham County
2009	Reviewer, NIH Cardiovascular and Sleep Epidemiology (CASE) *ad hoc* study section
2010-2012	Co-chair, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2012-2018	Reviewer, *pLOS 1*
2014-2018	Member, Advisory Committee for Arts, Sciences and University Transfer, Durham Technical Community College, Durham, NC
2013-2018	Reviewer, *Public Health*
2014 -2016	Chair, Cardiovascular Disease in Women and Special Populations National Committee, Clinical Council on Cardiology, American Heart Association
2015	Clinical Champion, ICD-10 Rollout, Durham VA Medical Center
2015-	Senior Public Policy Fellow, Notre Dame Institute for Ethics and Culture
2016-	Reviewer, *Issues in Law and Medicine*
2021-	Reviewer, *Journal of Medical Ethics*

Courses taught:

1997-1998 Principal Clinical Experience Gynecology Case Conference for first-year medical students, Harvard Medical School. This yearlong course focused on introducing medical students to clinical medicine through case studies, clinical vignettes and basic science and clinical instruction.

5/99 Obstetrics and Gynecology courses, Semipalatinsk National Medical Academy, Semipalatinsk, Kazakhstan. One to two-day courses focused on providing updates to former Soviet Union clinicians in basic science and clinical medicine.

2007 "Neurologic and psychiatric diseases in pregnancy and beyond". Course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, San Diego, CA. This course provided an update to practicing obstetricians-gynecologists on the diagnosis and management of neurologic and psychiatric disease in women.

"Rheumatologic disease effects before, during and after pregnancy". Course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, 2007, San Diego, CA. This course provided an update to practicing obstetricians-gynecologists on the diagnosis and management of rheumatologic diseases in women.

2008 "Pregnancy and long-term health risk", course given at the American College of Obstetrics and Gynecology Annual Clinical Meeting, 2007, San Diego, May 2008. The goal of the course was to introduce practicing obstetrician-gynecologists to the association between pregnancy complications and long-term cardiovascular disease in women.

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2009 "Common Urgent Gynecologic Problems in Women Veterans", course given at the Veterans Integrated Service Network 6 Primary Care Conference, Roanoke Rapids, VA, March 2009. This course provided an update for practicing clinicians on urgent gynecologic problems in women and their management.

2010 Clinical Skills Course in Obstetrics and Gynecology for second-year medical students, Duke University Medical School. This semester-long course was designed to bridge the transition between the preclinical-basic science curriculum in medical school and clinical training by introducing students to clinical reasoning, case studies, teamwork, and problem-solving.

2015 Clinical Maternal-Child health course for advanced practice nurses at the Mount Zion Special Care Nurses' Training Centers, Buea, Cameroon and Bamenda, Cameroon, West Africa. This two-day course taught core concepts in maternal-child health to advanced practice nurses.

2016 Obstetrics and Gynecology course for advanced practice nurses at the Mount Zion Special Care Nurses' Training Centers, Buea, Cameroon and Bamenda, Cameroon, West Africa. This two-day course taught gynecology, infectious diseases, and moral ethics to advanced practice nurses.

Obstetrics and Gynecology course for medical officers and allied health professionals at Kajo Keji Medical Training Institute, Kajo Keji, South Sudan. This two-day course provided instruction in primary, urgent and emergency care for women to medical officers, pharmacy technicians and laboratory technicians.

Obstetrics and Gynecology course for students at Kajo Keji Midwifery School, Kajo Keji, South Sudan. This two-day course provided instruction in obstetrics and gynecology in limited resource settings to midwifery students.

Past and present teaching responsibilities including continuing education:

Director, VA Gynecology Resident Rotation
Director, VA Gynecology Medical Student Rotation
Ambulatory and inpatient medical student and resident education and training
Ambulatory and inpatient Physician Assistant and Nurse Practitioner education and training
Fellow, resident and medical student mentoring
Undergraduate student mentoring

Areas of research interests (basic and applied):

Molecular biology of adverse pregnancy outcomes
Reproductive health and epidemiology, including epidemiology of adverse pregnancy outcomes
Global health
Health services research
Racial-ethnic disparities in women's health
Adverse pregnancy outcomes and long-term cardiovascular health
Women veterans' health and healthcare
Ethics in reproductive epidemiology and women's health

External support (past and present) - gifts, grants, and contracts:

a) **Past:**

NIH/NICHD Minority Supplement
Coagulation Polymorphisms and Adverse Pregnancy Outcomes
PI - John Thorp, MD
Role – co-investigator
%Effort – 80%
Purpose – To explore endothelial function gene polymorphisms and measures of uteroplacental vascular compromise as risk factors for adverse pregnancy outcomes.
Approximate amount – $697,000
Duration – 3/13/03-8/30/07

Centers for Medicare & Medicaid Studies
Shaw-Duke Maternal and Infant Mortality Initiative
PIs – Daniel Howard, PhD; Haywood Brown, MD
Role – co-investigator
%Effort – 25%

Purpose – The goal of this grant was to help reduce racial disparities for pregnant African American Medicaid recipients by studying patient and health services factors and using an educational intervention to improve pregnancy outcomes.
Approximate amount – $175,000
Duration – 10/2006-9/2008

Charles Hammond Fund Foundation Award, Duke University Medical Center Department of Obstetrics and Gynecology
PI – Monique Chireau, MD, MPH
Role – PI
%Effort – 7%
Purpose – This bridge grant supported continued exploration and development of the Duke Birth Database, (developed by Dr. Chireau), of pregnancy outcomes at Duke Medical Center over the last 25 years, and the generation of papers and grant submissions.
Approximate amount – $30,000
Duration – 2006-2008

IPA Agreement (Myers) 12/3/07-12/3/09
Department of Veterans Affairs
Addressing Birth Defect Prevention in Women Veterans
Major goal of project: to assist the Department of Veterans Affairs in development of birth defect prevention efforts by the Women Veterans Health Strategic Healthcare Group.
Role: Co-PI

Clinical and Translational Science Award Grant (Small/Chireau) 4/3/09 – 12/3/09
Durham Health Innovations
Duke Translational Medicine Institute, Duke Center for Community Research
We hypothesize that an *internatal care* model focusing on postpartum and preconception prevention and treatment will have a major impact on maternal-child health in Durham. We propose to plan and design and multidisciplinary, community-based care model to improve maternal-child health and interrupt the cycle of events leading to maternal and infant complications in the next pregnancy and beyond.
Role: Co-PI

Duke Clinical Research Unit Pilot Grant Program (Chireau) 4/30/10 – 5/1/2011
Duke University
This pilot grant supported exploration of the association between cardiovascular disease and adverse pregnancy outcomes in young women.
Role: PI

Clinical, Metabolomic and Proteomic Profiles in Preeclampsia (Chireau) 7/15/10 – 7/14/2011
Duke Translational Medicine Institute
This grant supported proteomic and metabolomic analyses of sera and placental tissue from preeclamptic women.
Role: PI

Clinical activity:
St. Joseph's Regional Medical Center, Mishawaka, IN

Past and present participation in academic and administrative activities:

Duke University Medical Center IRB
Duke Medical School Admissions Committee
Director, VA Gynecology Resident Rotation
Director, VA Gynecology Medical Student Rotation
Committee member, National Surgical Quality Improvement Program, GYN Surgery Subspecialty, for Duke University Medical Center and Veterans Administration
Executive Board Member, UNICEF
Executive Board Chair, Maternal and Newborn Health in Fragile Settings, The Partnership for Maternal, Newborn and Child Health

Exhibit 2

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)**

MIFEPREX is only available through a restricted program called the mifepristone REMS Program (5.3).
Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if they experience sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if they experience abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.

----------INDICATIONS AND USAGE----------
MIFEPREX is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. (1)

----------DOSAGE AND ADMINISTRATION----------
- 200 mg MIFEPREX on Day 1, followed 24-48 hours after MIFEPREX dosing by 800 mcg buccal misoprostol. (2.1)
- Instruct the patient what to do if significant adverse reactions occur. (2.2)
- Follow-up is needed to confirm complete termination of pregnancy. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card (3)

----------CONTRAINDICATIONS----------
- Confirmed/suspected ectopic pregnancy or undiagnosed adnexal mass (4)
- Chronic adrenal failure (4)
- Concurrent long-term corticosteroid therapy (4)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (4)
- Hemorrhagic disorders or concurrent anticoagulant therapy (4)
- Inherited porphyria (4)
- Intrauterine device (IUD) in place (4)

----------WARNINGS AND PRECAUTIONS----------
- Ectopic pregnancy: Exclude before treatment. (5.4)
- Rhesus immunization: Prevention needed as for surgical abortion. (5.5)

----------ADVERSE REACTIONS----------
Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Danco Laboratories, LLC at 1-877-432-7596 or medicaldirector@earlyoptionpill.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- CYP3A4 inducers can lower mifepristone concentrations. (7.1)
- CYP3A4 inhibitors can increase mifepristone concentrations. Use with caution. (7.2)
- CYP3A4 substrate concentrations can be increased. Caution with coadministration of substrates with narrow therapeutic margin. (7.3)

----------USE IN SPECIFIC POPULATIONS----------
- Pregnancy: Risk of fetal malformations in ongoing pregnancy if not terminated is unknown. (8.1)

See 17 for PATIENT COUNSELING INFORMATION, Medication Guide.

Revised: 01/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

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FULL PRESCRIBING INFORMATION

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections (e.g., *Clostridium sordellii*) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis *[see Warnings and Precautions (5.1)]*.**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding *[see Warnings and Precautions (5.2)]*.**

Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the mifepristone REMS Program *[see Warnings and Precautions (5.3)]*.

Before prescribing MIFEPREX, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if they experience sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if they experience abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting, or diarrhea) for more than 24 hours after taking misoprostol.

1 INDICATIONS AND USAGE

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Regimen

For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period. The duration of pregnancy may be determined from menstrual history and clinical examination. Assess the pregnancy by ultrasonographic scan if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected.

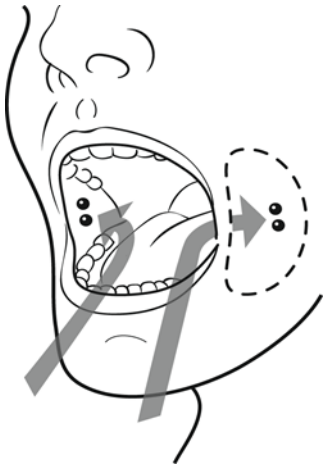
Remove any intrauterine device (“IUD”) before treatment with MIFEPREX begins [*see Contraindications (4)*].

The dosing regimen for MIFEPREX and misoprostol is:

- MIFEPREX 200 mg orally + misoprostol 800 mcg buccally
  - *Day One:* MIFEPREX Administration
    One 200 mg tablet of MIFEPREX is taken in a single oral dose.
  - *Day Two or Three:* Misoprostol Administration (minimum 24-hour interval between MIFEPREX and misoprostol)
    Four 200 mcg tablets (total dose 800 mcg) of misoprostol are taken by the buccal route.

    Tell the patient to place two 200 mcg misoprostol tablets in each cheek pouch (the area between the cheek and gums) for 30 minutes and then swallow any remnants with water or another liquid (see Figure 1).

    Figure 1

    2 pills between cheek and gum on left side + 2 pills between cheek and gum on right side

Patients taking MIFEPREX must take misoprostol within 24 to 48 hours after taking MIFEPREX. The effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours or more than 48 hours after mifepristone administration.

Because most women will expel the pregnancy within 2 to 24 hours of taking misoprostol *[see Clinical Studies (14)]*, discuss with the patient an appropriate location for them to be when taking the misoprostol, taking into account that expulsion could begin within 2 hours of administration.

2.2 Patient Management Following Misoprostol Administration

During the period immediately following the administration of misoprostol, the patient may need medication for cramps or gastrointestinal symptoms *[see Adverse Reactions (6)].*

Give the patient:

- Instructions on what to do if significant discomfort, excessive vaginal bleeding or other adverse reactions occur
- A phone number to call if the patient has questions following the administration of the misoprostol
- The name and phone number of the healthcare provider who will be handling emergencies.

2.3 Post-treatment Assessment: Day 7 to 14

Patients should follow-up with their healthcare provider approximately 7 to 14 days after the administration of MIFEPREX. This assessment is very important to confirm that complete termination of pregnancy has occurred and to evaluate the degree of bleeding. Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan. Lack of bleeding following treatment usually indicates failure; however, prolonged or heavy bleeding is not proof of a complete abortion.

The existence of debris in the uterus (e.g., if seen on ultrasonography) following the treatment procedure will not necessarily require surgery for its removal.

Patients should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of women may experience some type of bleeding for more than 30 days. Persistence of heavy or moderate vaginal bleeding at the time of follow-up, however, could indicate an incomplete abortion.

If complete expulsion has not occurred, but the pregnancy is not ongoing, patients may be treated with another dose of misoprostol 800 mcg buccally. There have been rare reports of uterine rupture in women who took MIFEPREX and misoprostol, including women with prior uterine rupture or uterine scar and women who received multiple doses of misoprostol within 24 hours. Patients who choose to use a repeat dose of misoprostol should have a follow-up visit with their healthcare provider in approximately 7 days to assess for complete termination.

Surgical evacuation is recommended to manage ongoing pregnancies after medical abortion *[see Use in Specific Populations (8.1)]*. Advise the patient whether you will provide such care or will refer them to another provider as part of counseling prior to prescribing MIFEPREX.

2.4 Contact for Consultation

For consultation 24 hours a day, 7 days a week with an expert in mifepristone, call Danco Laboratories at 1-877-4 Early Option (1-877-432-7596).

3 DOSAGE FORMS AND STRENGTHS

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card. MIFEPREX tablets are light yellow, cylindrical, and bi-convex tablets, approximately 11 mm in diameter and imprinted on one side with “MF.”

4 CONTRAINDICATIONS

- Administration of MIFEPREX and misoprostol for the termination of pregnancy (the “treatment procedure”) is contraindicated in patients with any of the following conditions:
  - Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy) *[see Warnings and Precautions (5.4)]*
  - Chronic adrenal failure (risk of acute adrenal insufficiency)
  - Concurrent long-term corticosteroid therapy (risk of acute adrenal insufficiency)
  - History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported *[see Adverse Reactions (6.2)]*)
  - Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)

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- Inherited porphyrias (risk of worsening or of precipitation of attacks)

- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device ("IUD") in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

5 WARNINGS AND PRECAUTIONS

5.1 Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX *[see Boxed Warning]*. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis (e.g., from *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting, or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. No causal relationship between MIFEPREX and misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

5.2 Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications, and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion *[see Boxed Warning]*.

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more. In general, the duration of bleeding and spotting increased as the duration of the pregnancy increased.

Decreases in hemoglobin concentration, hematocrit, and red blood cell count may occur in patients who bleed heavily.

Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Based on data from several large clinical trials, vasoconstrictor drugs were used in 4.3% of all subjects, there was a decrease in hemoglobin of more than 2 g/dL in 5.5% of subjects, and blood transfusions were administered to ≤ 0.1% of subjects. Because heavy bleeding requiring surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

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5.3 Mifepristone REMS Program

MIFEPREX is available only through a restricted program under a REMS called the mifepristone REMS Program, because of the risks of serious complications *[see Warnings and Precautions (5.1, 5.2)]*.

Notable requirements of the mifepristone REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form.
- Patients must sign a Patient Agreement Form.
- MIFEPREX must only be dispensed to patients by or under the supervision of a certified prescriber, or by certified pharmacies on prescriptions issued by certified prescribers.

Further information is available at 1-877-4 Early Option (1-877-432-7596).

5.4 Ectopic Pregnancy

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies *[see Contraindications (4)].* Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.

Patients who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

5.5 Rhesus Immunization

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Infection and sepsis *[see Warnings and Precautions (5.1)]*
- Uterine bleeding *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Information presented on common adverse reactions relies solely on data from U.S. studies, because rates reported in non-U.S. studies were markedly lower and are not likely generalizable to the U.S. population. In three U.S. clinical studies totaling 1,248 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally, women reported adverse reactions in diaries and in interviews at the follow-up visit. These studies enrolled generally healthy women of reproductive age without contraindications to mifepristone or misoprostol use according to the MIFEPREX product label. Gestational age was assessed prior to study enrollment using the date of the woman's last menstrual period, clinical evaluation, and/or ultrasound examination.

About 85% of patients report at least one adverse reaction following administration of MIFEPREX and misoprostol, and many can be expected to report more than one such reaction. The most commonly reported adverse reactions (>15%) were nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness (see Table 1). The frequency of adverse reactions varies between studies and may be dependent on many factors, including the patient population and gestational age.

Abdominal pain/cramping is expected in all medical abortion patients and its incidence is not reported in clinical studies. Treatment with MIFEPREX and misoprostol is designed to induce uterine bleeding and cramping to cause termination of an intrauterine pregnancy. Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most patients can expect bleeding more heavily than they do during a heavy menstrual period *[see Warnings and Precautions (5.2)]*.

Table 1 lists the adverse reactions reported in U.S. clinical studies with incidence >15% of women.

Table 1
Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. Clinical Studies

Adverse Reaction	# U.S. studies	Number of Evaluable Women	Range of frequency (%)	Upper Gestational Age of Studies Reporting Outcome
Nausea	3	1,248	51-75%	70 days
Weakness	2	630	55-58%	63 days
Fever/chills	1	414	48%	63 days
Vomiting	3	1,248	37-48%	70 days
Headache	2	630	41-44%	63 days
Diarrhea	3	1,248	18-43%	70 days
Dizziness	2	630	39-41%	63 days

One study provided gestational-age stratified adverse reaction rates for women who were 57-63 and 64-70 days; there was little difference in frequency of the reported common adverse reactions by gestational age.

Information on serious adverse reactions was reported in six U.S. and four non-U.S. clinical studies, totaling 30,966 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally. Serious adverse reaction rates were similar between U.S. and non-U.S. studies, so rates from both U.S. and non-U.S. studies are presented. In the U.S. studies, one studied women through 56 days gestation, four through 63 days gestation, and one through 70 days gestation, while in the non-U.S. studies, two studied women through 63 days gestation, and two through 70 days gestation. Serious adverse reactions were reported in <0.5% of women. Information from the U.S. and non-U.S. studies is presented in Table 2.

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Table 2
Serious Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. and Non-U.S. Clinical Studies

Adverse Reaction	U.S.			Non-U.S.		
	# of studies	Number of Evaluable Women	Range of frequency (%)	# of studies	Number of Evaluable Women	Range of frequency (%)
Transfusion	4	17,774	0.03-0.5%	3	12,134	0-0.1%
Sepsis	1	629	0.2%	1	11,155	<0.01%*
ER visit	2	1,043	2.9-4.6%	1	95	0
Hospitalization Related to Medical Abortion	3	14,339	0.04-0.6%	3	1,286	0-0.7%
Infection without sepsis	1	216	0	1	11,155	0.2%
Hemorrhage	NR	NR	NR	1	11,155	0.1%

NR= Not reported
* This outcome represents a single patient who experienced death related to sepsis.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of MIFEPREX and misoprostol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Infections and infestations: post-abortal infection (including endometritis, endomyometritis, parametritis, pelvic infection, pelvic inflammatory disease, salpingitis)
Blood and the lymphatic system disorders: anemia
Immune system disorders: allergic reaction (including anaphylaxis, angioedema, hives, rash, itching)
Psychiatric disorders: anxiety
Cardiac disorders: tachycardia (including racing pulse, heart palpitations, heart pounding)
Vascular disorders: syncope, fainting, loss of consciousness, hypotension (including orthostatic), light-headedness
Respiratory, thoracic and mediastinal disorders: shortness of breath
Gastrointestinal disorders: dyspepsia
Musculoskeletal, connective tissue and bone disorders: back pain, leg pain
Reproductive system and breast disorders: uterine rupture, ruptured ectopic pregnancy, hematometra, leukorrhea
General disorders and administration site conditions: pain

7 DRUG INTERACTIONS

7.1 Drugs that May Reduce MIFEPREX Exposure (Effect of CYP 3A4 Inducers on MIFEPREX)

CYP450 3A4 is primarily responsible for the metabolism of mifepristone. CYP3A4 inducers such as rifampin, dexamethasone, St. John's Wort, and certain anticonvulsants (such as phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering serum concentrations of mifepristone). Whether this action has an impact on the efficacy of the dose

regimen is unknown. Refer to the follow-up assessment *[see Dosage and Administration (2.3)]* to verify that treatment has been successful.

7.2 Drugs that May Increase MIFEPREX Exposure (Effect of CYP 3A4 Inhibitors on MIFEPREX)

Although specific drug or food interactions with mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum concentrations of mifepristone). MIFEPREX should be used with caution in patients currently or recently treated with CYP 3A4 inhibitors.

7.3 Effects of MIFEPREX on Other Drugs (Effect of MIFEPREX on CYP 3A4 Substrates)

Based on *in vitro* inhibition information, coadministration of mifepristone may lead to an increase in serum concentrations of drugs that are CYP 3A4 substrates. Due to the slow elimination of mifepristone from the body, such interaction may be observed for a prolonged period after its administration. Therefore, caution should be exercised when mifepristone is administered with drugs that are CYP 3A4 substrates and have narrow therapeutic range.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Risks to pregnant patients are discussed throughout the labeling.

Refer to misoprostol labeling for risks to pregnant patients with the use of misoprostol.

The risk of adverse developmental outcomes with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol is unknown; however, the process of a failed pregnancy termination could disrupt normal embryo-fetal development and result in adverse developmental effects. Birth defects have been reported with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol. In animal reproduction studies, increased fetal losses were observed in mice, rats, and rabbits and skull deformities were observed in rabbits with administration of mifepristone at doses lower than the human exposure level based on body surface area.

Data

Animal Data

In teratology studies in mice, rats and rabbits at doses of 0.25 to 4.0 mg/kg (less than 1/100 to approximately 1/3 the human exposure based on body surface area), because of the antiprogestational activity of mifepristone,fetal losses were much higher than in control animals. Skull deformities were detected in rabbit studies at approximately 1/6 the human exposure, although no teratogenic effects of mifepristone have been observed to date in rats or mice. These deformities were most likely due to the mechanical effects of uterine contractions resulting from inhibition of progesterone action.

8.2 Lactation

MIFEPREX is present in human milk. Limited data demonstrate undetectable to low levels of the drug in human milk with the relative (weight-adjusted) infant dose 0.5% or less as compared to maternal dosing. There is no information on the effects of MIFEPREX in a regimen with

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misoprostol in a breastfed infant or on milk production. Refer to misoprostol labeling for lactation information with the use of misoprostol. The developmental and health benefits of breast-feeding should be considered along with any potential adverse effects on the breast-fed child from MIFEPREX in a regimen with misoprostol.

8.4 Pediatric Use

Safety and efficacy of MIFEPREX have been established in pregnant females. Data from a clinical study of MIFEPREX that included a subset of 322 females under age 17 demonstrated a safety and efficacy profile similar to that observed in adults.

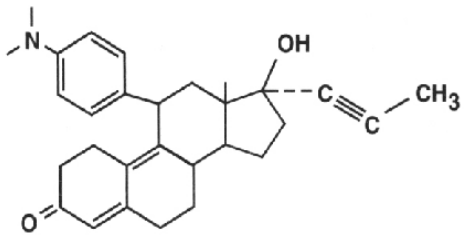
10 OVERDOSAGE

No serious adverse reactions were reported in tolerance studies in healthy non-pregnant female and healthy male subjects where mifepristone was administered in single doses greater than 1800 mg (ninefold the recommended dose for medical abortion). If a patient ingests a massive overdose, the patient should be observed closely for signs of adrenal failure.

11 DESCRIPTION

MIFEPREX tablets each contain 200 mg of mifepristone, a synthetic steroid with antiprogestational effects. The tablets are light yellow in color, cylindrical, and bi-convex, and are intended for oral administration only. The tablets include the inactive ingredients colloidal silica anhydrous, corn starch, povidone, microcrystalline cellulose, and magnesium stearate.

Mifepristone is a substituted 19-nor steroid compound chemically designated as 11ß-[*p*-(Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one. Its empirical formula is $C_{29}H_{35}NO_2$. Its structural formula is:



The compound is a yellow powder with a molecular weight of 429.6 and a melting point of 192-196°C. It is very soluble in methanol, chloroform and acetone and poorly soluble in water, hexane and isopropyl ether.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. Based on studies with various oral doses in several animal species (mouse, rat, rabbit, and monkey), the compound inhibits the activity of endogenous or exogenous progesterone, resulting in effects on the uterus and cervix that, when combined with misoprostol, result in termination of an intrauterine pregnancy.

During pregnancy, the compound sensitizes the myometrium to the contraction-inducing activity

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of prostaglandins.

12.2 Pharmacodynamics

Use of MIFEPREX in a regimen with misoprostol disrupts pregnancy by causing decidual necrosis, myometrial contractions, and cervical softening, leading to the expulsion of the products of conception.

Doses of 1 mg/kg or greater of mifepristone have been shown to antagonize the endometrial and myometrial effects of progesterone in women.

Antiglucocorticoid and antiandrogenic activity: Mifepristone also exhibits antiglucocorticoid and weak antiandrogenic activity. The activity of the glucocorticoid dexamethasone in rats was inhibited following doses of 10 to 25 mg/kg of mifepristone. Doses of 4.5 mg/kg or greater in human beings resulted in a compensatory elevation of adrenocorticotropic hormone (ACTH) and cortisol. Antiandrogenic activity was observed in rats following repeated administration of doses from 10 to 100 mg/kg.

12.3 Pharmacokinetics

Mifepristone is rapidly absorbed after oral ingestion with non-linear pharmacokinetics for Cmax after single oral doses of 200 mg and 600 mg in healthy subjects.

Absorption

The absolute bioavailability of a 20 mg mifepristone oral dose in females of childbearing age is 69%. Following oral administration of a single dose of 600 mg, mifepristone is rapidly absorbed, with a peak plasma concentration of 1.98 ± 1.0 mg/L occurring approximately 90 minutes after ingestion.

Following oral administration of a single dose of 200 mg in healthy men (n=8), mean Cmax was 1.77 ± 0.7 mg/L occurring approximately 45 minutes after ingestion. Mean $AUC_{0-\infty}$ was 25.8 ± 6.2 mg*hr/L.

Distribution

Mifepristone is 98% bound to plasma proteins, albumin, and α_1-acid glycoprotein. Binding to the latter protein is saturable, and the drug displays nonlinear kinetics with respect to plasma concentration and clearance.

Elimination

Following a distribution phase, elimination of mifepristone is slow at first (50% eliminated between 12 and 72 hours) and then becomes more rapid with a terminal elimination half-life of 18 hours.

Metabolism

Metabolism of mifepristone is primarily via pathways involving N-demethylation and terminal hydroxylation of the 17-propynyl chain. *In vitro* studies have shown that CYP450 3A4 is primarily responsible for the metabolism. The three major metabolites identified in humans are: (1) RU 42 633, the most widely found in plasma, is the N-monodemethylated metabolite; (2) RU 42 848, which results from the loss of two methyl groups from the 4-dimethylaminophenyl in position 11ß; and (3) RU 42 698, which results from terminal hydroxylation of the 17-propynyl chain.

Excretion

By 11 days after a 600 mg dose of tritiated compound, 83% of the drug has been accounted for by the feces and 9% by the urine. Serum concentrations are undetectable by 11 days.

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Specific Populations

The effects of age, hepatic disease and renal disease on the safety, efficacy and pharmacokinetics of mifepristone have not been investigated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No long-term studies to evaluate the carcinogenic potential of mifepristone have been performed.

Mutagenesis

Results from studies conducted *in vitro* and in animals have revealed no genotoxic potential for mifepristone. Among the tests carried out were: Ames test with and without metabolic activation; gene conversion test in *Saccharomyces cerevisiae* D4 cells; forward mutation in *Schizosaccharomyces pompe* P1 cells; induction of unscheduled DNA synthesis in cultured HeLa cells; induction of chromosome aberrations in CHO cells; *in vitro* test for gene mutation in V79 Chinese hamster lung cells; and micronucleus test in mice.

Impairment of Fertility

In rats, administration of 0.3 mg/kg mifepristone per day caused severe disruption of the estrus cycles for the three weeks of the treatment period. Following resumption of the estrus cycle, animals were mated and no effects on reproductive performance were observed.

14 CLINICAL STUDIES

Safety and efficacy data from clinical studies of mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation are reported below. Success was defined as the complete expulsion of the products of conception without the need for surgical intervention. The overall rates of success and failure, shown by reason for failure based on 22 worldwide clinical studies (including 7 U.S. studies) appear in Table 3.

The demographics of women who participated in the U.S. clinical studies varied depending on study location and represent the racial and ethnic variety of American females. Females of all reproductive ages were represented, including females less than 18 and more than 40 years of age; most were 27 years or younger.

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Table 3
Outcome Following Treatment with Mifepristone (oral) and Misoprostol (buccal) Through 70 Days Gestation

	U.S. Trials	Non-U.S. Trials
N	16,794	18,425
Complete Medical Abortion	97.4%	96.2%
Surgical Intervention*	2.6%	3.8%
Ongoing Pregnancy**	0.7%	0.9%

* Reasons for surgical intervention include ongoing pregnancy, medical necessity, persistent or heavy bleeding after treatment, patient request, or incomplete expulsion.
** Ongoing pregnancy is a subcategory of surgical intervention, indicating the percent of women who have surgical intervention due to an ongoing pregnancy.

The results for clinical studies that reported outcomes, including failure rates for ongoing pregnancy, by gestational age are presented in Table 4.

Table 4
Outcome by Gestational Age Following Treatment with Mifepristone and Misoprostol (buccal) for U.S. and Non-U.S. Clinical Studies

	≤49 days			50-56 days			57-63 days			64-70 days		
	N	**%**	**Number of Evaluable Studies**	**N**	**%**	**Number of Evaluable Studies**	**N**	**%**	**Number of Evaluable Studies**	**N**	**%**	**Number of Evaluable Studies**
Complete medical abortion	12,046	98.1	10	3,941	96.8	7	2,294	94.7	9	479	92.7	4
Surgical intervention for ongoing pregnancy	10,272	0.3	6	3,788	0.8	6	2,211	2	8	453	3.1	3

One clinical study asked subjects through 70 days gestation to estimate when they expelled the pregnancy, with 70% providing data. Of these, 23-38% reported expulsion within 3 hours and over 90% within 24 hours of using misoprostol.

16 HOW SUPPLIED/STORAGE AND HANDLING

is only available through a restricted program called the Mifepristone REMS Program *[see Warnings and Precautions (5.3)].*

MIFEPREX is supplied as light yellow, cylindrical, and bi-convex tablets imprinted on one side with “MF.” Each tablet contains 200 mg of mifepristone. One tablet is individually blistered on one blister card that is packaged in an individual package (National Drug Code 64875-001-01).

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

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17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide), included with each package of MIFEPREX. Additional copies of the Medication Guide are available by contacting Danco Laboratories at 1-877-4 Early Option (1-877-432-7596) or from www.earlyoptionpill.com.

Serious Infections and Bleeding

- Inform the patient that uterine bleeding and uterine cramping will occur [*see Warnings and Precautions (5.2)*].
- Advise the patient that serious and sometimes fatal infections and bleeding can occur very rarely [*see Warnings and Precautions (5.1, 5.2)*].
- MIFEPREX is only available through a restricted program called the Mifepristone REMS Program [*see Warnings and Precautions (5.3)*]. Under the mifepristone REMS Program:
    - Patients must sign a Patient Agreement Form.
    - MIFEPREX is only dispensed by or under the supervision of certified prescribers or by certified pharmacies on prescriptions issued by certified prescribers.

Provider Contacts and Actions in Case of Complications

- Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, or if the patient experiences complications including prolonged heavy bleeding, severe abdominal pain, or sustained fever *[see Boxed Warning]*.
-

Compliance with Treatment Schedule and Follow-up Assessment

- Advise the patient that it is necessary to complete the treatment schedule, including a follow-up assessment approximately 7 to14 days after taking MIFEPREX *[see Dosage and Administration (2.3)]*.
- Explain that
    - prolonged heavy vaginal bleeding is not proof of a complete abortion,
    - if the treatment fails and the pregnancy continues, the risk of fetal malformation is unknown,
    - it is recommended that ongoing pregnancy be managed by surgical termination *[see Dosage and Administration (2.3)]*. Advise the patient whether you will provide such care or will refer them to another provider.

Subsequent Fertility

- Inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses.
- Inform the patient that contraception can be initiated as soon as pregnancy expulsion has been confirmed, or before resuming sexual intercourse.

MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Manufactured for:
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

01/2023

Reference ID: 5103833

MEDICATION GUIDE

Mifeprex (MIF-eh-prex) (mifepristone tablets, for oral use

Read this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your healthcare provider.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your healthcare provider. You can write down your healthcare provider's telephone number here _____.

Be sure to contact your healthcare provider promptly if you have any of the following:

- **Heavy Bleeding.** Contact your healthcare provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).
- **Abdominal Pain or "Feeling Sick."** If you have abdominal pain or discomfort, or you are "feeling sick," including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your healthcare provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare provider right away. Fever may be a symptom of a serious infection or another problem.

If you cannot reach your healthcare provider, go to the nearest hospital emergency room.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy. In many cases, this surgical procedure can be done in the office/clinic. The chance of birth defects if the pregnancy is not ended is unknown.

Talk with your healthcare provider. Before you take Mifeprex, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifeprex.

What is Mifeprex?

Mifeprex is used in a regimen with another prescription medicine called misoprostol, to end an early pregnancy. Early pregnancy means it is 70 days (10 weeks) or less since your last menstrual period began. Mifeprex is not approved for ending pregnancies that are further along. Mifeprex blocks a hormone needed for your pregnancy to continue. When you use Mifeprex on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifeprex, to cause the pregnancy to be passed from your uterus.

The pregnancy is likely to be passed from your uterus within 2 to 24 hours after taking Mifeprex and misoprostol. When the pregnancy is passed from the uterus, you will have bleeding and cramping that will likely be heavier than your usual period. About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

Who should not take Mifeprex?

Some patients should not take Mifeprex. Do not take Mifeprex if you:

- Have a pregnancy that is more than 70 days (10 weeks). Your healthcare provider may do a clinical examination, an ultrasound examination, or other testing to determine how far along you are in pregnancy.
- Are using an IUD (intrauterine device or system). It must be taken out before you take Mifeprex.
- Have been told by your healthcare provider that you have a pregnancy outside the uterus (ectopic pregnancy).
- Have problems with your adrenal glands (chronic adrenal failure).
- Take a medicine to thin your blood.
- Have a bleeding problem.
- Have porphyria.
- Take certain steroid medicines.
- Are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Ask your healthcare provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifeprex.

What should I tell my healthcare provider before taking Mifeprex?

Before you take Mifeprex, tell your healthcare provider if you:

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifeprex can pass into your breast milk. The effect of the Mifeprex and misoprostol regimen on the breastfed infant or on milk production is unknown.
- are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
  Mifeprex and certain other medicines may affect each other if they are used together. This can cause side effects.

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How should I take Mifeprex?

- Mifeprex will be given to you by a healthcare provider or pharmacy.
- You and your healthcare provider will plan the most appropriate location for you to take the misoprostol, because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it.
- Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets.

Follow the instruction below on how to take Mifeprex and misoprostol:

<u>Mifeprex (1 tablet) orally + misoprostol (4 tablets) buccally</u>

Day 1:

- Take 1 Mifeprex tablet by mouth.

24 to 48 hours after taking Mifeprex:

- Take 4 misoprostol tablets by placing 2 tablets in each cheek pouch (the area between your teeth and cheek - see Figure A) for 30 minutes and then swallow anything left over with a drink of water or another liquid.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifeprex or later than 48 hours after Mifeprex.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your healthcare provider may send you home with medicines for these symptoms.

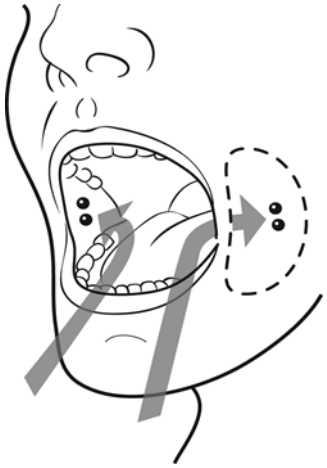

Figure A (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow-up with your healthcare provider about 7 to 14 days after you have taken Mifeprex to be sure you are well and that you have had bleeding and the pregnancy has passed from your uterus.
- Your healthcare provider will assess whether your pregnancy has passed from your uterus. If your pregnancy continues, the chance that there may be birth defects is unknown. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy.
- If your pregnancy has ended, but has not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or over-the-counter medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your healthcare provider about them because they may interfere with the treatment. Ask your healthcare provider about what medicines you can take for pain and other side effects.

What are the possible side effects of Mifeprex and misoprostol?

Mifeprex may cause serious side effects. See "What is the most important information I should know about Mifeprex?"

Cramping and bleeding. Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must follow-up with your healthcare provider approximately 7 to 14 days after taking Mifeprex. See "How should I take Mifeprex?" for more information on your follow-up assessment. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifeprex. Bleeding or spotting can be expected for an average of 9 to16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of passing the pregnancy.

The most common side effects of Mifeprex treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea and dizziness. Your provider will tell you how to manage any pain or other side effects. These are not all the possible side effects of Mifeprex.

Call your healthcare provider for medical advice about any side effects that bother you or do not go away. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Mifeprex.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Mifeprex. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider for information about Mifeprex that is written for healthcare professionals.

For more information about Mifeprex, go to www.earlyoptionpill.com or call 1-877-4 Early Option (1-877-432-7596).

Manufactured for: *Danco Laboratories, LLC*
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596) www.earlyoptionpill.com

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approval 01/2023

Exhibit 3

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC and BEVERLY GRAY, MD, Plaintiff, v. JOSHUA STEIN, TODD M. WILLIAMS, JIM O'NEILL, SPENCER MERRIWEATHER, AVERY CRUMP, JEFF NIEMAN, SATANA DEBERRY, WILLIAM WEST, LORRIN FREEMAN, BENJAMIN R. DAVID, KODY H. KINSLEY, MICHAUX R. KILPATRICK, MD, PHD, and RACQUEL INGRAM, PHD, RN, all in their official capacities Defendants. and PHILIP E. BERGER and TIMOTHY K. MOORE Intervenor-Defendants.	**Case No. 1:23-cv-480**

DECLARATION OF SUSAN BANE, M.D., Ph.D.

I, Susan Bane, MD, PhD, pursuant to the provision of 28 U.S.C. § 1746, do herby declare as follows:

1. I am at least 18 years of age and competent to testify. I have personal and professional knowledge of the statements contained in this declaration. The opinions I express in this declaration are based on my education, training, familiarity with the medical literature, and expertise as an obstetrician/gynecologist who sees

patients with unplanned pregnancies in Eastern North Carolina. These opinions are my own, and do not represent any group with which I am affiliated.

I. Introduction and Professional Background

2. I am a board-certified Obstetrician and Gynecologist. I completed my undergraduate degree at Atlantic Christian College, now Barton College, and majored in Chemistry. I attended the University of Illinois, completing both my Medical Degree (MD) and Doctorate (PhD) in Kinesiology. I completed my Obstetrics and Gynecology residency at Pitt Memorial Hospital, now ECU Health, which is affiliated with the Brody School of Medicine at East Carolina University in Greenville, North Carolina.

3. I have practiced obstetrics and gynecology for over 20 years in Eastern North Carolina since completing my residency. I was in private practice at Greenville Obstetrics and Gynecology for nine years. During that time, I provided obstetrical, gynecological, primary, and hospital-based care at Pitt Memorial Hospital, now ECU Health, in Greenville, North Carolina. I served as a community clinical preceptor in the outpatient and inpatient settings, teaching both medical students and resident physicians. I also lectured at the Brody School of Medicine on topics related to labor and delivery and was the primary instructor for a fourth-year medical elective titled "Residency 101."

4. During my time in private practice, I helped women deliver over 1000 babies and supervised midwives who helped women deliver several thousand babies. My obstetric practice was comprehensive, including, but not limited to vaginal

deliveries, vacuum-assisted vaginal deliveries, cesarean sections, care for women with medical emergencies, including ectopic pregnancies, care for women and pre-born children with life limiting conditions, care of women with miscarriages/fetal demise, prenatal care, and post-partum care. My gynecological practice was also comprehensive, including, but not limited to gynecological surgery, preventive and primary care.

5. I was sidelined in 2010 from delivering babies due to a shoulder injury and became a faculty member at Barton College in Wilson, NC, working there from 2011 to 2023. I was a tenured associate professor of Allied Health and Sport Studies. My teaching responsibilities included a wide variety of courses including, but not limited to anatomy and physiology, exercise physiology, allied health and sport studies, contemporary issues in medicine and health, nature of inquiry, health behavior theory, and health program planning, implementation, and evaluation.

6. My administrative responsibilities during my time at Barton College included serving as the Director of the Whitehurst Family Honors Program, Dean of the Graduate and Professional Studies Program, and Director of the Barton College-Area L AHEC Partnership.

7. I wrote and/or implemented grants to address community and campus health and well-being, as well as health careers diversity and workforce development. These included local, state, and federal grants. Funding was received from The Healthcare Foundation of Wilson, Health Resource Service Association (HRSA), Interfaith America, and North Carolina Department of Health and Human Services

(NC DHHS). Programming brought to campus through this work included health and wellness lectures, exercise programs/classes, farmer's market, health fair, mental health first aid, and a lecture series on the role of spirituality in medicine. I led the development of clinical virtual modules for students displaced from clinical experiences during COVID focusing on the value of the interprofessional health care team, health disparities, social determinants of health, cultural competency, the opioid crisis, aging, chronic disease, adverse childhood experiences, and pandemics. Currently, I am consulting through the Area L AHEC - Barton College partnership on an initiative for the College to become a trauma-informed campus.

8. I continued practicing medicine while a faculty member at Barton College, working in the student health center seeing patients, and then serving as a consultant to the student health center and the athletic department/athletic trainers during my time at Barton College. I care about patient health and healing deeply and examining the root causes of dysfunction and disease. These interests in health care led me to complete certifications in functional medicine, health coaching, emotional intelligence coaching, and theology, medicine, and culture while working at Barton College.

9. I have served as the medical director of Choices Women's Center for several years and in the past year became the medical director of two other pregnancy centers in rural Eastern North Carolina. I oversee all clinical aspects of the medical clinics and see patients with unintended pregnancies. I am in the trenches with women with unplanned pregnancies as they face a decision of massive consequence –

to give birth and parent, to give birth and decide about where to place their child (adoption), or give permission for a health care provider to end the life of their pre-born child.

10. My patients are often scared, alone, and coerced. They often face barriers when they experience an unplanned pregnancy. What we hear from women at our Centers is consistent with what the literature states are the most common reasons women choose to have induced abortions - socioeconomic factors such as interference with education or work, financial constraints, lack of support from the father of the baby, or poor timing (not ready to be a mother or finished having children).[1]

11. The specific reasons women choose to have an induced abortion are as multiple and diverse as the women who experience them. Day in and day out, I see women who are trapped in the cruel predicament in contemporary America in which they see giving permission to end the life of their very own pre-born children as their only option. Women with an unintended pregnancy have a massive decision in front of them that is often shrouded in secrecy and has the potential to haunt them for years to come. They need a place to go where they can receive exceptional medical care, are empowered with information, and gain confidence to face the barriers in front of them. That is exactly what we do at the three pregnancy centers for which I serve as the Medical Director.

[1] Chae, S., Desai, S., Crowell, M., & Sedgh, G. (2017). Reasons Why Women Have Induced Abortions: A Synthesis of Findings from 14 Countries. *Contraception (96):* 233-241. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5957082/.

II. Expert Opinions

A. Maternal Mortality and Induced Abortion in North Carolina

i) Abortion Is Common, Not Safe, and Not Essential Health Care.

12. The plaintiffs' witnesses claim that abortion is common, safe, and essential health care. Induced abortions are common. Approximately 1 in 4 women in America have had an induced abortion, with estimates from the CDC and Guttmacher Institute of 43,000,000 – 63,000,000 induced abortions since the landmark *Roe v. Wade* Supreme Court decision in 1973 that legalized abortion in our country.[2] Because abortion is common does not mean it is necessarily safe or essential. To unpackage the plaintiffs' claim that abortion is safe and essential health care, we must first define abortion and then examine both maternal mortality and abortion data in North Carolina.

ii) Abortion defined.

13. The term "abortion" in medical language represents any pregnancy that ends prior to 20 weeks gestation. It is an umbrella term used to describe various types of abortions in the clinical setting. For example, if a woman is cramping or bleeding, but everything looks normal on physical exam and ultrasound, she would likely be diagnosed with a "threatened abortion" or a pregnancy that is at risk of not surviving. A "spontaneous abortion" is a miscarriage that a woman passes on her own or naturally. This patient will often experience bleeding and/or cramping and may even see the embryo or fetus. A "missed abortion" occurs when a woman is asymptomatic,

[2] https://nrlc.org/uploads/factsheets/FS01AbortionintheUS.pdf.

and we are unable to find a heartbeat. With a missed abortion, the woman has yet to start bleeding or cramping and not passed the embryo or fetus. If a woman is in the process of miscarrying, the term "incomplete abortion" is used, as the miscarriage is not finished. The term "complete abortion" is used when a woman has already completed the miscarriage process (typically cramping and bleeding have already happened).

14. These types of abortion described above are completely different from an induced abortion which is at the center of this law. The CDC defines induced abortion as "an intervention performed by a licensed clinician (e.g., a physician, nurse-midwife, nurse practitioner, physician assistant) within the limits of state regulations, that is intended to terminate a suspected or known ongoing intrauterine pregnancy and that does not result in a live birth."[3]

iii) Maternal Mortality in North Carolina.

15. Obstetricians and gynecologists care for two patients – a maternal and fetal patient. Our profession of doctoring is one that is bound by an oath to heal – to work towards health and wholeness for both our patients. The Hippocratic Oath requires physicians to "first, do no harm." North Carolina cares about women and wants no woman "to die as a result of pregnancy" as stated in our state's 2021 Maternal Mortality Review Report that provides a comprehensive summary of

[3] https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.

maternal mortality statistics and strategies for reducing maternal mortality – for reducing harm and providing safety for our maternal patients.[4]

16. Pregnancy-associated death is the death of a woman while pregnant or within one year of the termination of pregnancy, regardless of the cause. These deaths are pregnancy-related deaths and pregnancy-associated, but not related deaths.

17. Historically, gathering accurate maternal mortality data at both the state and national level has been fraught with errors, leading to the inability to draw meaningful conclusions.[5] One national approach that was taken to improve data collection included the requirement to add a pregnancy checkbox to death certificates in 2003. The pregnancy checkbox was finally added to the North Carolina death certificate beginning in 2014 and all maternal mortalities identified through the pregnancy checkbox alone are then confirmed for accuracy. North Carolina links death and birth certificates to allow improved tracking of maternal deaths. Thus, if a woman who has had a live birth in the last year commits suicides the following year, we have a way to link those two events. Most importantly, North Carolina passed legislation in 2015 that led to the formation of a Maternal Mortality Review Committee (MMRC) to review pregnancy-associated deaths, make recommendations for prevention, and disseminate findings.

[4] https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.
[5] MacDorman, M.F., Declercq, E. Cabral, H, and Morton, C. (2016). Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends From Measurement Issues. Obstetrics Gynecology 128(3): 447-455.

18. As this report demonstrates, North Carolina has made advances in reducing maternal mortality for all women, but disparities clearly still exist. Key findings for 2014-2016 data reported in this 2021 report revealed that a total of 228 deaths occurred and 60 of those were pregnancy-related deaths.

19. Among the 60 pregnancy-related deaths, the most common causes of death included hemorrhage, pulmonary embolism (blood clot to the lungs), infections, cardiomyopathy, preeclampsia, eclampsia, cardiovascular and coronary disease, cerebrovascular accidents, mental health conditions, and homicide. After a thorough review of deaths from 2014 to 2016, the MMRC determined that more than two-thirds (70%) of North Carolina pregnancy-related deaths were preventable. [6]

20. Demographic factors that impacted the 60 pregnancy-related deaths included:

- Education: among the 60 pregnancy-related deaths, over half (65%) occurred to those with a high school education or less.
- Race/Ethnicity: 85% of all pregnancy-related deaths occurred among non-Hispanic white and non-Hispanic Black women.
- Urban/Rural: both rural and urban areas of the state accounted for similar proportions of all pregnancy-related deaths (37% and 40%, respectively). Regional cities/suburban areas comprised 23% of all deaths.

21. Recommendations and strategies aimed at preventing pregnancy-related deaths in North Carolina were given by the MMRC committee. Categories for classifying committee recommendations by contributing factors included:

[6] https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.

- Provider recommendations focusing on the education and training of providers on adherence to clinical guidelines and protocols, as well as proper patient screening and follow-up.

- Patient/Family recommendations focusing on the need for patient education before, during, and after pregnancy on essential health-related topics.

- System recommendations focusing on a variety of approaches from a systems level, including developing consistent guidelines across the state that would provide education on early warning signs and integrate early warning tools that create an appropriate rapid response to detect rapid deterioration.

- Facility recommendations focused primarily on policies and procedures that address patient safety.

- Community recommendations including provision of community education and awareness on various health-related topics.

22. Greater access to induced abortion as a safe and essential healthcare strategy for addressing maternal mortality is not found in this report. Rather, this report focuses on the transformative strategies that address root causes and barriers women face when pregnant with a goal to restore women's health with a non-violent and caring approach.

23. The Plaintiffs falsely claim that this law will harm women and is "an attack on families with low incomes, North Carolinians of color, and rural North Carolinians, who already face inequities in access to medical care and who will bear the brunt of the Act's cruelties."[7]

24. Understanding racial disparity in pregnancy-related mortality is imperative both in our state and country. The plaintiffs falsely claim that this law

[7] Farris Decl. ¶ 10.

that regulates induced abortion has a disparate negative impact on minority women. This argument serves to further target minorities by creating even higher rates of induced abortion which could lead to greater rates of maternal mortality – something that is already unacceptably high in North Carolina and the United States. There are significant differences in birth outcomes in black women in the United States when compared with non-Hispanic white women. The rates of natural losses are similar (16%), but 34% of pregnancies in black women end in induced abortion, compared to 11% for white women.[8] Less than half of pregnancies in black women result in the birth of a live baby (48%). Induced abortion is 3-4 times more common in black than in non-Hispanic white women, and black women more commonly have later abortions (13%) compared with white women (9%).

25. CDC researchers found that the risk of death from induced abortion increased by 38% for each additional week of gestation. Compared with women whose abortions were performed at or before 8 weeks of gestation, women whose abortions were performed in the second trimester were significantly more likely to die of abortion-related causes.[9] If black women already have 3-4 times higher induced abortion rates and higher maternal mortality rates, then access to more induced abortions is not the solution to reduce maternal mortality. It is possible that the higher rate of induced abortion and later abortions in black women account for a

[8] Jones, RK and Finer, LB. (2012). Who Has Second Trimester Abortions in the United States? Contraception. 85(6):544-551.
[9] Bartlett, L, Berg, C, Shulman, H, Zane, S, Green, C, Whitehead, S, & Atrash, H. (2004). Risk Factors for Legal Induced Abortion-Related Mortality in the United States. Obstetrics and Gynecology. 103(4):727-737.

portion of the racial disparity noted in pregnancy mortality and this law will actually be protective for black women.

26. The most recent data from the CDC on maternal mortality released in 2023 present a harsh reminder that our nation's women desperately continue to need better access to high-quality healthcare. 2021 saw a 40% rise in maternal deaths and the highest numbers since 1965. [10] The U.S.'s poor maternal health is shameful.

27. The causes of our maternal mortality numbers are multi-factorial and include deeply rooted socioeconomic inequalities. However, most causes are preventable and not improved by increasing access to induced abortion. [11]

28. North Carolina's MMRC report aligns with these recent U.S. maternal mortality data and directly contradicts the claims by plaintiffs that the law targets these vulnerable populations. Eighty-five percent of the pregnancy-related deaths in North Carolina occurred in women who were non-Hispanic white and non-Hispanic Black women and over half (65%) occurred to those with a high school education or less (correlated with lower income). Both rural and urban areas of the state had similar proportions of all pregnancy-related deaths. If induced abortion was essential health care for these vulnerable populations as the plaintiffs' claim, this report would have highlighted this need. It does not. Rather, North Carolina's 2021 MMRC document focuses on essential health care solutions that make North Carolinian women who are pregnant safer, just as documents cited above from the CDC do. The

[10] https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.
[11] Peterson, E. et al. (2019). Racial/Ethnic Disparities in Pregnancy-Related Deaths- United States MMWR Morbidity and Mortality Weekly Report 68(35): 762-765.

state of North Carolina recognizes that women need health care solutions that focus on root causes of maternal mortality, from a system level to an individual level. They address maternal mortality without including induced abortion because induced abortion is not essential health care.

iv) Abortion Data in North Carolina

30. Unlike maternal mortality, there is no mandatory requirement to report numbers of abortion or complications of abortions nationally or in individual states. Reporting to the CDC at the state level is also voluntary. The North Carolina Department of Health and Human Services (NCDHHS) provides vital statistics for reported pregnancies. North Carolina's 2021 abortion statistics were published online by the NCDHHS in May 2023.[12] The report states that the total pregnancies represent the sum of all induced abortions, live births, and fetal deaths 20 or more weeks of gestation reported in the state. Spontaneous fetal deaths (still births) occurring prior to 20 weeks gestation are not reportable to the state. Unlike maternal mortality data in North Carolina in which death and birth certificates are linked, death certificates and induced abortion data are not linked and thus we have incomplete data related to induced abortion.

31. Data provided from this North Carolina report, as well as national reports, are underestimations of both numbers of abortions and complications from abortions.[13] In 2021, there were 32,454 abortions reported in North Carolina, an

[12] https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2021/.
[13] Studnicki, J. et al. (2017). Improving Maternal Mortality: Comprehensive Reporting for All Pregnancy Outcomes. Open Journal of Preventive Medicine; 7:162-181.

increase of 8.2 percent from 2020. Chemical abortions increased by 21 percent from 2020 and represented 66 percent of resident abortions. Non-Hispanic black women composed the largest group of North Carolina residents undergoing abortions, making up 49 percent of the total even though non-Hispanic black women make up just 24 percent of North Carolina's overall population of women of childbearing age. Twenty-seven percent of the abortions were on non-Hispanic white women. Based on reported induced abortions, there is a large difference between the abortion rates of non-Hispanic black and white women of childbearing age in North Carolina. The black abortion rate in North Carolina in 2021 was 27.3, four times higher than the white abortion rate of 6.3.

32. Reporting of the number of induced abortions and complications will be mandatory with this law and thus allow more accurate understanding of the number of women in North Carolina who have induced abortion, as well as the risks of those abortions. Until then, we must look outside the state to other sources of more accurate data collection.

33. When looking at countries where comprehensive and transparent data collection is performed, a much clearer picture of the impact of induced abortion is presented. According to a 2016 study conducted in Finland, after termination of pregnancy by induced abortion, the mortality rate for external causes was 8.1/100,000 after pregnancies ending with delivery, whereas after termination of pregnancy, the mortality was sixfold higher (49.5/100,000). Importantly, for all pregnancy outcomes, in all age groups under 40, mortality rates were highest after termination of

pregnancy.[14] A study of maternal mortality data from 32 states in Mexico by Koch, et al, revealed that laws that restrict abortion do not lead to an increase in maternal mortality - a claim that is made by plaintiffs. Koch's study showed that states with less permissive abortion legislation exhibited lower maternal mortality ratios (MMR) overall (38.3 vs 49.6), MMR with any abortive outcome (2.7 vs 3.7) and induced abortion.[15] Additionally, geographically diverse countries which prohibit abortion after previously allowing it have not seen their maternal mortality worsen, rather it has improved. This is compared to South Africa which has seen maternal mortality worsen after the legalization of abortion.[16]

34. There are two primary types of induced abortions: chemical abortions and surgical abortions. Chemical abortions typically consist of a two-drug regimen. Mifepristone is taken first, followed by misoprostol 24-48 hours later. Mifepristone leads to death of the embryo/fetus and misoprostol causes uterine contractions which leads to expelling the embryo/fetus. This regimen is approved by the FDA through 70 days or 10 weeks gestation. Surgical abortions involve the mechanical dilation of the cervix followed by vacuum aspiration or removal of the fetus by dismemberment, depending on the gestational age of the embryo/fetus.

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[14] Karalis, E., Ulander, V. M., Tapper, A. M., & Gissler, M. (2017). Decreasing mortality during pregnancy and for a year after while mortality after termination of pregnancy remains high: a population-based register study of pregnancy-associated deaths in Finland 2001–2012. BJOG:An International Journal of Obstetrics & Gynaecology, 124(7), 1115-1121.

[15] Koch E, Chireau M, Pliego F,et al. Abortion legislation, maternal healthcare, fertility, female literacy, sanitation, violence against women and maternal deaths: a natural experiment in 32 Mexican states. BMJ Open2015;5:e006013. doi:10.1136/bmjopen-2014-006013.

[16] Hogan MC, Foreman KJ, Naghavi M,et al. Maternal mortality for 181 countries, 1980–2008: a systematic analysis of progress towardsMillennium Development Goal 5. Lancet 2010; 375: 1609–23.

35. Induced abortion is associated with several documented short- and long-term risks. The 2022 Clinical Guidelines from the National Abortion Federation (a professional association of abortion providers) state that the minimum risks that must be addressed for all abortion procedures include hemorrhage, infection, uterine perforation, damage to organs including hysterectomy, continued pregnancy, and death.[17] Complications can occur with both chemical and surgical induced abortion, though rigorous registry-based studies show that chemical abortions have a 4x higher risk of complications compared to surgical abortions. [18] Risk of complications for both chemical and surgical abortions are proportional to gestational age. At 10 weeks gestation, the current upper limit approved by FDA for a chemical induced abortion, 1 in 10 women will require a surgery to complete their abortion. This increases to 1 in 2-3 women at 13 weeks gestation.[19] Because uterine perforation and damage to organs can occur in surgical abortions, this adds an additional layer of risk for women who have a complication from a chemical abortion and subsequently need a surgical abortion.

36. Long term complications include risk for pre-term birth (PTB) and mental health issues.

v) Pre-term birth

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[17] National Abortion Federation. 2022 Clinical Policy Guidelines for Abortion Care. https://prochoice.org/wp-content/uploads/2022-CPGs.pdf. Accessed 12/17/2022.

[18] Niinimäki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009 Oct;114(4):795-804. doi: 10.1097/AOG.0b013e3181b5ccf9. PMID: 19888037.

[19] Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011Feb 11. PMID: 21317416.28 https://www.accessdata.fd.

37. The Institute of Medicine (now the National Academy of Medicine) has listed induced abortion as an immutable risk factor for preterm birth (PTB).[20] A single induced abortion increases the risk. Hanes et al., determined that a single prior abortion increased the risk of a future very preterm birth by 64 percent.[21] More than one abortion has been show to increase the risk for preterm birth by 93 percent.[22]

38. This increased risk of preterm birth is especially impactful in the black population that has a 2x higher PTB rate and a 3-4x higher induced abortion rate.[23] Non-hispanic black race (compared with non-hispanic white race) is a consistent risk factor for preterm birth and adverse pregnancy outcomes in the United States. In a large systematic review of 30 studies, black women were found to have a 2-fold increased risk compared with whites.[24]

vi) Mental Health

39. In addition to the physical ramifications of induced abortion, there is also a relationship between induced abortions and mental health complications, including depression, suicide, substance use disorder, and suicide. Mota et al. in 2010 discovered that abortion was associated with an increased likelihood of several

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[20] Institute of Medicine. Preterm Birth: Causes, Consequences, and Prevention Committee on Understanding Premature Birth and Assuring Healthy Outcomes; Behrman RE, Butler AS, editors. Washington (DC): National Academies Press (US); 2007.

[21] Hanes M. Swingle, Tarah T. Colaizy, M. Bridget Zimmerman & Frank H. Morris, Jr. Abortion and the Risk of Subsequent Preterm Birth: A Systematic Review with Meta-analyses. J. REPRODUCTIVE MED. 95-108 (2009)14.

[22] Shah PS, Zao J; Knowledge Synthesis Group of Determinants of preterm/LBW births. Induced termination of pregnancy and low birth weight and preterm birth: a systematic review and meta-analysis. BJOG 2009;116(11):1425-1442.

[23] Behrman, R.E. & Butler, A.S. (Eds.). (2007). Preterm birth: causes, consequences, and prevention. National Academies Press.

[24] Schaaf JM, Liem SM, Mol BW, Abu-Hanna A, Ravelli AC. Ethnic and racial disparities in the risk of preterm birth: a systematic review and meta-analysis. Am J Perinatol. 2013 Jun; 30(6):433-50.

mental disorders, mood disorders, anxiety disorders, substance use disorders, as well as suicidal ideation and suicide attempts.[25] Fergusson et al. in 2008 found that women who had abortions had 30% increased rates of mental disorders, [26] Coleman used data from the National Longitudinal Study of Adolescent Health, and found that adolescents who aborted an unwanted pregnancy were more likely than adolescents who delivered to seek psychological counseling and they reported more frequent problems sleeping and more frequent marijuana use.[27]

40. A Finnish study on maternal mortality showed an alarming 7x higher suicide rate after abortion when compared to giving birth. The mortality rate for suicides was 3.3/100,000 in ongoing pregnancies and pregnancies ending in birth while it was 21.8/100,000 after termination of pregnancy and 10.2/100,000 among non-pregnant women, showing a protective effect from giving birth.[28]

41. It is rational for the State of North Carolina to regulate induced abortions for interventions with such potentially catastrophic risks.

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[25] Mota, N.P., Burnett, M., & Sareen, J. (2010). Associations between abortion, mental disorders, and suicidal behavior in a nationally representative sample. The Canadian Journal of Psychiatry, 55 (4), 239-247.

[26] Fergusson, D.M., Horwood, L. J., & Boden, J. M. (2008). Abortion and mental health disorders: evidence from a 30-year longitudinal study. The British Journal of Psychiatry, 193, 444-451.

[27] Coleman, P. K. (2006). Resolution of unwanted pregnancy during adolescence through abortion versus childbirth: Individual and family predictors and psychological consequences. The Journal of Youth and Adolescence, 35, 903-911.

[28] Karalis, E., Ulander, V. M., Tapper, A. M., & Gissler, M. (2017). Decreasing mortality during pregnancy and for a year after while mortality after termination of pregnancy remains high: a population-based register study of pregnancy-associated deaths in Finland 2001–2012. BJOG: An International Journal of Obstetrics & Gynaecology, 124(7), 1115-1121.

vii) Fetal Mortality

42. While we are unable to clearly delineate the number of women who have had induced abortions in North Carolina, who have had complications from these induced abortions, or who may have died because of these complications, we are able to clearly identify the fetal mortality associated with induced abortion.

43. The second patient that obstetricians and gynecologists care for is our fetal patient (including embryos {conception to 8 weeks gestation} and fetuses {after 8 weeks until birth}). The purpose of an induced abortion is to produce a dead embryo or fetus. The intention of the procedure is for it to "not result in a live birth" as stated in the CDC's definition. With certainty, all 32,454 induced abortions in North Carolina reported in 2021 resulted in 32,454 fetal deaths. This violent approach forced on our second patient is most certainly not safe or essential health care for that pre-born child.

44. Maternal-fetal medicine is a sub-specialty in the field of Obstetrics and Gynecology that requires additional training to learn how to treat medical complications related to pregnancy. This sub-specialty is not just called maternal medicine, rather it is maternal-fetal medicine because there are two separate human beings that need exceptional medical care. The direct and intentional killing of a human being, whether born or pre-born is never the purpose of health care. Induced abortion is not health care nor is it essential or safe for our fetal patients.

45. Our fetal patients are defined by science as living humans at their earliest stage of human development. Embryology is the branch of biology that

studies the prenatal development of embryos and fetuses, as well as congenital disorders or birth defects. When I was in medical school years ago, the textbook for our class was Keith Moore's, "The Developing Human." That same textbook, updated over the years, remains widely used. The first page of Chapter 1, 10th edition, states: "human development is a continuous process that begins when an oocyte (ovum) from a female is fertilized by a sperm (spermatozoon) from a male. Cell division, cell migration, programmed cell death (apoptosis), differentiation, growth, and cell rearrangement transform the fertilized oocyte, a highly specialized, totipotent cell, a zygote, into a multicellular human being. Most changes occur during the embryonic and fetal periods; however, important changes occur during later periods of development: neonatal period (first 4 weeks), infancy (first year), childhood (2 years to puberty), and adolescence (11 to 19 years). Development does not stop at birth; other change, in addition to growth, occur after birth (e.g., development of teeth and female breasts)."[29] On the same page, the text summarizes the development periods, dividing human development into prenatal (before birth) and postnatal (after birth) periods. The prenatal period has two main periods: embryonic (through the first eight weeks after conception) and fetal (after eight weeks until birth). The postnatal period is divided into infancy, childhood, puberty, and adulthood.

46. Given the scientific fact that human development begins at conception, it is no surprise that so few obstetrician/gynecologists perform induced abortions. Desai et al surveyed obstetricians in private practice and found that only 7%

[29] Moore, K. (2016). The Developing Human: Clinically Orientated Embryology. Saunders.

performed an induced abortion in 2013-2014.[30] Grossman et al conducted a cross-sectional survey of a national sample of ACOG Fellows and Junior Fellows, and found that in 2016-2017, 72% reported having a patient in the prior year who needed or wanted an induced abortion, with only 23.8% reporting having provided an induced abortion. The most common reasons for not providing abortions included personal, religious, or moral beliefs against abortion (34%), practice setting restrictions against abortion provision (19%), office staff attitudes (16%), no perceived need (10%), and their patients had access to another provider or they referred out (8%).[31]

47. Obstetrician/gynecologists in North Carolina can provide safe and essential health care for both our maternal and fetal patients without providing induced abortion. Induced abortion is never safe for our fetal patients and complication rates associated with induced abortion are not fully known given the reporting structure that was in place prior to this law. The plaintiffs' claims that abortion is common, safe, and essential health care is false.

B. Increasing Safety for North Carolina Pregnant Women

48. The lack of safety of induced abortion for our fetal patients has been established. Induced abortions ends the life of all our fetal patients and is never safe. The safety of maternal patients who have induced abortions in North Carolina is unknown given the current reporting structures. What is known, however, is that

[30] Desai S, Jones RK, Castle K. Estimating abortion provision and abortion referrals among United States obstetrician-gynecologists in private practice. Contraception. 2018 Apr;97(4):297-302. doi: 10.1016/j.contraception.2017.11.004. Epub 2017 Nov 21. PMID: 29174883; PMCID.

[31] Grossman, D., Grindlay, K, Altshuler, A., & Schulkin, J et al(2019).Induced Abortion Provision Among a Sample of Obstetricians-Gynecologists. Obstetrics and Gynecology. 133(3):477-483.

North Carolina prioritizes safety for all North Carolina women who are pregnant and thus this law has two very important provisions that address maternal safety: 1) the requirement of induced abortions after 12 weeks gestation to occur in a hospital and 2) the requirement that an intrauterine pregnancy be documented prior to a chemical abortion.

i) Hospitalization Requirement

49. This law limits induced abortion after 12 weeks gestation except in complex cases. These complex cases include the exceptions for medical emergencies in which induced abortions can occur throughout the entirety of pregnancy, life limiting anomalies in which induced abortions can occur through 24 weeks, and rape/incest in which induced abortions can occur through 20 weeks.

50. Complex cases require complex care. Obstetricians and gynecologists complete four years of general ob/gyn training (residency) after medical school. There is an option to complete a fellowship in a variety of specialty areas, including complex family planning. This fellowship is an ACGME-accredited, two-year fellowship for obstetrics and gynecology (Ob-Gyn) residency graduates focused on subspecialist training in research, teaching, and clinical practice in complex abortion and contraception.[32]

51. It is rational for the state of North Carolina to want to protect pregnant women who are experiencing complex issues in their pregnancy to have care in a hospital instead of an outpatient setting. All the exceptions for the North Carolina

[32] https://societyfp.org/fellowship/.

law in which induced abortions after 12 weeks are available are complex and it is my opinion that they should take place in a hospital setting given the risks already discussed associated with induced abortions. Hospitals can handle major problems, including life-threatening hemorrhage, uterine perforation, damage to organs, and death that may occur during a surgical abortion or immediately afterwards. Hospitals have more resources to manage these complications, including blood banks for transfusions during emergencies, nurse anesthetists/anesthesiologists who can provide immediate intubation, code carts and code teams, as well as intensive care units. Performing induced abortions in hospitals after 12 weeks also prevents the need for transfer from an outpatient clinic to the nearest hospital facility should complications arise during the surgery, reducing the time for women to receive life-saving interventions.

52. Women in North Carolina in each of the exception categories have unique situations for which a hospital is best able to address. Women who are pregnant with a medical emergency clearly need to be in a hospital setting for the best chance for survival. Women in North Carolina who are victims of rape or incest have had horrific violence against them. Hospitals and emergency departments receive training to care for these women and ensure the forensic chain of evidence is followed.[33] Women in North Carolina who are pregnant with a fetus with a life-limiting condition are often in devastating situations in which both intense medical

[33] https://www.acep.org/patient-care/policy-statements/management-of-the-patient-with-the-complaint-of-sexual-assault.

and psychological support is essential. They may also need genetic testing, autopsy, and/or funeral arrangements which are available in a hospital setting.

ii) Documentation of Intrauterine Pregnancy Requirement

53. The plaintiffs' witnesses argue that documentation of an intrauterine pregnancy is not medically necessary prior to a chemical abortion. The use of chemical abortion not only jeopardizes the life of every preborn human being exposed to it but also represents one of the greatest threats to the health of women related to abortion. Chemical abortions have a 4x higher risk of complications than do surgical abortions in women who have been examined by a physician and the drugs are given through nine weeks gestation.[34]

54. The drugs used to induce an abortion are indicated for the first 10 weeks of pregnancy (current upper limit approved by FDA, though Dr. Farris states they knowingly use it through 11 weeks). After that, the risk of hemorrhaging increases and a surgical abortion is recommended. At 10 weeks gestation, 1 in 10 women will require a surgery to complete their abortion. At 13 weeks gestion, this complication increases to 1 in 2-3 women.[35] This a significant issue for many North Carolinian women that do not have immediate access to a hospital with 24/7 emergency surgical services available.

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[34] Niinimäki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, Heikinheimo O. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009 Oct;114(4):795-804. doi: 10.1097/AOG.0b013e3181b5ccf9. PMID: 19888037.

[35] Mentula MJ, Niinimäki M, Suhonen S, Hemminki E, Gissler M, Heikinheimo O. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. Hum Reprod. 2011 Apr;26(4):927-32. doi: 10.1093/humrep/der016. Epub 2011Feb 11. PMID: 21317416.

55. The American College of Obstetricians and Gynecologists' Committee Opinion 700 was developed in coordination with the American Institute for Ultrasound in Medicine and Society for Maternal Fetal Medicine and states a proper estimated date of delivery (EDD) is paramount during pregnancy to improve outcomes and is a research and public health imperative. This Committee Opinion states that approximately one half of women accurately recall their last menstrual period (LMP) and thus ultrasound proves valuable to determine the actual estimated date of delivery (EDD).[36] Typically, between 5-6 weeks pregnancy a crown-rump length of the embryo can be performed by ultrasound to determine the gestational age and EDD.

56. Chemical abortion is not approved by the FDA after 10 weeks gestation or 70 days. It is essential that an accurate gestational age is documented by ultrasound prior to making decisions about the viability of a pregnancy.[37]

57. Without ultrasound to document an IUP, gestational age cannot be confirmed and women cannot possibly be adequately counseled on their risks if their gestational age is unknown. An abortion is a medical procedure, and an informed consent is required by law for all medical procedures.

58. An ultrasound is required to adequately rule out an ectopic pregnancy, one of the main contraindications to medication abortion. An ectopic pregnancy is defined as a pregnancy that occurs outside the uterine cavity. The most common site

[36] ACOG Committee Opinion 700. (2017). Methods of Estimating the Due Date: ACOG.

[37] ACOG Practice Bulletin 200. (2018). Early Pregnancy Loss: ACOG.

is the fallopian tube, which is why ectopic pregnancies are often called tubal pregnancies. Practice Bulletin 191 from the American College of Obstetricians and Gynecologists (ACOG), *Tubal Ectopic Pregnancy,* states that ectopic pregnancy accounts for approximately 2% of all pregnancies or 1 in 50 pregnancies.[38] An ectopic pregnancy cannot grow normally and most of these embryos die spontaneously. An ectopic pregnancy can be a life-threatening situation for the woman if the fallopian tube ruptures, causing internal bleeding.

59. The management of ectopic pregnancy remains the same pre and post *Roe*. An abortion is never used to treat an ectopic pregnancy. Treatment involves surgery or medication to terminate the pregnancy. These interventions are designed to save the pregnant woman's life but may have the unintended consequence of ending the embryo or fetus' life.

60. ACOG states in this same Practice Bulletin that "an untreated ectopic pregnancy is life-threatening; withholding or delaying treatment can lead to death." This death comes from internal bleeding, typically if the fallopian tube ruptures, and according to the CDC accounts for 2.7% of maternal deaths or deaths during pregnancy.[39] Determination of pregnancy location, intrauterine (in the uterus) versus ectopic (outside the uterus) requires an ultrasound as ACOG states in this same bulletin – "the minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."[40]

[38] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.
[39] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.
[40] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.

61. Since the medications used to induce an abortion do not treat ectopic pregnancy, women who desire an induced abortion and receive abortion medications (mifepristone and misoprostol) without an ultrasound may result in delayed detection and treatment of an ectopic pregnancy, increasing the risk of greater internal bleeding and risk for death. The pregnant woman with an ectopic pregnancy may actually confuse the pain and bleeding of a ruptured ectopic pregnancy with the severe pain and bleeding experienced by chemical abortion drugs and thus delay potentially life-saving treatment leading to the catastrophic loss of women's lives in North Carolina.

62. This law requires that a physician document in the women's medical chart the existence of an intrauterine pregnancy prior to a chemical abortion. This is essential for the safety of the women of North Carolina. The plaintiff's witnesses discuss a protocol they use in their clinic in which they measure HCG levels at the same time of giving mifepristone. This approach is not standard of care and is dangerous. They falsely claim that HCG levels alone can be used to diagnose an ectopic. HCG levels must be interpreted in light of ultrasound findings and using HCG alone is not predictive of an ectopic pregnancy. ACOG's Practice Bulletin 191 states that an ectopic pregnancy is diagnosed with ultrasound.[41]

68. The state of North Carolina values each woman's life and it is rational then for the state to require a documented IUP prior to an induced abortion to determine gestational age to determine if a chemical abortion or surgical abortion is

[41] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.

provided and to rule out an ectopic pregnancy. This opinion is consistent both my profession opinion and with our states 2021 MMRC report that has as a goal to "make sure no woman dies as a result of pregnancy."[42]

I declare under penalty of perjury that the foregoing is true and correct. Executed on August 6, 2023.

Susan Bane, M.D., Ph.D.

Susan Bane, M.D., Ph.D.

[42] https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.

Exhibit A

Susan Maxwell Bane, MD, PhD
drpinkglasses@gmail.com
4831 Wimbledon Court, Wilson, NC 27896
252-717-1891/252-399-6514

SKILLS SUMMARY

- **Physician.** Engaged listener with the ability to empathize with others, solve complex problems, and collaborate with other professionals in an environment that has multiple, simultaneous demands.
- **Teacher.** Award-winning teacher who understands and values the importance of incorporating liberal arts education within professional studies; adapts curriculum to optimize learning while meeting the needs of students.
- **Community leader.** Volunteer who identifies and meets the needs of the community through advocacy, education, and service on boards and organizations.
- **Effective communicator.** Experienced presenter and published author.
- **Administrator.** Analytical manager who identifies and solves problems by leading a team to collaborate and create solutions.
- **Consultant.** Professional development coaching for individuals, teams, and organizations, teaching the value of character strengths and emotional intelligence to create stronger teams. Innovator with success in recognizing strengths and challenges, listening to stakeholders, and leading organizations and groups forward .

EDUCATION AND TRAINING

Medical Training
Resident, Department of Obstetrics and Gynecology, East Carolina University School of Medicine, 1997- 2001
Doctor of Medicine, University of Illinois, 1997
Licensed to practice medicine in North Carolina
Graduate School
Doctor of Philosophy, Kinesiology, University of Illinois, 1995
Master of Science, Kinesiology, University of Illinois, 1989
Undergraduate School
Bachelor of Science, Chemistry, Atlantic Christian College/Barton College, 1987

PROFESSIONAL EXPERIENCE

Eastern North Carolina Pregnancy Centers

Pregnancy Centers with medical clinics within them provide exceptional medical care to women with unplanned pregnancies. They educate, support, and empower women facing unplanned pregnancies with compassionate and professional medical care.

Medical Director, Choices Women's Center 2013-present
Medical Director, Albemarle Pregnancy Resource Center and Clinic, 2023 – present
Medical Director, WaterLife Pregnancy Center, 2023-present

Administration

- Provides strategic direction and vision for Clinical operations.
- Works with the Board of Directors and Executive Director in setting clinic policy and ensuring full compliance in issues of ethics, legality, and compliance with all federal, state, and regulatory agencies including required reporting.

Clinical

- Serves as the Chief Medical Officer overseeing medical procedures within the clinic, including direct patient care.
- Keeps the Board of Directors and Executive Director informed of medical activities and development and prepares/submits recommendations for review and adoption.

Barton College, Wilson, NC

Barton College is a four-year, private liberal arts institution in eastern NC that believes in college on a first-name basis. Barton blends liberal arts and professional programs for 1100 traditional and adult students, has 18 Division II athletic teams, and shares a great relationship with the Wilson community.

Director, Barton College-Area L AHEC Partnership, 2021-2023
Associate Professor of Allied Health and Sport Science, 2010-2023
Director, Area L AHEC Scholars Program, 2017-2021
Dean, Graduate and Professional Studies, 2017-2019
Coordinator Health Promotions Major, 2013-2021
Women's Health Physician, 2010-2023
Director of the Honors Program, 2011-2017

TEACHING AND REASSIGNED TIME

Professor

- Teach a variety of interdisciplinary classes each semester including *Anatomy and Physiology, Anatomy and Physiology Lab, Autism: Brain Disorder or Disorder That Affects the Brain, Exercise Physiology, Exercise Prescription, Psychological and Social Aspects of Sport, Health and Wellness, Sport and Character Development,* and honors courses: *Nature of Inquiry* and *Mental Illness and the Movies*
- Helped develop professionalism curriculum for Department of Physical Education and Sports Studies, 2011-2012
- Supervisor for multiple students for Independent and Directed Study

Physician

- Women's Health Physician, Lee Student Health Center
- Medical Director, Choices Women's Center
- Leader in campus wellness initiatives for students, faculty, and staff

Director of Barton College-Area L AHEC Partnership

- Provide strategic planning for college, high school, and middle school health careers workforce development
- Oversee the AHEC Scholars Program by recruiting, teaching, and mentoring students for a Health Resources and Services Administration (HRSA) 5-year grant designed to provide students in health-related majors exposure to didactic and clinical opportunities
- Collaborate with faculty to develop and improve curriculum
- Network with local health care providers to connect students for clinical rotations

SCHOLARSHIP

Peer Reviewed Publications

Bane, S. (2015). Postpartum Exercise and Lactation. *Clinical Obstetrics and Gynecology*, 58(4), 885-892

Craven, K., Bane, S., & Kolasa, K. (2013). The Dance: Minimizing Weight Gain with Improved Blood Glucose Control. *Nutrition Today, 48,* 19-25

Peer Reviewed Presentations

Bane, S. *The Science of Decision Making: Implications for Pregnancy Centers,* Care Net National Conference, August 2022.

Bane, S., Christiansen, S., Thomas, A., & O'Connor, A. *Four Women and A Baby: A Medical-Legal Conversation about the Dobbs Opinion. Care Net National Conference,* August 2022.

Bane, S. & Venturella, G. *Covid and Clinicals: An Innovative Virtual Clinical Experience for NC AHEC Scholars,* National Area Health Center Education Organization, July 2021.

Bane, S. & Mihalko, S. *Functional Medicine: Training Physicians to Accomplish the SBM Mission,* Society of Behavioral Medicine National Meeting, April 2015

Stuart, L., Coen, J., Trump, C., & Bane, S. *Learning Behavior.* Workshop presented at the North Carolina Exceptional Children's Symposium, Pinehurst, NC, 2013.

Stuart, L., Trump, C., & Bane, S. *The impact of Verbal Behavior Implemented in the Classroom on the Families of Individuals with Autism,* North Carolina Autism Society, October 2013

Non-Peer Reviewed Publications

AHEC Scholars, Clinical Virtual Modules, 2021

Monthly Opinion Column, Wilson Daily Times, 2021-present

Bane, S. Youth Mission Trip Inspires Adult, *NC Catholic,* 2013, pp. 6-7

Non-Peer Reviewed Presentations

Bane. A Witness for our Patients: Our Response Post-Roe/Dobbs. SFL Health Professions Workshop, July 29. 2023.

Bane, S. *Women Deserve Exceptional Medical Care: Reviewing Key Components for our PRC Medical Clinics*. Lifelink State Medical Conference, Mar 4, 2023

Bane, S. and Renfrow, L. *Diversity and Inclusion in the Workplace: Strategies to Create a Thriving, Inclusive Culture at Area L AHEC,* 4-part lecture series, Spring 2021

Bane, S. & Greene, J. *Resiliency in the Workplace*, 4-part lecture series, Fall 2021.

Bane, S. *Does Compassion Matter: An Examination and Application of the Scientific Evidence,* Eastern AHEC Pharmacy Symposium, September 2020

Bane, S. *Character Strengths Matter:* Eastern AHEC Scholars Program, Greenville, NC: September 2019
Bane, S. *Emotional Intelligence Workshop*: Americorp Vistas, June 2019.
Bane, S. *Chronic Disease in the 21st Century: Using Functional Medicine to Create a Culture of Health*: Area L AHEC Pharmacy Continuing Education Presentation, 2018
Bane, S. *Parent Advocacy,* University of Georgia guest lecturer SPED 2000: Survey into Special Education, September 2016
Bane, S. *Healthy Selfishness*, Life Matters Retreat, April 2016
Bane, S. *Why Do You March?* St. Peters Catholic Church Life Teen, January 2016
Bane, S. *Welcome to Holland.* Farmville Middle School 4th Annual Exception Children's Awards Day, May 2015
Bane, S. *When Your Best Isn't Good Enough: Coping with Breastfeeding Failure,* Breastfeeding Symposium, Eastern Area AHEC Breastfeeding Symposium, August 2015
Bane, S. *Improving Sportsmanship,* CIC Athletic Conference Facilitator, August 2015
Bane, S. *Gratitude*. First Christian Church, Wilson, NC, November 2015
Bane, S. *Fear, Faith, and Freedom*, Life Matters Table Talk, February 2015
Bane, S. *Labor and Delivery: True Stories-Lessons Learned,* Breastfeeding Symposium, Eastern Area AHEC Breastfeeding Symposium, August 2014
Bane, S. EAHEC Department of Nursing Education Breastfeeding Symposium. *Minimizing Stress: Maximizing Success,* August 9, 2013
Craven, K., Bane, S., & Kolosa, K. *The Dance: Minimizing Weight Gain with Improved Blood Glucose Control.* Brody School of Medicine at East Carolina University Women's Health Conference, February 2012

Keynote Presentations
Bane, S. *Purpose, Passion, and Perinatology: Strategies to Move from Fatigue to Fulfillment.* Mountain AHEC Perinatal Substance Use Disorder Conference, November 2022.
Bane, S. *The Science of Decision Making: Implications for Pregnancy Centers*, Care Net National Conference, August 2022.
Bane, S. *Does Compassion Matter: An Examination and Application of the Scientific Evidence,* Eastern AHEC Continuing Education, September 2020
Walking the Tightrope: Breastfeeding and the Professional Woman, Eastern Area AHEC Breastfeeding Symposium, August 2014.
The Medical Side of Autism: Simple and Effective Ways You Can Help Your Child, Wilson County Schools, 2013.

Peer Review Editing
Peer Reviewer, Obstetrics & Gynecology, 2023-present.
Associate Editor, *Therapeutic Recreation Journal,* Spring 2014-2017.
Peer Reviewer, *Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs, 5th ed.* by the American Association of Cardiovascular and Pulmonary Rehabilitation, 2013.
Peer Reviewer for Society of Behavioral Medicine Conference, 2017-2021

Grants
NCDHHS grant through Area L AHEC, Trauma-informed campus community, 2022-2023.
Interfaith Youth Corp, 2022-2023, $4000 to develop lectures on medicine and spirituality.

HRSA NC AHEC Grant, 2020-2021, $90,000 to develop Clinical Virtual Modules for AHEC Scholars across the State of North Carolina.
Healthcare Foundation of Wilson Grant: Wilson Fit: Using a Functional Medicine Approach to Prevent and Reduce Obesity - $426,000.
Healthcare Foundation of Wilson 2017-2018, $185,000
Faculty Development Grant, Spring 2017, $2500
Faculty Development Grant, Fall 2014, $1530
Faculty Development Grant, Summer 2014, $1530
Faculty Development Grant, Spring 2014, $3060
Faculty Development Grant, Fall 2013, $1530

Awards
BartonFIT/Barton College: Winner of the National Healthy Campus Week Physical Fitness Challenge: Healthier Campus Initiative, Fall 2019
Senior Leadership Academy Participant, 2015-2016
Faculty Club Advisor of the Year, 2016
Bulldog Club Award, 2014
Jefferson Pilot Faculty Member of the Year, 2012-2013

Professional Organizations
North Carolina Medical Society, 2023-present
American Association of Prolife Obstetricians and Gynecologists, 2020-present
American College of Obstetricians and Gynecologists, 1997 - 2021
Institute for Functional Medicine, 2013-2021

Board Membership
National Medical Advisory Board, Care Net, 2021-present
National Board, American Association of Prolife Obstetricians and Gynecologists, 2022-present

Certifications
Theology, Medicine, and Culture Certification, Duke Divinity School, 2022
Nationally Board-Certified Health and Wellness Coach, 2017
Institute for Functional Medicine Certified Practitioner, 2015
Emotional Intelligence Coach, 2016

SERVICE

Professional Development, 2017-present
- **Emotional Intelligence Training**
  - Students/Student Athletes
  - Athletic Coaches
- **Character Strengths Training**
  - Students/Student Athletes
  - Athletic Coaches
  - Senior Administration

Day of Scholarship Team Leader, 2013-2018
- Recruited faculty and students to serve on team
- Led planning and event management for the symposium
- Helped restructure the application process for participants
- Organized Scholars Symposium Archival Research presentation for Retired Faculty Society

Barton FIT, 2016-2021
- Successfully wrote and received a grant to expand employee wellness programming
- Implemented a functional medicine intervention for employees who were overweight or obese
- Brought a weekly farmers market to campus
- Organized monthly lunch and learn sessions
- Enhanced the human performance lab with equipment for fitness testing
- Provided opportunities for allied health majors to participate in "hands-on trainaing"
- Striving to make Barton a culture of health and one in which the health and well-being of employees is valued

Guest Speaker Representing Barton
Wilson Rotary Club, Spring 2023
Wilson Noon Kiwanis Club, June 2018
Greenville Rotary Club, January 2018
Wilson Optimist Club, Summer 2017
Honors Program presentation to Board of Trustees, Spring and Fall 2013
Barton College Scholarship Luncheon, April 2013

Keynote Speaker
Alpha Chi Induction, March 2016
Women in Sports Day, February 2014
Administrative Assistant Luncheon, April 2012
Alpha Chi Honor Society Induction, March 2012

Guest Speaker at Barton
Bane, S. *Roe V Wade Overturned: How Does the Dobbs Supreme Court Decision Impact You?* Barton College Intellectual Bluepirnt Event, April 2023.
Bane, S. *Does Compassion Matter: An Examination and Application of the Scientific Evidence,* Junior Nursing Class, November, 2020.
Character Strengths Matter: Barton College Senior Leadership Team, Monthly, 2019-2020
A Baseball, A Breath, and A Life: Brandon Warren's Story, August 2019
Gratitude, Student Affairs, November 2017
What Kind of Life is Truly Worth Living, Vocations Avila Retreat, February, 2017
The Legacy of the Barton Women's Tennis Team, Women's Tennis Team, April 2017
Healthy Choices, FYS Class, February, 2016
Research through the Barton Archives, Rare Book Symposium, Barton College, October 2015
Abortion, FYS Class, October 2015
Faculty Forum: presented details of the new Health Promotions Major, February 2014

Panelist, discussed cervical cancer in the context of the book, *The Immortal Life of Henrietta Lacks,* 2012
First Year Seminar workshop, discussed Health Promotions Major, Summer 2014
Important Health Issues I Know Now, But Wish I Had Known As a College Student, Residence Hall Association, March 2014
Panelist for an STD educational program for students on campus, March 2014
My Story, FYS class, November 2013
Shine on, Teach On: *Stress Management for Student Teachers*, September 2012
Healthy Choices, FYS, two classes, Fall 2011
What Do You Believe and Why? Fellowship of Christian Athletes, October 2012
Introduction to Exceptional Children's class*,* April 2012

Sport Psychology, Professional Development Consultant, Barton Athletic Department
Men's Volleyball, Spring 2022
Women's Softball, Fall 2013
Women's Soccer Team, Spring 2013
Men's Golf Team, Fall 2012
Men's and Women's Tennis Teams, Fall 2012

Barton Service Positions
Faculty Athletic Mentor, Women's Lacrosse, 2022-2023
Faculty Athletic Mentor, Men's Volleyball, Spring 2022
Faculty Representative to the Board of Trustees 2016-2018
Moderator, Faculty Forum, 2014-2018
Advisor, Barton Autism Society
Advisor, Barton Catholic Campus Student Ministry
CARE team member
Strategic Planning Committee 2015-2016, 2019-2020
- Chair of Subcommittee on developing motivation and resilience in students
- Strategy Champion (Emotional Intelligence)
    - Helped organize training for 10 employees to become certified in administering and debriefing the EQ-i2
    - Collaborated with FYS team to incorporate emotional intelligence into FYS course

Wilson Community Service Projects
- Help organize annual Autism Awareness Day
    - Open house for middle and high school students with autism, 2012-present
    - Light It Blue Party for Wilson County Schools students with special needs 2013
- Coordinated presentation of Personal Fitness Badges, Boy Scouts of America, 2013-present
- Coordinated and planned "Dig Pink" event with Barton College Women's volleyball team and the Pink Ladies of Wilson Medical Hospital Foundation

Community Service Positions
Medical Director, Wilson Pregnancy Center, 2014-present
Committee Member, Pre-born to End-of-Life Advisory Committee, Diocese of Raleigh, 2013-2020

Community Service Presentations

Preparing for a Post-Roe Albemarle Pregnancy Center: Albemarle Pregnancy Center, June 2022
Preparing for a Post-Roe Wilson: St. Therese Catholic Church, May 2022
Preparing for a Post-Roe Wilson: Choice's Women's Center, March 2022
Fetal Development: Wilson Pregnancy Center, October 2019, October 2020
Character Strengths Matter: Department of Social Services, December 2019.
Character Strengths Matter: GIG360, December 2019
Why March? St. Therese Confirmation Class, January 2018
Mind, Body, Medicine: Wilson YMCA, January 2018
Labor and Delivery: True Stories, Lessons Learned. Eastern North Carolina Women in Business Conference, Greenville, NC, March 2014.
The Beginning of Life: True Stories: Lessons Learned, The Diocese of Raleigh Catholic Convention, October 2013.
Mental Muscle, Community Christian School Girls' Soccer Team, May 2013.
Smart, Educated, and Love Jesus? St. Peters Catholic Church Life Teen, January 2013.
Shine On: Keeping Your Light and Life Bright. Wilson Community Church MOPS, Wilson, NC, January 2013.
It Is the Most Wonderful Time of the Year. St. James United Methodist Church Women's Conference, Greenville, NC, 2012, 2013.
Labor and Delivery: The Value of Life. St. Peters Catholic Church, October 2012.
Keeping Your Light Shining. First Baptist Church Women's Conference, Farmville, NC, October 2012.
Staying Healthy in the Midst of the Rat Race. Second Annual Eastern North Carolina Women in Business Conference, March 2011.

Committees

Wilson Forward Wellness Collaboration, 2018-present
Health Care Advancement Collaborative, Eastern North Carolina, 2022-present
Faculty Representative to the Board of Trustees 2016-2017
Campus Welfare Committee 2016-2020
Faculty Representative to the Barton Alumni Board 2015-2016
Institutional Review Board, 2014-2015
Research Task Force, 2013-2015
Honors Council, 2013-2018
Compliance Campus Regulatory Compliance Task Force, 2011-2014
Academic Quality, 2011-2013
Pool Working Group, 2012

Physicians East, PA, Greenville, NC

Multi-specialty medical practice consisting of a team of healthcare professionals committed to helping individuals improve and maintain their health by providing compassionate, state-of-the-art care.

Partner and Shareholder, 2004-2010
Obstetrician/Gynecologist, 2001-2010
Clinical Professor, 2001-2010

Adjunct Professor, 2001-2010

ADMINISTRATIVE

Partner and Shareholder
Greenville Obstetrics and Gynecology, A Division of Physician's East, August 2004-May 2010

- Managed $5 million practice with 50 employees and 2500 patients
- Directed and coordinated activities of nurses, assistants, therapists, ultrasonographers, and business and other medical staff
- Oversaw resource allocation of budget with partners
- Marketed practice through branding and strategic advertising and community relations
- Supervised four midwives in the practice, including managing personnel concerns
- Played an active role in human resources, particularly hiring new employees and physicians
- Led positive workplace culture initiatives, such as wellness programming, incentives, and staff social activities
- Developed FitEast, a Comprehensive Wellness Program for 400 employees of Physicians East, PA, 2005

Legal Consultant
For medical malpractice and legal claims, 2006-present
For Catholic Diocese of Raleigh on legal documentation for end of life issues, 2013-present

CLINICAL

Obstetrician/Gynecologist
Greenville Obstetrics and Gynecology, A Division of Physician's East, August 2001-May 2010

- Collected, recorded, and maintained patient information, such as medical histories, reports, and examination results
- Prescribed or administered therapy, medication, and other specialized medical care to treat or prevent illness, disease, or injury
- Cared for and treated women during prenatal, intrapartum, and postnatal periods
- Performed surgical procedures
- Analyzed records, reports, test results, or examination information to diagnose medical condition of patient
- Explained procedures and discussed test results or prescribed treatments with patients
- Monitored patients' conditions and progress and reevaluated treatments as necessary
- Referred patients to medical specialist or other practitioner when necessary
- Consulted with or provided consulting services to other physicians
- Provided opportunities for numerous high school and pre-med students to shadow

Clinical Professor
Department of Obstetrics and Gynecology, East Carolina University, August 2001-May 2010

Taught the following:
- Third- and fourth-year ECU medical school students in office and hospital setting

- First- and second-year UNC-Chapel Hill medical school students in the office and hospital setting
- *Residency 101,* elective course for fourth-year medical students to better prepare them for residency, 2003-2006

Co-Coordinator, Resident Journal Club, Department of OB/GYN, 2004-2010

Adjunct Professor
Department of Exercise and Sports Science, East Carolina University, August 1999-August 2011

- Guest lecturer in ECU Department of Exercise and Sports Science
- Consulted with department on student master's thesis research

Author
Women's Health Column, HER Magazine, 2007-2012

Professional Awards
Attending of the Year, Clinical Faculty, Presented by the Obstetrics and Gynecology Residents for Outstanding Teaching, 2003, 2005, 2006, 2007
Outstanding Community Physician Award, presented by Brody School of Medicine Class for Outstanding Teaching 2006, 2007, 2008, 2009

Professional Organizations
Society of Behavioral Medicine
American College of Sports Medicine
North Carolina Society of Obstetrics and Gynecology
Institutional Function
American Congress of Obstetrics and Gynecology

PRESENTATIONS

Non-Peer Reviewed Presentations
Heal Thyself: Finding Life Balance. Regional Perinatal Symposium, 2010.
Exercise and Pregnancy. Brody School of Medicine Pediatric Conference, 2008.
Sexual Dysfunction: She Loves Me, She Loves Me Not. Brody School of Medicine Family Practice Women's Health Conference, 2007.
Fit for Life. Brody School of Medicine Family Practice Women's Health Conference, 2007.
The Risk and Management of a Few Extra Pounds. Women's Health Conference, Family Practice Department, East Carolina University School of Medicine, February 2003.
The Risk and Management of a Few Extra Pounds. Seaboard Medical Society, June 2003.

SERVICE

Community Service Positions
Chairman of the Board, TRAC Educational Services, Winterville, NC, 2007-2010

Alumna of Barton College

Keynote Speaker, Barton Fall Convocation, 2009

Community Service Positions
Volunteer Softball Coach, Pitt County Girls' Softball League, 2006
- Coached softball team for girls ages 5-12
- Identified need for sportsmanship program and created The Sportsmanship Zone
- Developed comprehensive training program and presented strategic plan to board of directors for approval
- Raised $28,000 to fund program
- Created and executed branding campaign to increase public awareness of the program and educate the community about sportsmanship
- Trained coaches, parents, and players

Volunteer Softball Coach
- St. Peter's Catholic School, 2008
- Farmville Central High School, Junior Varsity team, Farmville, NC, 2011

Team Leader, St. Peter's Catholic Church Mission Trip, 2011, 2012, 2014

Service Awards
Barton College Alumni Achievement Award, 2010
Pitt County Girls Softball League Recognition Award, 2010

Community Service Presentations
- Coordinator/Lecturer: *It Is Good to Be a Woman* community seminar sponsored by Greenville OB/GYN, 2006.
- Coordinator/Lecturer: *Wednesday Women's Wellness* community series sponsored by Greenville OB/GYN, 2001-2004.

Barton College Community Service
Academic Quality Committee, Barton College, Wilson, NC, 2010
Board of Advisors, Barton College, Wilson, NC, 2009-2010

Committees
Block Committee, SurgiCenter, Greenville, NC, 2005-2010
Board of Directors, Fellowship of Christian Athletes, Greenville, NC, 2002-2006
Labor and Delivery Advisory Board, Vidant Medical Center, Greenville, NC, 2003
Post-Partum Depression Committee, Vidant Medical Center, Greenville, NC, 2002

Department of Obstetrics and Gynecology, East Carolina University School of Medicine

ECU School of Medicine, located in Greenville, NC, serves the rural population of Eastern NC. The four-year residency program includes additional training in medicine and surgery, research, and teaching.

OB/GYN Resident, 1997- 2001
Performed the duties of a licensed OB/GYN under the supervision of attending physician

SCHOLARSHIP

Peer Reviewed Publications

Bane, S.M. and McAuley, E. (1998) Body Image and Physical Activities. Measurement Issues. In J. Duda (Ed.), *Advances in Sport and Exercise Psychology Measurement* (p. 311-324). Fitness Information Technology: Morgantown, WV.

Katea, J.A., McAuley, E., Mihalko, S.L., and Bane, S.M. (1998) Mirror, Mirror on the Wall: Exercise Environmental Influences on Self Efficacy. *Journal of Social Behavior and Personality,* 13,219-232.

McAuley, E., Mihalko, S.L., and Bane, S.M. (1997). Exercise and Self-Esteem in Middle Aged Adults: Multidimensional Relationships and Physical Fitness and Self-Efficacy Influences. *Journal of Behavior Medicine,* 20, 67-83.

Martin, K.A., Rejeski, W.J., Leary, M.R., McAuley, and Bane, S.M. (1997). Is the Social Physique Anxiety Scale Really Multidimensional: Conceptual and Statistical Argument for a Unidimensional Model? *Journal of Sport and Exercise Psychology,* 19, 359-369.

Peer Reviewed Presentations

Bane, S.M. *Fever of Unknown Origin: Stump the Professor.* American College of Obstetrics and Gynecology, District IV Meeting, October 2000.

Bane, S.M. *Writing an Exercise Prescription.* Seaboard Medical Association Meeting, June 1999.

Bane, S.M. and McAuley, E. *Comparison of Body Image in Caucasian and African American Females: Implications for Practice.* American College of Obstetrics and Gynecology, District IV Meeting, October 1999.

Bane, S.M., McAuley, E., & Shackelford, P. *Exercise, Weight and Body Image in College Females: Putting Theory into Clinical Practice.* Paper presented at the American College of Obstetrics and Gynecology, District IV Meeting, October 1998.

Awards

Outstanding Teaching Resident, East Carolina University, Presented by the Graduating Medical School Class of 2001

Second Year Resident of the Year, Presented by the 1999 Intern Class in Obstetrics and Gynecology Residency

Outstanding Junior Fellow Presentation, ACOG District IV Meeting, 2nd place, October 1999

Outstanding Junior Fellow Presentation, ACOG District IV Meeting, 2nd place, October 1999

Athletic Hall of Fame, Barton College, 1998

SERVICE

Community Service Presentations

Exercise and Pregnancy. East Carolina Physical Therapy Graduation Seminar, May 2001.

Writing an Exercise Prescription. North Carolina Ob/Gyn Society Annual Meeting, April, 2001.

Exercise and Pregnancy. Department of Obstetrics and Gynecology Grand Rounds, September, 2000.

Enjoying a Healthy Body Image. Seaboard Medical Association, June 2000.

Exercise for a Lifetime. Seaboard Medical Association, June 2000.

Exercise and Pregnancy. Pulse Athletic Club, 2000.

Fresh Start 2000: Exercise Guidelines for Health and Fitness. Pulse Athletic Club, January 2000.

Exercise, Weight and Body Image. Women's Health Conference, AHEC, October 1999.
The Ten Commandments for Life. Currituck County High School Graduation, 1999.
Writing an Exercise Prescription: Putting Research into Clinical Practice. Department of Obstetrics and Gynecology Grand Rounds, October 1998.
Enjoying a Healthy Body Image. Pulse Athletic Club, Greenville, NC, September 1998.

University of Illinois, Urbana, IL

The medical school at the University of Illinois offers a four-year program leading to the MD degree at four different sites in Illinois. The University of Illinois graduate program provides opportunities for students to research, learn, and teach while earning a graduate degree.

Medical School Student, 1991-1997
Graduate School Student, 1987-1995
Graduate School Teaching Assistant, 1987-1995
Research Assistant, Department of Special Education, 1987- 1989
Research Assistant, Department of Kinesiology, 1994-1997
Men's Tennis Coach, Parkland Junior College, 1988-1990

Peer Reviewed Publications

McAuley, E., Mihalko, S.L., and Bane, S.M. (1996). Acute Exercise and Anxiety Reduction: Does the Exercise Environment Matter? *Journal of Sport and Exercise Psychology,* 18, 408-419.
Mihalko, S.L., McAuley, E. and Bane, S.M. (1996). Self-efficacy and Affective Response to Acute Exercise in Aged Adults. *Journal of Social Behavior and Personality,* 11, 375-385.
Bane, S.M. and McAuley, E. (1995). Reducing Physique Anxiety in College Females. *Medicine and Science in Sports and Exercise.* Vol 27(5), Supplement.
McAuley, E., Bane, S.M. & Bozoian, S.L. (1995). Exercise in Middle-Aged Adults: Self-Efficacy and Self-Presentational Strategies. *Preventive Medicine,* 24, 319-328.
McAuley, E., Bane, S.M., Rudolph, D. & Lox, C. (1995). Physique Anxiety and Exercise in Middle-Aged Adults. *Journal of Gerontology: Psychological Sciences.* 50B, 229-235.
Kennedy, C., Reis, J., Bane, S.M. and Stang, J. (1995). A Comparison of Body Image in Exercising and Nonexercising College Students. *Wellness Perspectives,* 11(3).
Bane, S.M. and McAuley, E. (1994). Physical Attributes, Self-Perceptions and Social Physique Anxiety in College Female: A Self-Presentational Perspective. *Medicine and Science in Sports and Exercise, Vol. 26:5,* Supplement.
Halle, J., Gabler-Halle, P., McKee, M., Bane, S.M. & Boyer, T. (1991). *Enhancing the Aerobic Fitness of Individuals with Moderate and Severe Disabilities: A Peer Mediated Aerobic Conditioning Program.* Champaign, IL: Sagamore Publishing.
Bane, S.M., dos Anjos, L.A., Boileau, R.A., Misner, J.E. & Soares, J. (1989). Comparison of the 40 second run with traditional aerobic field tests and the Wingate Test. Anais do *IX Congress Brasileiro de Medicine Esportiva,* Sao Paulo, Brazil, p. 10.

Peer Reviewed Presentations

Bane, S.M. & McAuley, E. *The Role of Efficacy Cognitions in Reducing Physique Anxiety in College Females.* American College of Sports Medicine Conference, June 1996.
McAuley, E. & Bane, S.M. *Exercise and Body Image in College Females.* American College of Sports Medicine Conference, June 1996.

Bane, S.M. & McAuley, E. *Exercise and Cognitive Behavioral Effects on Body Image.* Society of Behavioral Medicine Conference, March 1996.

Bane, S.M. & McAuley, E. *Body Image in African American and Caucasian College Females: A Self-Presentational Perspective.* Society of Behavioral Medicine Conference, March 1996.

McAuley, E., Bozoian, S. & Bane, S. *Exercise and Self-Esteem in Middle-Aged Adults.* Society of Behavioral Medicine Conference, March, 1995.

Bane, S. & McAuley, E. *Exercise, Efficacy and Physique Anxiety in College Females.* Society of Behavioral Medicine Conference, March 1995.

Bane, S. & McAuley, E. *Reducing Social Physique Anxiety and Enhancing Body Image in College Females: A Self-Presentational Perspective.* American College of Sports Medicine, June 1995.

McAuley, E., Bane, S & Bozoian, S.L. *Self-Efficacy, Exercise and Physique Anxiety in Older Adults.* American College of Sports Medicine, June 1995.

Bozoian, S.L., McAuley, E. & Bane, S. *Self-Esteem and Exercise Relations in Middle-Aged Adults.* American College of Sports Medicine, June 1995.

Bane, S. & McAuley, E.: *Physical Attributes, Self-Perceptions and Social Physique Anxiety in College Females: A Self-Presentational Perspective*. Paper presented at the Medical Scholars Research Symposium, February 1994.

Bane, S. & McAuley, E.: *Physical Attributes, Self-Perceptions and Social Physique Anxiety in College Females: A Self-Presentational Perspective*. Paper presented at the American College of Sports Medicine, June 6, 1994.

Graduate School Awards

Outstanding Teaching Assistant, University of Illinois, 1989-1994

Outstanding Graduate Student, Department of Kinesiology, University of Illinois, 1995

Phi Kappa Phi Honor Society 1995

Avery Brundage Scholarship, 1990, 1991

Grants and Fundraising

Dissertation Grant, Department of Kinesiology, University of Illinois Graduate School, 1995, $650

Laura Huelster Award, Department of Kinesiology, University of Illinois Graduate School, 1995, $1200

Dissertation Grant, American College of Sports Medicine Foundation, 1995, $2255

American College of Sports Medicine Graduate Student Research Grant, 1994

Community Service Presentations: Medical School

Writing an Exercise Prescription. St. Francis Hospital, Peoria, Illinois 1996.

Internal Medicine Resident's Conference, September 1996.

Enjoying a Healthy Body Image. St. Joseph's Hospital, Bloomington, Illinois, Community Lecture Series, June 1996.

What is a Healthy Body Image? Morton High School Women's Athletic Teams, Morton, Illinois, October 1995.

Enjoying a Healthy Body Image. St. Joseph's Hospital, Bloomington, Illinois Center for Healthy Living, October 1995.

Enjoying a Healthy Body Image. St. Joseph's Hospital, Bloomington, Illinois Center for Healthy Living, May 1995.

Community Service Presentations: Graduate School

Developing a Healthy Body Image. Parkland College Staff Development, October 1994.
Developing a Healthy Body Image. Twin City Fitness Associates, July 1994.
Exercise and Pregnancy. McKinley Health Center, Urbana, IL, June 1994.
Exercise and Weight Control. International Student Symposium, University of IL, Urbana, IL, April 1994.
Exercise and Pregnancy. McKinley Health Center, Urbana, IL, February 1994.
Exercise and Pregnancy. McKinley Health Center, Urbana, IL, October 1993.
Body Image. Northwest Naval Base, June 1993.
Body Consciousness. Champaign Junior Women's League, May 1993.
Fitness Through Daily Activity. North West Naval Base, April 1993.
Exercise and Pregnancy. McKinley Health Center, Urbana, IL, March 1993.
Mirror Mirror in My Mind. Northwest Naval Base, January 1993.
Exercise and Pregnancy. McKinley Health Center, Urbana, IL, December 1992.

Undergraduate Awards at Atlantic Christian College/Barton College

Summa Cum Laude, 1987
Faculty Cup for Most Outstanding Senior, 1987
Academic All-American (tennis), 1986, 1987
Honorable Mention All-American (tennis), 1987
All-District (tennis), 1985, 1986, 1987
All-Conference (tennis), 1985, 1986, 1987
Most Valuable Player (tennis), 1987
Edward E. Cloyd Top Academic Athlete Award, 1987
Female Athlete of the Year, 1987
Homecoming Queen, 1984