UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*, Plaintiffs, v. JOSHUA STEIN, *et al.*, Defendants, and PHILIP E. BERGER and TIMOTHY K. MOORE, Defendant-Intervenors.	)	**Case No. 1:23-cv-480** **DEFENDANT-INTERVENORS' CROSS-MOTION FOR SUMMARY JUDGMENT**

Defendant-Intervenors Phillip E. Berger and Timothy K. Moore respectfully move for summary judgment on all claims under Federal Rule of Civil Procedure 56(a) and Local Rule 56.1. As explained in the attached memorandum in support of this motion, Plaintiffs have failed to meet their burden of showing that the IUP Determination Requirement, N.C. Gen. Stat. § 90-21.83B(a)(7), is vague or that it is not rationally related to a legitimate state interest under the Due Process Clause. Plaintiffs have also failed to meet their burden that the Hospitalization Requirement, N.C. Gen. Stat. §§ 90-21.81A, 90-21.81B(3)–(4), 90-21.82A(c), is vague or that it is not rationally related to a legitimate state interest under the Equal Protection and Due

Process Clauses. Defendant-Intervenors designate the following evidence in support of this motion:

- Exhibit 1: Rebuttal Expert Report of Christy M. Boraas Alsleben, M.D., M.P.H.
- Exhibit 2: Expert Report of Monique Chireau Wubbenhorst, M.D., M.P.H.
- Exhibit 3: Expert Report of Catherine J. Wheeler, M.D.
- Exhibit 4: Expert Report of Susan Bane, M.D., Ph. D.
- Exhibit 5: Rebuttal Expert Report of Timothy R.B. Johnson, M.D.
- Exhibit 6: Rebuttal Expert Disclosure of Katherine Farris, M.D. F.A.A.F.P.
- Exhibit 7: Addendum to December 2023 Report of Dr. Bane
- Exhibit 8: ACOG Bulletin No. 193, Tubal Ectopic Pregnancy

Because there is no genuine issue of material fact, Defendant-Intervenors are entitled to judgment as a matter of law.

RESPECTFULLY SUBMITTED THIS 1st day of April, 2024.

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*** *Notice of Special Appearance Filed*

Attorneys for Intervenor-Defendants

CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2024, 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/ Erin M. Hawley
Erin M. Hawley

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

REBUTTAL EXPERT REPORT OF CHRISTY M. BORAAS ALSLEBEN, M.D., M.P.H.

Pursuant to Federal Rules of Civil Procedure 26(a)(2)(C) and 26(a)(2)(D)(ii), Christy M. Boraas Alsleben, M.D., M.P.H., makes the following disclosures:

BACKGROUND AND QUALIFICATIONS

1. I submit this rebuttal report in further support of the litigation that Plaintiffs Planned Parenthood South Atlantic ("PPSAT") and Dr. Beverly Gray filed to block two components of North Carolina Session Law 2023-14 ("S.B. 20") (codified as amended by Session Law 2023-65 ("H.B. 190") at N.C. Gen. Stat. art. 1I, Ch. 90 (the "Act")), which bans abortion after the twelfth week of pregnancy with narrow exceptions.

2. A summary of my qualifications and publications is contained within the November 13, 2023 expert report that I prepared for this litigation (the "Report"). The

Report also contains a list of the cases in which I have testified as an expert in the last four years. The Report's statement of compensation also applies to this rebuttal report. I have attached an updated CV as Exhibit A to this rebuttal report.

3. As with the Report, the opinions I state here are based on my education, clinical training, experience as a practicing physician, regular review of medical research in my field, and regular attendance and presentation at professional conferences, including conferences for abortion providers. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this report.

4. Counsel for plaintiffs asked me to review and respond to the expert reports that Drs. Susan Bane, Catherine Wheeler, and Monique Chireau Wubbenhorst submitted in this litigation. I offer my opinion on certain assertions in those expert reports. The fact that I do not address a particular statement or assertion in the reports does not mean that I agree with the statement or assertion.

STATEMENT OF MY OPINIONS AND THE BASIS AND REASONS FOR THEM

The Obligations of Doctors to Patients

5. As a starting point, Dr. Bane's report discusses the obligations of doctors to our patients.[1] I consider it my responsibility and my honor to provide high-quality, evidence-based health care for all of my patients. Sometimes that care includes abortion. Sometimes it involves labor and delivery. I have an ethical obligation to honor my patients' decisional autonomy by respecting the values and preferences of each one. I support the right of my patients to decide whether to have children, the number and

[1] *See* Expert Report of Susan Bane, M.D., Ph.D. ("Bane") ¶¶ 19-26.

spacing of children and to have full, evidence-based information and access to health services to meet their reproductive health goals. And I honor each patient as the best decision maker about their pregnancy. My medical practice and beliefs are consistent with those stated by the American College of Obstetricians and Gynecologists (ACOG), which recognizes that an obstetrician-gynecologist's "primary duty is to the pregnant woman. This duty most often also benefits the fetus. However, circumstances may arise during pregnancy in which the interests of the pregnant woman and those of the fetus diverge. These circumstances demonstrate the primacy of the obstetrician–gynecologist's duties to the pregnant woman."[2] The Intervenors' witnesses' lack of acknowledgment of abortion's importance as part of reproductive health care dishonors the lived experience of patients and their bodily autonomy; undermines the compassion, empathy, and humanity of abortion providers; and functions only to further stigmatize abortion care and alienate patients.

The Safety of Abortion

6. The Intervenors' witnesses characterize abortion as an unsafe, risky procedure, but the objective fact is that abortion is extremely safe. Leading, reputable, mainstream medical authorities agree, and an abundance of literature supports,[3] that both

[2] Comm. on Ethics, *Committee Opinion No. 664: Refusal of Medically Recommended Treatment During Pregnancy*, ACOG (June 2016), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2016/06/refusal-of-medically- recommended-treatment-during-pregnancy.

[3] *See, e.g.*, Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 217 (2012); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); Nat'l

medication abortion and procedural abortion are two of the safest procedures in medical practice,[4] carry a low risk of complications, and a very low risk of complications requiring hospitalization, "stand[ing] in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services."[5]

7. Intervenors' experts rely on a host of inappropriate conclusions from low quality and/or outdated research to support their conclusions. Much of this research (1) does not involve second trimester abortion; (2) studied patients in international contexts not generalizable to the United States[6]; (3) does not reflect contemporary abortion practice[7]; or (4) suffers from other limitations, such as organizational biases,[8] that renders it unreliable. The intervenors' experts' approach to summarizing research omits nationally representative, high quality, U.S.-based research. Their reports also draw conclusions based on conjecture, which is not an accepted practice in the field of medicine or in the provision of evidence-based medical care.

8. Dr. Wubbenhorst's and Dr. Bane's suggestions that complications related to medication abortion are underreported to the FDA demonstrates their lack of familiarity with the FDA's regulation of medication abortion and how it monitors prescription drug

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Acads. Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States*, at 77-78 (2018), available at http://nap.edu/24950 [hereinafter "Nat'l Acads."].

[4] Nat'l Acads., *supra* note 3 at 77 ("The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective.").

[5] *Id.*

[6] *See, e.g.*, Bane ¶ 48 (citing a study assessing medication abortion in Finland).

[7] *See, e.g.*, Expert Report of Monique Chireau Wubbenhorst, M.D., M.P.H. ("Wubbenhorst") ¶ 44 (citing study that reported on data from 1972–78).

[8] *See, e.g.*, Wubbenhorst ¶ 54 (citing the American Association of Pro-Life Obstetricians and Gynecologists' criticisms of credible studies).

safety more broadly. Wubbenhorst ¶¶ 23–28, 178–79; Bane ¶ 36. They ignore that for fifteen years—from mifepristone's approval in 2000 until March 2016—the FDA specifically required that all mifepristone prescribers comprehensively report any serious adverse events associated with mifepristone to the drug manufacturer, and the manufacturer was then required to report all such events to the FDA. This mandatory reporting, imposed as part of the FDA's Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, included any hospitalizations, transfusions, serious infections, death, or "[o]ther serious and unexpected adverse events" associated with mifepristone, as well as ongoing pregnancies.[9]

9. In 2016, the FDA's scientific review team lifted the REMS requirement that all serious adverse events associated with mifepristone be specially reported, explaining that the "FDA has received such reports for 15 years, and it has determined that the safety profile of Mifeprex is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely."[10] And, after reviewing those 15 years of comprehensive data, the FDA concluded that serious adverse events associated with mifepristone are "exceedingly rare."[11] In other words, the FDA's rigorous data collection for mifepristone far exceeds its data collection for most prescription drugs and aligns with the extensive body of high-quality research confirming that mifepristone is extremely safe.

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[9] Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Risk Assessment and Risk Mitigation Review(s)*, U.S. Food & Drug Admin. 1, 10 (2016).
[10] Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Medical Review(s)*, U.S. Food & Drug Admin. 1, 8 (2016).
[11] *Id.* at 47.

10. The studies that Dr. Wubbenhorst and Dr. Bane reference in support of their claims that abortion has a high complication rate have serious limitations. For example, Dr. Wubbenhorst cites a study from Finland by Gissler, et al., to support the argument that death rates are higher after abortion compared to childbirth up to 1 year. Wubbenhorst ¶ 99. However, this old study reported on pregnancy-associated mortality, defined as death while pregnant or within one year from the end of pregnancy, regardless of cause. The conclusions reached by Gissler et al. are thus flawed and unreliable because they include "all-cause mortality," such as homicide and accidental deaths, for which abortion cannot logically be the "cause."[12] For example, it would be inappropriate to claim that abortion "caused" a patient's death if they died in a car accident months after the procedure. Additionally, the CDC has robust data on deaths attributable to abortion in the U.S. The CDC concluded that the "national case-fatality rate for legal induced abortion for 2013-2019 was 0.43 deaths … per 100,000 reported legal abortions."[13] In 2020, the most recent year for which the CDC has reviewed Pregnancy Mortality Surveillance System data for pregnancy-related deaths, six women *in total*—out of the

[12] Mika Gissler et al., *Pregnancy Associated Deaths in Finland 1987–1994: Definition Problems and Benefits of Record Linkage*, 76 Acta Obstetricia et Gynecologica Scandinavica 651 (1997); Mika Gissler et al., *Pregnancy-Associated Mortality After Birth, Spontaneous Abortion, or Induced Abortion in Finland 1987–2000*, 190 Am. J. Obstetrics & Gynecology 422 (2004).

[13] Katherine Kortsmit et al., *Abortion Surveillance—United States, 2020*, 71 CDC Morbidity & Mortality Wkly. Rep. Surveillance Summaries 1, 6 (2022).

620,327 abortions that year[14]—died as a result of complications from legal induced abortion.[15]

11. In addition, all of Intervenors' experts selectively cite a 2009 study by Niinimäki et al. to imply that medication abortion is unsafe, Wubbenhorst ¶ 254; Bane ¶ 48; Expert Report of Catherine J. Wheeler, M.D. ("Wheeler") ¶ 56, but that study included evaluations of medication abortion regimens that have never been used in the United States.[16] More critically, the Niinimäki study (1) was based on a Finnish health registry that coded all follow-up visits as "complications" regardless of the degree of concern; and (2) inappropriately reported as "hemorrhage" all patient reports of heavy bleeding, even if they were within the expected range for medication abortion and did not require treatment.[17] In response to criticism on these points, the authors themselves acknowledged that in the records they used, "many of the 'complications' are not really such, but rather concerns or adverse events that bring women back to the health care system. . . . [The] [r]ate of serious, 'real' complications is rare and rather similar between [procedural] and medical abortion."[18]

12. Dr. Bane criticizes PPSAT's off-label use of mifepristone through 77 days of pregnancy, Bane ¶ 60, but ignores the fact that the Act *permits* medication abortion

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[14] *Id.*.
[15] Katherine Kortsmit et al., *Abortion Surveillance - United States, 2021*, 72 CDC Morbidity & Mortality Wkly. Rep. Surveillance Summaries 1, 1 (2023).
[16] Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795, 796 (2009).
[17] Mary Fjerstad et al., *Letters to the Editor: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010); Niinimäki et al., *supra* note 16, at 799–800.
[18] Fjerstad, *supra* note 17.

"during the first 12 weeks [i.e., 84 days] of a woman's pregnancy." Section 90-21.81B(2). What's more, off-label medication use is common in the medical field, and the off-label use of mifepristone has been shown to be safe at more advanced gestations than that approved by the FDA.[19] I understand that Plaintiffs provide first-trimester medication abortion through 77 days, which is a safe and common evidence-based practice that I offer to my patients as well.[20]

13. Intervenors' experts state that Upadhyay et al.'s studies finding low complication rates are flawed. Bane ¶ 37, Wubbenhorst ¶¶ 55–57. While no study is perfect, these were high quality studies and their findings can and should be relied upon. The 2015 Upadhyay et al. study used a high-quality data set, examining billing data from California's state Medicaid program, particularly because California is one of the limited number of states whose Medicaid program covers abortion. The study started with identifying health care Common Procedure Coding codes for abortion and then searched for additional insurance claims for any visit in any setting (including the emergency department) for the 6 weeks subsequent to the abortion without loss to follow up. Because the billing codes used are specific to abortion type, there is no reason to think

[19] Comm. on Practice Bulletins–Gynecology & Soc'y of Family Planning, *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, ACOG (reaffirmed 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[20] *See, e.g.*, Ilana G. Dzuba et al., *A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review*, 102 Contraception 104 (2020); Ilana G. Dzuba et al., *A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64–70 days and 71–77 Days of Gestation*, 101 Contraception 302 (2020).

that inaccurate coding was any more of an issue in this study than it is in any study that uses billing codes.[21] The 2018 Upadhyay study, while it used a different data set (from the Nationwide Emergency Department Sample), found a similarly low rate of complications.[22] Meanwhile, Dr. Bane cites a 2021 study by Studnicki et al. to support her claim that ER visits for abortions are growing in number, with medication abortions "associated with more postabortion ER visits," Bane ¶ 38, but the Studnicki study is methodologically flawed in that it both (1) conflates association with causation and (2) relies on overinclusive outcome measures that are not valid proxies for complications from procedural or medication abortion.[23] By contrast, as the National Academies of Science, Engineering, and Medicine recognized and as I discussed in my Report, numerous high-quality studies—including Upadhyay's—exist on the incidence of complications, and those studies converge on a single conclusion: risks of complications from abortion are very low.[24]

14. Intervenors' experts highlight that the risks of abortion increase with gestational age, Wubbenhorst ¶¶ 43–51, Wheeler ¶¶ 34–36, but because they are very low to begin with, abortion remains a very safe procedure even later in the second trimester.[25] Contrary to the Intervenors' experts' assertions, *see, e.g.*, Wubbenhorst ¶ 62, abortion is

[21] Upadhyay et al. (2015), *supra* note 3.
[22] Upadhyay et al. (2018), *supra* note 3.
[23] James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, 8 Health Servs. Rsch. & Managerial Epidemiology 1, 1–8 (2021).
[24] Nat'l Acads., *supra* note 3, at 10–11, 55–56, 60–65, 77–78 ("[s]erious complications are rare; in the vast majority of studies, they occur in fewer than 1 percent of abortions").
[25] Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998–2010*, 126 Obstetrics & Gynecology 258, 262–63 (2015); Nat'l Acads., *supra* note 3, at 10–11, 65.

much safer than carrying a pregnancy to term and childbirth, including in the second trimester.[26]

15. Intervenors' witnesses argue that abortion-related deaths and complications are subject to undercounting and underreporting, *see* Wubbenhorst ¶¶ 63–71, Bane ¶¶ 35–36, Wheeler ¶ 56, but this view is not supported by credible evidence. Further, they do not explain how underreporting of the kind they suggest, for abortion or for maternal mortality, *see* Bane ¶¶ 28–34, casts doubt on the consensus finding that abortion is less likely to end in complications and death than carrying a pregnancy to term.

16. The 2015 study by Upadhyay and colleagues, cited above and in my initial report, tracked any complications the study population experienced "without loss to follow-up, addressing a common methodologic limitation of other studies."[27] Because California's state Medicaid program covers abortion, the study authors were able to track each individual who had an abortion after their abortion using billing data, eliminating loss to follow-up.

17. Dr. Wubbenhorst's criticism of the Centers for Disease Control and Prevention's (CDC) data on abortion and abortion-related morbidity, on the theory that there is no comprehensive national data on the occurrence of complications from abortion, is misplaced. *See* Wubbenhorst ¶¶ 14–20. The CDC calculates the number of

[26] Raymond & Grimes, *supra* note 3, at 217.
[27] Upadhyay et al. (2015), supra note 3, at 182 ("This study examines postabortion ED visits and complications up to 6 weeks and across multiple facilities without loss to follow-up, addressing a common methodologic limitation of other studies."). In fact, the authors noted that their study might overestimate abortion complication rates because it focused on a population with lower incomes and more overall health problems than the general population of abortion patients. *Id*.

abortions and abortion-related deaths as part of its Pregnancy Mortality Surveillance System, which defines a pregnancy-related death as "a death while pregnant or within 1 year of the end of pregnancy from any cause related to or aggravated by the pregnancy"—a definition that includes both childbirth-related deaths and abortion-related deaths.[28]

18. Moreover, the CDC does not rely solely on voluntary reporting by states to generate this data, as Dr. Wubbenhorst suggests. Wubbenhorst ¶ 19. Rather, it uses death records, linked birth records, fetal death records, and "additional available data from all fifty states, New York City, and Washington, DC."[29] And although the CDC does rely on voluntary reporting to calculate the total number of abortions performed each year, the

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[28] CDC, *Pregnancy Mortality Surveillance System*,, (last reviewed Jan. 3, 2024), https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm. The CDC has monitored abortion-related deaths through its Pregnancy Mortality Surveillance System since 1987 using both voluntary reporting by states and other means including "state vital records; media reports, including computerized searches of full-text newspaper and other print media databases; and individual case reports by public health agencies, including maternal mortality review committees, health care providers and provider organizations, private citizens, and citizen groups. For each death that possibly is related to abortion, CDC requests clinical records and autopsy reports. Two medical epidemiologists independently review these reports to determine the cause of death and whether the death was abortion related. Discrepancies are discussed and resolved by consensus. Each death is categorized by abortion type as legal induced, illegal induced, spontaneous, or unknown type." Tara C. Jatlaoui et al., *Abortion Surveillance — United States, 2015*, 67 CDC Morbidity & Mortality Wkly. Rep. Surveillance Summaries 1, 5 (2018).

[29] CDC, *supra* note 28. Dr. Wubbenhorst is wrong to suggest that research based on Finnish death certificates is a more appropriate basis for calculating mortality rates in the United States. *See* Wubbenhorst ¶ 66. As the National Academies of Sciences, Engineering, and Medicine concluded, "no clear conclusions regarding the association between abortion and long-term mortality can be drawn from" those studies. Nat'l Acads., *supra* note 3, at 152.

vast majority of the central health agencies asked to report this data do so.[30] For instance, in 2021, the CDC "request[ed] abortion data from the central health agencies for the 50 states, the District of Columbia, and New York City," and "a total of 48 reporting areas" agreed to provide it; of these, 47 reporting areas provided data each year during 2012-2021.[31]

The Hospitalization Requirement Impedes Access to Abortion Without Adding to Patient Health and Safety.

19. As I detailed in my Report, the vast majority of procedural abortions, including the vast majority of procedural abortions after the twelfth week of pregnancy, can be safely provided in an outpatient facility, and therefore there is no reason to categorically require that all abortions after the twelfth week of pregnancy in cases of rape, incest, or life-limiting fetal anomaly occur in a hospital. *See* Report ¶ 40.

20. In my Report, I highlighted the fact that throughout the country, legal abortions are safely and routinely performed in doctors' offices and outpatient health center settings, and only 3% of abortions are performed in hospitals in the U.S. annually.[32] Report ¶ 31. There are many reasons that patients justifiably prefer abortions in outpatient centers including shorter appointments, lower costs, sedation options, and treatment from staff and medical professionals with more experience providing abortions. *See* Report ¶ 40.

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[30] Kortsmit et al., *supra* note 13, at 1.
[31] Kortsmit et al., *supra* note 15 at 2.
[32] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. on Sexual & Reprod. Health 128, 134 tbl. 3 (2022).

21. I disagree with Dr. Bane's statement that "hospitals are more equipped than outpatient settings to handle major complications in our maternal patients." Bane ¶ 50. No medical procedure is entirely risk free. Intervenors' experts describe certain complications that can arise as a result of an abortion after 12 weeks. *See* Wubbenhorst ¶ 86; Wheeler ¶ 30; Bane ¶¶ 48, 50. For many patients, these complications—which are exceedingly rare, as described above—can be treated in the outpatient clinic where the abortion was performed. In my experience, outpatient facilities are well-equipped to treat cervical lacerations or tears, infections, and moderate bleeding. In the rare instance of moderate bleeding, most cases can be managed in the outpatient clinic setting with uterotonics, medications that cause uterine contractions and reduce bleeding. Dr. Wheeler cites literature that is over 30 years old for the proposition that the uterus does not respond to uterotonics during D&Es performed for abortion as well as it does for term induction. Wheeler ¶ 14. Her statement is out of date and does not reflect the fact that prophylactic oxytocin has been shown to decrease blood loss and frequency of hemorrhage when used in second trimester D&Es, which is why its use in second trimester D&Es has become common medical practice in modern times.[33]

22. As with many other types of procedures performed in outpatient settings, outpatient abortion clinics have protocols to ensure safe transfer to an emergency department in the rare situation where that is necessary. I understand from Dr. Farris's

[33] *See* Katherine Whitehouse et al., *Effects of Prophylactic Oxytocin on Bleeding Outcomes in Women Undergoing Dilation and Evacuation: A Randomized Controlled Trial*, 133 Obstetrics & Gynecology 484 (2019).

report that PPSAT has such a protocol for safe transfer. Dr. Bane claims that performing abortions in a hospital "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." Bane ¶ 50. But this is not necessarily the case. In my experience, transferring a patient between departments within the same hospital can vary greatly depending on the size of the hospital and where each department is located. For example, the operating room where patients are able to access abortion care may be in a different building on a medical campus than the desired unit for postoperative care, such as a surgical intensive care unit.

23. Dr. Bane also makes inflammatory and inaccurate statements about "live births" after induction abortions. Bane ¶ 51. My understanding is that PPSAT does not perform induction abortions. Additionally, my understanding is that PPSAT only provides abortions up to 20 weeks LMP, when no fetus is viable outside the uterus.

24. Dr. Bane's statements about anesthesia, *see id.* ¶ 52, are similarly misplaced. It is not unusual or unsafe for certain types of sedation to be administered by professionals who are not anesthesiologists, such as during a dental appointment. Aspiration abortion performed in the first trimester and early second trimester, regardless of setting, almost never entails the use of general anesthesia; similarly, minimal or moderate sedation with local anesthesia are sufficient for the majority of D&Es. *See* Report ¶ 35. The American Society of Anesthesiologists' "Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who are Not Anesthesia Professionals" cited by Dr. Bane, Bane ¶ 52, explicitly supports the idea that

moderate sedation can be "used [in] any facility—hospital, ambulatory care or physician's, dentist's, or podiatrist's office," including by appropriately trained practitioners who are not anesthesiologists.[34]

25. It is my understanding that PPSAT does not use deep sedation medications such as propofol or general anesthesia. Practitioners are trained, both at PPSAT and the places where I practice, to assess levels of sedation in a manner consistent with the American Society of Anesthesiologists' guidelines. Under moderate sedation, "patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation," whereas under deep sedation, "patients cannot be easily aroused but respond purposefully following repeated or painful stimulation."[35] In my experience, the difference is extremely clear.

26. Dr. Wubbenhorst's statement that "pain control [for abortion] is often suboptimal and problematic," Wubbenhorst ¶ 83, is unrelated to any need for hospitalization related to abortion as compared to miscarriage. Any physical pain caused by second trimester aspiration or D&E is no different between miscarriage management and abortion, and patients undergoing both should be able to access any level of sedation they desire that is safe for their particular circumstances. There is no clinical reason that hospitalization should be required for all abortion care after the twelfth week of

[34] Comm. on Ambulatory Surgical Care, *Statement on Granting Privileges for Administration of Moderate Sedation to Practitioners Who are Not Anesthesia Professionals*, Am. Soc'y Anesthesiologists (last amended Oct. 13, 2021), https://www.asahq.org/standards-and-practice-parameters/statement-on-granting-privileges-for-administration-of-moderate-sedation-to-practitioners-who-are-not-anesthesia-professionals.

[35] *Id.*

pregnancy but not for miscarriage management at equivalent gestational durations simply because a small minority of patients may need or desire higher levels of sedation.

27. Intervenors' witnesses also attempt to distinguish miscarriage management from abortion care more generally. *See* Bane ¶¶ 54–57, Wheeler ¶¶ 15, 50. However, as even Dr. Wheeler acknowledges, from a clinical perspective aspiration and D&E procedures are the same for abortion and for miscarriage management. *See* Wheeler ¶ 50 ("[T]echnically the procedure is similar"). In fact, in certain circumstances second-trimester miscarriage management can be riskier than second-trimester abortion at the same gestational age due to the rare but real risk of disseminated intravascular coagulation ("DIC"). DIC occurs when abnormal blood clots form inside blood vessels and use up clotting factors, which can lead to severe bleeding in other places. DIC is one of the serious potential complications associated with spontaneous intrauterine fetal demise treated via D&E in the mid-second trimester or beyond. However, DIC is associated with the pregnancy loss, not the D&E procedure itself, and my experience and research both indicate that there is a greater risk of DIC when performing D&E for miscarriage management rather than for an abortion.

28. Second-trimester abortion is safe, as are abortions overall. Procedural abortion via dilation and evacuation has "minimal rates of complications[] ranging from 0.05 to 4 percent."[36] One study by Turok et al. that examined second-trimester abortions in Utah found that patients undergoing D&E or induction abortions in a hospital setting were more likely to experience major complications than those undergoing an in-clinic

[36] Nat'l Acads, *supra* note 3 at 63.

D&E.[37] Drs. Wubbenhorst and Wheeler critique the Turok study on the basis that because hospital D&E patients generally have more or greater pregnancy complications before the procedure, any difference in complication rate should be attributable to the patient population rather than the setting of the abortion. *See* Wubbenhorst ¶¶ 139–142; Wheeler ¶¶ 44–47. However, the study explicitly found that "the increase in complication rates for D&E and induction in the hospital groups persisted when controlling for maternal medical complications, preexisting infections, parity and gestational age in a multivariate regression model."[38] And even the critique underlines the point that there is no reason to require that all abortions after the twelfth week of pregnancy take place in hospitals; patients with particularly complicated cases would be treated in hospitals regardless, and other abortions can be performed safely in outpatient clinic settings. Further, the study also found that "[l]ow volume of second trimester D&E at the [hospital] likely contributed to a higher complication rate for patients,"[39] reinforcing that outpatient facilities—where 97% of abortions in the United States take place[40]—are a safe setting for the provision of abortion.

29. Drs. Bane and Wheeler both cite the creation of a two-year fellowship in complex family planning for the proposition that D&Es, specifically D&E abortions, are complex and technically difficult. Bane ¶ 57; Wheeler ¶ 25. Their framing is an inaccurate oversimplification. While *some* D&Es may be medically or procedurally

[37] David K. Turok et al., *Second Trimester Termination of Pregnancy: A Review by Site and Procedure Type*, 77 Contraception 155 (2008)..
[38] *Id.* at 160.
[39] *Id.* at 161.
[40] Jones et al., *supra* note 32.

complex, it is not true that *all* D&Es are medically or procedurally complex, and there is no clinical difference between performing a D&E for abortion and performing one for miscarriage management. The completion of a *complex* family planning fellowship is not necessary for an abortion provider (or other physician) to safely provide a D&E; rather, it simply provides specialized training for practitioners who treat the subset of family planning cases that are more complex

30. Intervenors' experts claim that hospitals are better equipped than outpatient facilities to support patients who have experienced sexual violence, abuse, or trafficking, but in my experience, many times this is not the case. *See* Wubbenhorst ¶ 168; Bane ¶ 58; Wheeler ¶ 49. Many providers of reproductive care, including outpatient providers like PPSAT, as I understand from Dr. Farris's report, receive training in order to identify patients who are victims of abuse or trafficking who have been coerced into either seeking an abortion or continuing a pregnancy, and help direct them to resources where they can receive support. In my experience, not all physicians and staff employed at a hospital receive this type of training, and staff at the outpatient centers are often better trained to support patients who have experienced abuse.

31. Further, Dr. Wubbenhorst's statement that "many abortions are coerced" is mistaken and ignores the true role of coercion in reproductive decision making. *See* Wubbenhorst ¶ 165. Dr. Wubbenhorst assumes coercion is unidirectional—that people experience coercion only as an effort to force them to choose abortion. In reality, reproductive coercion takes many other forms beyond pressure to have an abortion, including pressuring a person to become pregnant and carry a pregnancy to term,

pressuring or coercing a person to have sex, and threatening to leave a relationship if someone does not get pregnant.[41] While most people seeking abortion do not experience coercion, all patients deserve support and a safe environment to discuss their experiences and options. I understand that PPSAT screens every patient for abortion coercion. *See* Farris ¶ 94. Coercion screening is also required at the Planned Parenthood health center where I provide care.

32. The Turnaway Study examined patients' experiences with abortion and unintended pregnancy in the U.S., and researchers found that among 954 participants, only one respondent used language that indicated overt pressure from their partner to get an abortion.[42] On the other hand, patients reporting intimate partner violence were more than three times as likely to identify their partner as a reason for wanting an abortion compared to patients not reporting intimate partner violence.[43] But those identifying an abusive partner as a reason for seeking an abortion reported that they were choosing abortion not because their partner was coercing them to do so. Rather, they perceived an abortion as their best option to end the abusive relationship.[44]

33. Contrary to Dr. Wheeler's assertion, Wheeler ¶ 49, there is no inherent clinical or procedural difference between an abortion performed for a patient who has

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[41] ACOG Comm. on Healthcare for Underserved Women, *Committee Opinion No. 554: Reproductive & Sexual Coercion*, 121 Obstetrics & Gynecology 411, 411 (2013).
[42] *See* Diana Greene Foster, *The Turnaway Study: Ten Years, a Thousand Women, and the Consequences of Having—or Being Denied—an Abortion* (2020). The Turnaway Study studied patients from 21 states over 5 years.
[43] *Id.*
[44] Karuna S. Chibber et al., *The Role of Intimate Partners in Women's Reasons For Seeking Abortion*, 24 Women's Health Issues e131 (2014).

survived rape and incest and one who has not. In fact, in my experience, some patients who have survived sexual violence prefer to avoid hospital settings, especially if procedures in those settings might involve a greater likelihood of the use of general anesthesia per an anesthesiologist's preference. *See* Report ¶ 35.

34. Intervenors' experts also claim that hospitals have more resources to support patients who have received fetal anomaly diagnoses. *See* Wubbenhorst ¶¶ 171–75; *see also* Bane ¶ 58. However, many times, the doctors providing the abortion are not the same doctors diagnosing the fetal anomaly. If the diagnosing doctor is not able to perform the abortion themselves, they may refer the patient to an outpatient provider like PPSAT. Normally, by the time I see a patient who is seeking an abortion due to a life-limiting fetal anomaly, the patient has already received detailed information about the fetal diagnosis, discussed their options with the provider who made the diagnosis and/or their obstetrician, and made the decision to have an abortion.

35. For instance, when I see patients seeking an abortion after receiving a fetal diagnosis from their perinatologist, their records reflect extensive patient education about the diagnosis, the prognosis, and options, including continuing the pregnancy, giving birth, and seeking perinatal hospice care. These patients have already made the extremely personal decision to terminate their pregnancy, and for the majority of these patients their abortion may be safely performed in an outpatient setting.

Medication Abortion is Safe and Effective in Terminating Pregnancies of Unknown Location.

36. The Protocol (as defined in my Report ¶¶ 44–46) that I, PPSAT, and many other medical institutions use to safely provide medication abortion to patients with early pregnancies of unknown location has been shown to be safe and effective, both in research studies and in my daily practice.

37. Intervenors' witnesses mischaracterize and oversimplify the Protocol. First, Dr. Bane implies that PPSAT is using "serum hCG values alone" to rule out ectopic pregnancy. Bane ¶ 67. This is inaccurate. I understand that North Carolina law requires all patients to receive an ultrasound before obtaining an abortion. Patients whose pregnancies are not visible by ultrasound are screened for level of risk for an ectopic pregnancy through a detailed conversation about medical history and current symptoms and often a physical examination. High-ectopic-risk patients are referred for further ectopic pregnancy evaluation. Low-ectopic-risk patients who choose medication abortion receive serial hCG testing and close follow-up to rule out ectopic pregnancy while simultaneously receiving their medication abortion. Report ¶¶ 47–49. While serial hCG levels are certainly an important factor, they are not the only factor.

38. As stated in my Report, clinicians at both hospitals and outpatient health centers routinely provide detailed counseling and conduct a symptom assessment to identify patients at risk for ectopic pregnancies, including by considering known risk factors, symptoms, and prior and current health history—all of which can be assessed by

a detailed conversation with the patient.[45] Report ¶ 49. Dr. Wubbenhorst's critique of a study that I co-authored, "Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study," Wubbenhorst ¶ 58, implies incorrectly that the study "disregard[ed]" caring for patients with ectopic pregnancies. Rather, because medication abortion does not harm patients who have ectopic pregnancies, it was not the focus of this study (and all patients were contacted for follow-up and had access to members of their care teams). Dr. Wubbenhorst's criticism does not negate the study's central finding that "screening for medication abortion eligibility by history alone was effective and safe."[46] Her critique is also irrelevant because PPSAT's Protocol is multi-faceted and does not rely only on history-based screening; taking a detailed patient history is one among multiple components that makes it effective and safe.

39. If a patient with a pregnancy of unknown location is not determined to be low risk, it would not be appropriate to go forward with a medication abortion, and the patient would be counseled to seek further assessment to determine whether they have an ectopic pregnancy. To be clear, if a patient is determined to be at high risk for an ectopic

[45] *See, e.g.*, Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynaecology 1464, 1466 (2021) (explaining that patients "were offered a consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made," which included assessing whether "they had a low risk of ectopic pregnancy"); *see also* Ushma D. Upadhyay, Christy M. Boraas et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 J. Am. Med. Ass'n Internal Med. 482 (2022).

[46] Upadhyay, Boraas et al., *supra* note 43..

pregnancy, medication abortion is not prescribed, and Dr. Wubbenhorst's assertions about when an ectopic pregnancy should be considered suspected or confirmed is consistent with PPSAT's protocol. *See* Wubbenhorst ¶¶ 203–204. Dr. Wubbenhorst's discussion of the evaluation and treatment of pregnancies of unknown location, *Id.* ¶¶ 216–223, is similarly in line with PPSAT's practice.

40. Dr. Bane also criticizes the Protocol because "approximately one half of women accurately recall their last menstrual period (LMP)," Bane ¶ 61, implying that providers are making ectopic determinations based on incomplete information from the patients themselves. Similarly, Dr. Wheeler states that screening based on risk factors is "grossly ineffective," citing a study that "found that of the women who were ultimately diagnosed with an ectopic pregnancy, only 12.9% had a 'major ectopic risk factor,' defined by the authors as a history of ectopic pregnancy, history of tubal surgery, or in situ IUD." Wheeler ¶ 61. Both Dr. Bane's and Dr. Wheeler's criticisms ignore the multifaceted nature of the Protocol, which assesses current symptoms like unilateral pain or unusual bleeding in addition to medical-history-based risk factors, does not rely on LMP alone to assess a patient's risk for ectopic pregnancy, screens for more risk factors than the ones listed in the study cited by Dr. Wheeler, may include a physical examination, and also incorporates ultrasound and serial hCG testing. Report ¶¶ 47–49. Indeed, even as Dr. Wubbenhorst claims that "serial hCG levels and transvaginal ultrasound are the standard of care for diagnosis of ectopic pregnancy," Wubbenhorst ¶ 213, she ignores that both are already part of PPSAT's Protocol.

41. Dr. Wubbenhorst criticizes the St. Paul Study[47] (as defined in my Report, Report ¶ 44), claiming that the rates of loss to follow up were "very high" and thus "no conclusions can be drawn related to risk for complications." Wubbenhorst ¶ 243; *see also* Wheeler ¶¶ 69–70. However, the loss-to-follow-up rates of the St. Paul Study are consistent with those documented in abortion care literature and a known general limitation of retrospective research studies. In my experience, patients who experience problems do return for care, making a successful, uncomplicated abortion the most likely outcome for those who do not follow up with their abortion provider. Furthermore, in my experience of using the Protocol to administer medication abortion in cases of pregnancies of unknown location, I have seen firsthand that it is a safe and patient-centered practice.

42. Dr. Wubbenhorst also criticizes the St. Paul Study on the basis that "the initially undiagnosed ectopic pregnancy rates were high in all [study] groups," "patients underwent unnecessary interventions," and that "the efficacy of abortions was higher" if clinicians waited to provide abortion until pregnancy location was ascertained. Wubbenhorst ¶¶ 240–246; *see also* Wheeler ¶ 72. These criticisms misunderstand the point of the Protocol and the population to whom it applies. First, it is neither surprising nor a negative reflection on the study that the initially undiagnosed ectopic pregnancy rates were higher than the national average; the study subjects were patients *with pregnancies of unknown location*, and the rate of ectopic pregnancy in that population is

[47] Karen Borchert, Christy M. Boraas et al., *Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study*, 122 Contraception 109980 (2023).

higher than for pregnant people generally. Indeed, that is why this population was the focus of our research on the safety and efficacy of a method for simultaneously providing medication abortion and diagnosing and excluding ectopic pregnancy. Second, patients in the study were educated on both the risks of ectopic pregnancy and the slightly elevated risk that medication abortion might not be completely successful very early in pregnancy (thus necessitating follow-up care to complete the abortion), they were told all their options, and *they chose* to proceed. Supporting patients in making decisions that are in accordance with their wishes and medically safe is the hallmark of patient-centered care.

43. Dr. Wheeler also criticizes the St. Paul study's comparison of days to diagnosis for patients who received same-day medication abortion with patients who chose to delay for diagnosis, claiming that the two groups are "incomparable." Wheeler ¶ 73. Dr. Wheeler ignores that serial hCG testing was the main driver to determine days to diagnosis for both groups, rendering them comparable.

44. In the Goldberg study (discussed in my Report, Report ¶ 46), the patients were seen for care at earlier gestational duration than most pregnant are: people who intend to continue their pregnancies are not generally seen for an initial prenatal visit until the eighth week of pregnancy, but people seeking abortion before their pregnancy is visible by ultrasound are necessarily less than five or six weeks into their pregnancy. Comparing the Goldberg study patients who chose medication abortion with those who chose to delay for diagnosis, the Protocol actually led to *earlier* exclusion of ectopic pregnancy than waiting to see whether an intrauterine pregnancy could be diagnosed by ultrasound—directly refuting Dr. Wheeler's assertion that providing medication abortion

to patients with pregnancies of unknown location "may place women at increased risk for complications from undiagnosed ectopic pregnancy, including a delay in diagnosis." Report ¶ 46; Wheeler ¶ 78. Both the St. Paul Study and the Goldberg study showed that early medication abortion is safe for patients who have pregnancies of unknown location who have been screened and determined to be low risk for an ectopic pregnancy.

45. Dr. Wheeler cites a study by Bharadwa et al. for the proposition that "there is no quality published evidence… for differentiating ectopic pregnancy from effective chemical abortion." Wheeler ¶ 75. That misstates the central conclusion of the study, which was that "serial serum hCG testing is an effective means of confirming successful medication abortion and identifying patients who require further follow up due to either an unsuccessful medication abortion or ectopic pregnancy."[48] In other words, the study supports the safety and efficacy of providing medication abortion to patients with pregnancies of unknown location while simultaneously conducting serial hCG testing to exclude ectopic pregnancy, and *refutes* Dr. Wheeler's claims about the Protocol.

46. Dr. Bane incorrectly states that the Protocol is "contraindicated." Bane ¶ 68. Mifeprex is contraindicated for "*confirmed/suspected* ectopic pregnancy,"[49] not for patients who are eligible for medication abortion under the Protocol, who are patients with pregnancies of unknown location who are deemed low risk for ectopic pregnancy—i.e., patients for whom ectopic pregnancy is *not suspected*. Similarly, Dr. Wubbenhorst incorrectly implies that mifepristone is harmful to patients who have an

[48] Sonya Bharadwa et al., *hCG Trends After Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, Contraception (2023).
[49] Def.-Intervenors' Resp. in Opp. to Pls.' Am. Mot. for Prelim. Inj., Ex. 2, DE 65-2.

ectopic pregnancy or who are miscarrying. *See* Wubbenhorst ¶ 230 (stating that because ectopic pregnancy is listed as a contraindication on the mifepristone product labeling, it therefore must be ruled out before using mifepristone). However, although mifepristone is not FDA approved for the *treatment* of an ectopic pregnancy (which is why it is listed as a contraindication), a patient with an ectopic pregnancy will not be harmed by taking mifepristone. Of course, it is still important to identify any patient who has an ectopic pregnancy, which is why the Protocol includes a robust screening process and emphasizes close surveillance and follow up with each patient. Likewise, a patient who is experiencing a miscarriage will not be harmed by mifepristone; in fact, the medication regimen of mifepristone and misoprostol is evidence-based therapy and the standard of care for medical management of miscarriage.

47. Additionally, research has shown that the incidence of ectopic pregnancy diagnosis following medication abortion is extremely low (0.02 percent), indicating that pretreatment screening methods are highly successful.[50] Further, there is absolutely no evidence to suggest that medication abortion treatment increases the rates of complications for women with ectopic pregnancies.[51]

48. Intervenors' witnesses further criticize the Protocol, stating that patients may confuse the symptoms of a ruptured ectopic pregnancy with the effects of medication abortion. Bane ¶ 66; Wheeler ¶¶ 53–54; Wubbenhorst ¶ 212. In my experience, this is extremely unlikely because generally patients with ectopic pregnancy

[50] Caitlin Shannon et al., *Ectopic Pregnancy and Medical Abortion*, 104 Obstetrics & Gynecology 161, 161 (2004).
[51] *Id.*

experience sharp, severe, and typically unilateral lower abdominal pain that differs from the more midline cramping and discomfort that medication abortion patients often experience. Dr. Wubbenhorst also emphasizes a case in which a ruptured ectopic pregnancy took several days to detect in a patient who had self-managed a medication abortion. Wubbenhorst ¶¶ 255–56. Unlike the self-managed abortion scenario, the Protocol includes patient education about what to expect during a medication abortion, description of the signs and symptoms associated with ectopic pregnancy and detailed information about what signs or symptoms should prompt immediate evaluation in an emergency department, and close follow up with patients to ensure that the abortion was completed. It is my understanding that PPSAT also has an emergency helpline that patients can call if they have questions or are concerned about their symptoms.

49. Dr. Bane cites the 2018 ACOG Bulletin to support her position that ultrasounds are required for ectopic evaluation. Bane ¶ 65. My understanding is that PPSAT complies with North Carolina's legal requirement that abortion patients receive ultrasounds, *see supra* ¶ 37, but I nevertheless disagree with Dr. Bane's position. The Bulletin states that "the minimum diagnostic evaluation of a *suspected* ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."[52] I agree—if an ectopic pregnancy is suspected, ultrasonography is required to ultimately determine the location of the pregnancy. However, a pregnancy of unknown location is *not* a suspected ectopic. If a patient is determined to be low risk—i.e., an ectopic pregnancy is *not*

[52] Comm. on Practice Bulletins–Gynecology, *ACOG Practice Bulletin No. 191: Tubal Ectopic Pregnancy*, 131 Obstetrics & Gynecology e65, e66 (2018) (emphasis added).

suspected—then ultrasound confirmation of an intrauterine pregnancy is not required before administration of medication abortion in accordance with the Protocol.

50. The safety of my patients is my top priority. As research and my personal experience have shown, with the proper protocol, counseling, surveillance, and follow-up, medication abortion may be safely and effectively administered to low-ectopic-risk patients with pregnancies of unknown location who prefer that method of treatment. Thus, there is no medical reason to require the confirmation of an intrauterine pregnancy before administering medication abortion.

51. In fact, the IUP Documentation Requirement actively causes harm to patients. Dr. Wubbenhorst downplays the negative impact that the IUP Documentation Requirement has on patients, stating that embryonic "cardiac activity…can be seen as early as 5 weeks gestation," that ultrasound imaging can confirm an IUP "at about 6 weeks, 2 days' gestation," and that "most intrauterine pregnancies are visible by 8 weeks." Wubbenhorst ¶¶ 196–198. Dr. Wubbenhorst ignores that patients might have physical, emotional, financial, and/or logistical reasons for wanting to have their abortions as soon as possible. She also ignores that early gestational limits on abortion make the need for prompt access to abortion care of the utmost importance.

52. Forcing PPSAT to deny medication abortion to low risk patients who have pregnancies of unknown location will not lead to the earlier detection of any ectopic pregnancy; in fact, it might delay it, since there is no way to guarantee that those patients will seek medical care elsewhere. Turning patients away is what causes "fragmented care," *id.* ¶ 237, not treating them and keeping them under medical supervision according

to the Protocol. Further, Dr. Wheeler's statement that there is "no clinical urgency nor clinical benefit" to providing medication abortion according to the Protocol, Wheeler ¶ 64, is not patient-centered and ignores the lived experience of patients and the myriad of reasons they have for strongly preferring medication abortion without delay. *See* Report ¶ 43. Patients with pregnancies of unknown location are counseled on the risk, highlighted by Dr. Wheeler, that medication abortion may not successfully terminate a pregnancy and follow-up care might therefore be needed. Wheeler ¶ 79. Many of them still choose medication abortion, and since it is a safe and evidence-based care option, it should remain available to them without unnecessary delay.

Dated: January 8, 2024

Signed: _____

Christy M. Boraas Alsleben, M.D., M.P.H.

EXHIBIT A

CURRICULUM VITAE FOR PROMOTION AND TENURE

CHRISTY M. BORAAS, M.D., M.P.H
United States

PROFESSIONAL ADDRESS

Address M Health Fairview Women's Clinic
606 24th Avenue South, Suite 300
Minneapolis, MN 55454
Telephone [redacted]
FAX [redacted]
Email [redacted]

Address Planned Parenthood North Central States
671 Vandalia Street
St. Paul, MN 55114
1200 Lagoon Avenue
Minneapolis, MN 55408
Telephone [redacted]
FAX [redacted]
Email [redacted]

IDENTIFYING INFORMATION

Education

Degree	**Institution**	**Date Degree Granted**
B.A.	St. Olaf College, Northfield, MN *Biology and English, magna cum laude*	2001
	University of Pittsburgh, Pittsburgh, PA *Semester at Sea Study Abroad Program*	Fall 2000
M.P.H.	University of Minnesota School of Public Health, Minneapolis, MN *Epidemiology*	2004
M.D.	University of Minnesota Medical School, Minneapolis, MN *With Honors*	2008
Residency in Obstetrics and Gynecology	The Ohio State University Medical Center, Columbus, OH	07/2008-06/2012
Fellowship in Family Planning	Magee-Womens Hospital, University of Pittsburgh, Pittsburgh, PA	07/2012-07/2014
Certificate in Clinical Research	Institute for Clinical Research Education, University of Pittsburgh, Pittsburgh, PA	07/2012-07/2014

Fellowship in Reproductive Health Advocacy	Leadership Training Academy, Physicians for Reproductive Health, New York, NY	07/2013-06/2014

Certifications

Fellow, American Board of Obstetrics and Gynecology (#9028922) 2017-present

Licenses

Medical Physician and Surgeon, Minnesota (#58304) 2014-present

Medical Physician and Surgeon, Pennsylvania (#MD445822) 2012-2014

Academic Appointments

University of Minnesota Minnesota Population Center
Faculty Member 2019-present

University of Minnesota Medical School, Twin Cities (2016-2022)
Center for Global Health and Social Responsibility
Associate Global Health Faculty 2016-present

University of Minnesota Medical School, Twin Cities (2015-2022)
Department of Obstetrics, Gynecology and Women's Health
Assistant Professor 2015-present

Department of Obstetrics, Gynecology and Reproductive Sciences
University of Pittsburgh School of Medicine, Pittsburgh, PA
Clinical Instructor 2012-2014

University of Pittsburgh School of Medicine, Pittsburgh, PA
Center for Family Planning Research
Investigator 2012-2014

Academic Administrative Appointments

University of Minnesota Medical School, Twin Cities
Ryan Residency Training Program in Abortion and Family Planning
Director 2015-present

University of Minnesota Medical School, Twin Cities
Fellowship in Family Planning (ACGME approval pending)
Director 2015-present

Planned Parenthood Minnesota, South Dakota, North Dakota, St. Paul, MN
Director of Obstetrics and Gynecology Resident Education 2014-present

The Ohio State University, Columbus, OH
Department of Obstetrics and Gynecology
Chief Administrative Resident 2011-2012

Clinical/Hospital Appointments

M Health Fairview Women's Clinic, Minneapolis, MN
Staff Physician 2015-present

University of Minnesota Medical Center, Minneapolis, MN
Staff Physician 2014-present

Planned Parenthood Minnesota, South Dakota, North Dakota, St. Paul, MN
Associate Medical Director 2014-present
Director of Research 2014-present

Whole Woman's Health Twin Cities, Minneapolis, MN
Staff Physician 2014-present

Planned Parenthood of Western Pennsylvania, Pittsburgh, PA
Staff Physician 2012-2014

Consulting Positions

ViiV Healthcare 2022-present

American College of Obstetricians and Gynecologists, Optimizing Care for Pregnancy Loss (OCPL) Program Trainer 2021-present

American College of Obstetricians and Gynecologists, Implementing Progress in Abortion Care and Training (IMPACT) Trainer 2021-present

University of Global Health Equity, Rwanda 2020-present

American College of Obstetricians and Gynecologists, Immediate Postpartum Long-Acting Reversible Contraception Trainer 2018-present

Minnesota Department of Health 2017-present

Basic Health International 2014-present

American Refugee Committee International 2013-present

Current Membership and Offices in Professional Organizations

Member, Consortium of Abortion Providers Abortion Equity Cohort 2021-2023

Member, Education Committee, Fellowship in Complex Family Planning 2020-present

Minnesota Public Health Association (MPHA)
Member 2018-present
Member, MPHA Global Health Committee 2018-present

Society of Family Planning (SFP) (2015-2022)
Member, Finance Committee 2021-present

Member, Research Implementation Special Interest Group	2021-present
Junior Fellow	2012-present
Member, Program Committee	2019-2020
Member, Annual Meeting Session Working Group	2019
Member, Audit Committee	2015-2018
Minnesota Medical Association (MMA) (2014-2022)	
Chair, Abortion Policy Work Group	2021-2023
Member, Policy Council	2017-2023
Member	2014-present
Member, Medical Practice and Quality Committee	2014-2018
Minnesota section of ACOG (MN ACOG) (2014-2022)	
Member, Annual Meeting Planning Committee	2021-present
Member, Advisory Council	2019-present
Member	2014-present
Member, Legislative Committee	2014-present
Member, Association of Professionals of Gynecology and Obstetrics (APGO)	2014-present
Member, Physicians for Reproductive Health	2010-present
American Congress of Obstetricians and Gynecologists (ACOG) (2008-2022)	
Fellow	2017-present
Junior Fellow	2008-2017
Member, Academy of Breastfeeding Medicine	2013-2016
Member, Association of Reproductive Health Professionals	2009-2016

Visiting Professorships or Visiting Scholar Positions

American Refugee Committee International	
Ban Don Yan Refugee Camp, Sangkhlaburi, Thailand	
Family Planning Specialist	2013
Kilimanjaro Christian Medical Center, Moshi, Tanzania	
Clinical Instructor in Obstetrics and Gynecology	2011
Pro-Link Organization, Accra, Ghana	
Reproductive Health Epidemiologist	2003

HONORS AND AWARDS FOR RESEARCH, TEACHING, PUBLIC ENGAGEMENT AND SERVICE

University of Minnesota

Gold Humanism Honor Society	2007-2008
Medical School Basic Science Overall Top Honors (Top 20%)	2006
Student Research Grant, Minnesota Medical Foundation	2005

Walter H. Judd Fellowship in Global Health	2003, 2007

External Sources

UMP Clinical Excellence Award	2022, 2023
Top Doctor, Minnesota Monthly Magazine	2018, 2021, 2022, 2023
Rising Star, Mpls St. Paul Magazine	2021
David E. Rogers Fellowship	2005
Phi Beta Kappa	2001
St. Olaf College Biological Honor Society	2001
Semester at Sea Dean's List	2000

RESEARCH AND SCHOLARSHIP

Grants and Contracts

External Sources

Current

1. Role: Co-Investigator
   PI: Sharon Allen, MD, PhD
   Grant Number: 5R01DA047287
   External Agency: National Institutes of Health
   Grant Title: Bupropion for the Prevention of Postpartum Smoking Relapse
   Project Dates: 09/01/18-08/30/23
   Total costs: $2,372,039
   Direct costs/year: $440,350
   % Effort/salary support: 5%

2. Role: Co-Investigator
   Principal Investigator: Alison Ojanen-Goldsmith
   External Agency: Male Contraceptive Initiative
   Grant Title: Acceptability, preferences, and values related to contraception for people who produce sperm
   Project Dates: 12/01/20-11/30/22
   Total costs: $150,000
   Direct costs/year: $71,442.50
   Funded salary support: 1%

3. Role: Site Principal Investigator
   External Agency: Mayo Clinic
   Grant Title: Validation study of self-collected rectal and pharyngeal swabs for Chlamydia and Gonorrhea testing
   Project Dates: 10/01/21 - 10/01/22
   Direct costs/year: $34,793.94
   Funded salary support: 1%

4. Role: Site Principal Investigator

External Agency: Gynuity Health Projects
Grant Title: Medication Abortion with Autonomous Self-Assessment
Submitted: November 2021
Project Dates: 03/01/2022-02/28/2023
Total costs: $34,345.84
Direct costs/year: $25,759.38
Funded salary support: 1%

Pending

1. Role: Site Principal Investigator
   External Agency: Gynuity Health Projects
   Grant Title: Extending outpatient medical abortion in the late first trimester of pregnancy
   Submitted: September 2020
   Project Dates: 10/01/22-TBD
   Total costs: TBD
   Direct costs/year: TBD
   Funded salary support: 1%

Completed

1. Role: Site Principal Investigator
   External Agency: University of Pennsylvania
   Grant Title: Development of an implementation strategy to integrate HIV pre-exposure prophylaxis into family planning care
   Project Dates: 11/01/21 - 11/01/22
   Total costs: not applicable
   Direct costs/year: not applicable
   Funded salary support: 1%

2. Role: Site Principal Investigator
   Principal Investigator: Elizabeth Raymond, MD
   External Agency: Gynuity Health Projects
   Grant Title: Feasibility of Medical Abortion by Direct-to-Consumer Telemedicine.
   Project Dates: 09/01/19-11/01/21
   Total costs: $85,000
   Direct costs/year: $63,750
   Funded salary support: 1%

3. Role: Co-Investigator
   PI: Rebecca Shlafer, PhD
   Grant Number: 5R03HD093961
   External Agency: National Institutes of Health
   Grant Title: Efficacy and Cost-Effectiveness of Doula Care for Incarcerated Pregnant Women
   Project Dates: 07/01/17 - 06/30/20
   Total cost: $154,000
   Direct costs/year: $50,000
   Funded salary support: 10%

4. Role: Co-investigator

Principal Investigator: Vivian Bardwell, PhD
Grant Number: 5R01HD084459
External Agency: National Institutes of Health
Grant Title: Control of Trophoblast Differentiation in Placental Development
Project Dates: 03/01/16-01/01/18
Total costs: $1,424,260
Direct costs/year: $215,463
Funded salary support: 0%

5. Role: Site Principal Investigator
Principal Investigator: Ilana Dzuba, MHSc.
External Agency: Gynuity Health Projects
Grant Title: Non-surgical alternatives to treatment of failed medical abortion: A randomized controlled double-blind trial.
Project Dates: 03/01/17-01/31/18
Total costs: $24,000
Direct costs/year: $18,000
Funded salary support: 1%

6. Role: Principal Investigator
External Agency: William and Flora Hewlett Foundation
Grant Title: Quantifying contraceptive failure with unprotected intercourse 6-14 days prior to contraceptive initiation.
Project Dates: 11/01/16-08/30/18
Total costs: $63,000
Direct costs/year: $50,400
Funded salary support: 10%

7. Role: Site Principal Investigator
External Agency: Gynuity Health Projects
Grant Title: Simplified Medical Abortion Screening: A Pilot Demonstration Project
Project Dates: 08/01/16-01/31/17
Total: $24,000
Direct costs/year: $19,200
Funded salary support: 1%

8. Role: Principal Investigator
External Agency: Society of Family Planning Research Fund
Grant Title: Quick start levonorgestrel intrauterine contraceptive initiation in the setting of unprotected intercourse: a pilot study.
Project Dates: 02/01/14-12/31/15
Total costs: $30,000
Direct costs/year: $24,000
Funded salary support: 5%

9. Role: Principal Investigator
External Agency: Society of Family Planning Research Fund
Grant Title: Dilapan-S with Adjunctive Misoprostol for Same-day Second Trimester

Dilation and Evacuation: A Randomized, Double-Blind, Placebo-Controlled Trial
Project Dates: 06/01/13-07/31/14
Total costs: $70,000
Direct costs/year: $56,000
Funded salary support: 10%

Business and Industry (Clinical) Trials

Current

1. Role: Site Principal Investigator
   External Agency: Quidel Ortho Corporation
   Title: Savanna HVT Validation Study
   Submitted: May 2023
   Project Dates: 11/01/2023-10/31/2024
   Total cost: $198,373.50
   Direct costs/year: $61,200
   Funded salary support: 1%

2. Role: Site Principal Investigator
   External Agency: BD
   Title: IDS-QSCTGCClinicalStudy Clnical Validation of the BD Elience POC CT/GC Assay
   Submitted: March 2023
   Project Dates: 11/01/23-05/01/24
   Total cost: $282,717.50
   Direct costs/year: $241,540.00
   Funded salary support: 1%

3. Role: Site Principal Investigator
   External Agency: Sebela, Inc.
   Title: A Phase 3, Prospective, Multi-Center, Single-Arm, Open-Label Study to Evaluate VeraCept®, a Long-Acting Reversible Intrauterine Contraceptive for Contraceptive Efficacy, Safety, and Tolerability.
   Submitted: March 2017
   Project Dates: 10/01/18-06/01/24
   Total cost: $1,165,751
   Direct costs/year: $124,901.89
   Funded salary support: 1%

4. Role: Site Principal Investigator
   External Agency: Merck, Inc.
   Title: A Phase 3, Open-Label, Multi-Center, Single Arm Study to Assess Contraceptive Efficacy and Safety of the Etonogestrel (MK-8415) Implant during Extended Use Beyond 36 months from Insertion in Premenopausal Females up to 35 years of age.
   Submitted: June 2020
   Project Dates: 12/01/20-11/30/22
   Total costs: $761,364
   Direct costs/year: $266,477.40
   Funded salary support: 1%

5. Role: Site Principal Investigator
   External Agency: Visby Medical
   Title: Clinical Evaluation of Visby Medical Personal PCR Women's Sexual Health Test for the Detection of Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), and Trichomonas vaginalis (TV) Using Self-Collected Vaginal Swabs.
   Submitted: Jan 2023
   Project Dates: 03/01/23-03/01/24
   Direct costs/year: $124,500
   Funded salary support: 1%

6. Role: Site Principal Investigator
   External Agency: Becton Dickinson
   Title: Clinical Validation of the BD Elience™ POC CT/GC Assay
   Submitted: July 2023
   Project Dates: 10/01/23-10/01/24
   Direct costs/year: $135,200
   Funded salary support: 1%

Pending

1. Role: Site Principal Investigator
   External Agency: PRA Health Sciences, Inc.
   Title: A Phase 3, Prospective, Multi-Center, Single-Arm, Open-Label Study to Evaluate LevoCept™, a Long-Acting Reversible Intrauterine System (IUS) for Contraceptive Efficacy, Safety, and Tolerability.
   Submitted: May 2020
   Project Dates: 01/01/22-12/31/29
   Total Costs: TBD
   Direct costs/year: TBD
   Funded salary support: TBD

Completed

1. Role: Site Principal Investigator
   External Agency: Roche Molecular Systems, Inc.
   Title: Prospective Women's Health Sample Collection_RMS_BAM
   Submitted: Feb 2023
   Project Dates: 01/01/23-10/31/23
   Direct costs/year: $96,817
   Funded salary support: 1%

2. Role: Site Principal Investigator
   External Agency: Roche Molecular Systems, Inc.
   Title: cobas® CT/NG/MG Nucleic acid test for use on the cobas® Liat® System: Clinical Performance Evaluation
   Submitted: Nov 2022
   Project Dates: 01/01/23-09/30/23
   Direct costs/year: $229,687
   Funded salary support: 1%

3. Role: Site Principal Investigator
   External Agency: Cepheid
   Title: 248C3: Clinical Evaluation of the Xpert Xpress CT/NG Test in Female Extragenital Specimens
   Submitted: July 2022
   Project Dates: 10/01/22-04/30/2023
   Total costs: $149,349.50
   Direct costs/year: $104,544.65
   Funded salary support: 1%

4. Role: Site Principal Investigator
   External Agency: Beckman Coulter, Inc.
   Title: Access HBV Serological Markers Subject Enrollment US Protocol, Access HCV AB Assay Subject Enrollment US Protocol, Access HIV AG/AB Combo Assay US Enrollment Protocol
   Submitted: October 2021
   Project Dates: 11/01/21-11/01/22
   Total Costs: $828,281.25
   Direct costs/year: $621,210.94
   Funded salary support: 1%

5. Role: Site Principal Investigator
   External Agency: EvoFem Biosciences
   Title: Phase 3 double-blind placebo-controlled efficacy trial of EVO100 vaginal gel for the prevention of urogenital Chlamydia trachomatis and Neisseria gonorrhea infection
   Submitted: July 2020
   Project Dates: 10/21/20-10/21/22
   Total costs: $279,977.50
   Direct costs/year: $193,692.50
   Funded salary support: 1%

6. Role: Site Principal Investigator
   External Agency: Abbott Molecular, Inc.
   Title: Alinity m HR HPV Specimen Collection Study from Women Referred to Colposcopy
   Submitted: May 2021
   Project Dates: 05/01/21-05/01/22
   Total costs: $240,000
   Direct costs/year: $168,000
   Funded salary support: 1%

7. Role: Site Principal Investigator
   External Agency: Cepheid
   Title: Clinical Evaluation of the Xpert Xpress CT/NG Test in Female Urogenital Specimens
   Submitted: April 2020
   Project Dates: 04/28/20-4/28/21
   Direct costs/year: $50,000
   Funded salary support: 1%

8. Role: Site Principal Investigator
   External Agency: Cepheid

Title: Pre-Clinical Evaluation of the Xpert Xpress CT/NG Test
Submitted: April 2019
Project Dates: 07/08/19-10/30/19
Direct costs/year: $28,475
Funded salary support: 1%

9. Role: Site Principal Investigator
   External Agency: Visby Medical (Click Dx)
   Title: Clinical Evaluation of the Click Sexual Health Test for the Detection of Neisseria gonorrhoeae, Trichomonas vaginalis, and Chlamydia trachomatis in Women.
   Submitted: July 2019
   Project Dates: 09/19/19-12/30/19
   Direct costs/year: $28,650
   Funded salary support: 1%

10. Role: Site Principal Investigator
    External Agency: Abbott (Alere) San Diego
    Title: Alere hCG Test Method Comparison Study.
    Submitted: February 2019
    Project Dates: 03/15/19-07/30/19
    Direct costs/year: $55,050
    Funded salary support: 5%

11. Role: Site Principal Investigator
    External Agency: HRA Pharma
    Title: Multi-Center Study to Test the Comprehension of the Ovrette® OTC Drug Facts Label
    Project Dates: 10/01/16-01/31/17
    Direct costs/year: $8,450
    Funded salary support: 1%

12. Role: Site Principal Investigator
    External Agency: Hologic, Inc.
    Title: Prospective Collection and Testing of Lesion Specimens for the Development of a Herpes Simplex Virus Assay.
    Project Dates: 10/01/14-07/31/16
    Direct costs/year: $30,300
    Funded salary support: 1%

University of Minnesota Sources

Current

1. Role: Co-Principal Investigator
   Principal Investigator: Karen Borchert, MD
   Internal Agency: University of Minnesota Medical School, Department of Family Medicine
   Title: Pregnancy of Unknown Location in Abortion Care: Management and Outcomes.
   Project Dates: 01/01/17-12/31/22
   Direct costs/year: non-applicable

Completed

1. Role: Principal Investigator
   Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology and Women's Health Progressive Grant, Phase II
   Title: Identifying predictors of post-abortion contraceptive uptake using a comprehensive, multisite database
   Project Dates: 07/01/20-06/30/22
   Direct Costs/Year: $20,000
   Funded salary support: 0%

2. Role: Principal Investigator
   Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology and Women's Health Research Support Grant
   Title: Quantifying contraceptive failure with unprotected intercourse 6-14 days prior to contraceptive initiation
   Project Dates:01/01/17-6/30/21
   Total Cost: $3,500
   Funded salary support: 0%

3. Role: Principal Investigator
   Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology and Women's Health Research Support Grant
   Title: Contrasperm: the Future of Male Birth Control
   Project Dates: 08/01/19-07/31/20
   Total Cost: $4,500
   Funded salary support: 0%

4. Role: Principal Investigator
   Internal Agency: University of Minnesota Medical School, Department of Obstetrics, Gynecology and Women's Health Progressive Grant, Phase I
   Title: Identifying predictors of post-abortion contraceptive uptake using a comprehensive, multisite database
   Project Dates: 08/01/19-07/31/20
   Total cost: $10,000
   Funded salary support: 0%

Publications

Impact Analytics

***h*-Index**	***h(fl)*-Index**	**Total Publications**	**First/Last Author Publications**	**Total Citations**	**First/Last Author Citations**
8	**2**	**18**	**6**	**231**	**18**

Publication #1-2 not yet in Manifold

Peer-Reviewed Publications

1. Wise MK, Okuyemi O, Flint M, Biscaye EM, Tessier KM, Traxler SA, **Boraas CM**. Intrauterine Device Placement Success for Adolescents and Young Adults at Community-based

Reproductive Health Clinics. J Pediatr Adolesc Gynecol. 2023 Dec 8:S1083-3188(23)00451-5. doi: 10.1016/j.jpac.2023.11.013. Online ahead of print.
Impact Factor: 2.298; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

2. Raymond EG, Frye LJ, Tocce K, Gingras S, Almquist A, Firstenberg A, Ortega C, Blumenthal PD, Winikoff B, **Boraas C.** Evaluation of a "smart" screening tool for asynchronous assessment of medication abortion eligibility: A pilot study. Contraception. 2023 Nov 20:110340. doi: 10.1016/j.contraception.2023.110340. Online ahead of print.
Impact Factor: 2.335; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

3. Hassan A, Ojanen-Goldsmith A, Hing A, Mahoney M, Traxler SA, **Boraas CM**. More than tears: associations between exposure to chemical agents used by law enforcement and adverse reproductive health outcomes. Front. Epidemiol. Sec. Occupational and Environmental Epidemiology. 2023 Aug 23:3 - 2023. https://doi.org/10.3389/fepid.2023.1177874 https://www.frontiersin.org/articles/10.3389/fepid.2023.1177874/full
Impact Factor: n/a; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

4. Martins SL, **Boraas CM.** Willingness to use novel reversible methods of male birth control: a community-based survey of cisgender men in the United States. Contracept Reprod Med. 2023 Aug 10;8(1):41. doi: 10.1186/s40834-023-00242-y.
Impact Factor: 2.9; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

5. Borchert K, Thibodeau C, Varin P, Wipf H, Traxler S, **Boraas CM.** Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study. Contraception. 2023 Jun;122:109980. doi:10.1016/j.contraception.2023.109980.
Impact Factor: 2.335; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

6. Koenig LR, Raymond EG, Gold M, **Boraas CM**, Kaneshiro B, Winikoff B, Coplon L, Upadhyay UD. Mailing abortion Pills does not delay care: a cohort study comparing mailed to in-person dispensing of abortion medications in the United States. Contraception. 2023 Jun;122:109962. doi: 10.1016/j.contraception.2023.109962.
Impact Factor: 2.335; Times Cited: 0; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

7. Groene EA*, **Boraas CM**, Smith MK, Lofgren SM, Rothenberger MK, Enns EA. Evaluation of Strategies to Improve Uptake of Expedited Partner Therapy for *Chlamydia trachomatis* Treatment in Minnesota: A Decision Analytic Model. MDM Policy Pract. 2023 Jan 22;8(1):23814683221150446. doi: 10.1177/23814683221150446. eCollection 2023 Jan-Jun.

Impact Factor: 1.54; Times Cited: 0; Role: Developed study concept and design, defined intellectual content, conducted data acquisition, manuscript preparation, editing and review.

8. Groene EA*, **Boraas CM**, Smith MK, Lofgren SM, Rothenberger MK, Enns EA. A statewide mixed-methods study of provider knowledge and behavior administering Expedited Partner Therapy for chlamydia and gonorrhea. Sex Transm Dis. 2022 Jul 3. doi: 10.1097/OLQ.0000000000001668.
Impact factor: 3.686; *Times Cited: 0; Role: Protocol creation, manuscript preparation, editing and review.*

9. Ralph JA, Westberg SM, **Boraas CM**, Terrell CA, Fischer JR. PrEP-aring the General Gynecologist to Offer HIV Pre-exposure Prophylaxis. Clin Obstet Gynecol. 2022 Jun 16. doi: 10.1097/GRF.0000000000000713. Online ahead of print.
Impact factor: 1.619; Times Cited: 0; Role: manuscript preparation, editing and review.

10. Henke L*, Martins S*, **Boraas CM**. Associations Between Income Status and Perceived Barriers to Using Long-Acting Reversible Contraception: An Exploratory Study. Front Reprod Health, 12 April 2022. https://doi.org/10.3389/frph.2022.856866
Impact factor: NA; Times Cited: 0: Role: Protocol creation, data acquisition, manuscript preparation, editing and review.

11. Upadhyay UD, Raymond EG, Koenig LR, Coplon L, Gold M, Kaneshiro B, **Boraas CM**, Winikoff B. Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study. JAMA Intern Med. 2022 Mar 21. Online ahead of print.
impact factor: 44.41; Times Cited: 26; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

12. Anger HA, Raymond EG, Grant M, Haskell S, **Boraas C**, Tocee K, Banks J, Coplon L, Shochet T, Platais I, Winikoff B. Clinical and service delivery implications of omitting ultrasound before medication provided abortion via direct-to-patient telemedicine and mail. Contraception. 2021 Dec;104(6):659-665. doi: 10.1016/j.contraception.2021.07.108. Epub 2021 Jul 28.
Journal Impact Factor: 2.335; Times Cited: 8; Role: Protocol editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

13. Chong E, Shochet T, Raymond E, Platais I, Anger HA, Raidoo S, Soon R, Grant MS, Haskell S, Tocce K, Baldwin MK, **Boraas CM**, Bednarek PH, Banks J, Coplon L, Thompson F, Priegue E, Winikoff B. Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Contraception. 2021 Jul;104(1):43-48. doi: 10.1016/j.contraception.2021.03.019. Epub 2021 Mar 27.
Journal Impact Factor: 2.335; Times Cited: 50; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

14. **Boraas CM**, Sanders JN, Schwarz EB, Thompson I, Turok DK. Risk of Pregnancy With Levonorgestrel-Releasing Intrauterine System Placement 6-14 Days After Unprotected Sexual Intercourse. Obstet Gynecol. 2021 Apr 1;137(4):623-625.

Journal Impact Factor: 4.982; Times Cited: 0; Role: Protocol review and editing, grant writing and submission, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

15. Raymond EG, Anger HA, Chong E, Haskell S, Grant M, **Boraas C**, Tocce K, Banks J, Kaneshiro B, Baldwin MK, Coplon L, Bednarek P, Shochet T, Platais I. "False positive" urine pregnancy test reults after successful medication abortion. Contraception. 2021 Jun;103(6):400-403. doi: 10.1016/j.contraception.2021.02.004. Epub 2021 Feb 14.
Journal Impact Factor: 2.335; Times Cited: 0; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

16. Schlafer R, Saunders JB, **Boraas CM**, Kozhimannil KB, Mazumder N, Freese R. Maternal and neonatal among incarcerated women who gave birth in custody. Birth. 2021 Mar;48(1):122-131. doi: 10.1111/birt.12524. Epub 2020 Dec 27.
Impact factor 3.689; Times cited 6; Role: Developed study concept and design, defined intellectual content, manuscript preparation, editing and review.

17. Thompson I, Sanders JN, Schwarz EB, **Boraas C,** Turok DK. Copper intrauterine device placement 6-14 days after unprotected sex. Contraception. 2019 Sep;100(3):219-221. doi: 10.1016/j.contraception.2019.05.015. Epub 2019 Jun 7.
Impact factor 2.335; Times cited 10; Role: Protocol review and editing, grant writing and submission, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

18. Raymond EG, Tan YL, Comendant R, Sagaidac I, Hodorogea S, Grant M, Sanhueza P, Van Pratt E, Gillespie G, **Boraas C**, Weaver MA, Platais I, Bousieguez M, Winikoff B. Simplified medical abortion screening: a demonstration project. Contraception. 2018 Apr;97(4):292-296. doi: 10.1016/j.contraception.2017.11.005. Epub 2017 Nov 21. PMID: 29170088
Impact factor 2.335; Times cited 27; Role: Protocol review and editing, site administration of multicenter trial, data acquisition, manuscript preparation, editing and review.

19. **Boraas CM**, Chappell CA, Krajewski CM. Use of an Endotracheal Tube for Surgical Abortion Complicated by a Leiomyomatous Uterus: A Case Report. J Med Case Rep. 2017 August 25;11(1):236. doi: 10.1186/s13256-017-1408-y. PMID: 28838323.
Impact factor 1.07; *Times cited 1; Role: Developed case report design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.*

20. Paul J*, **Boraas CM**, Duvet M*, Chang JC. YouTube and the single-rod contraceptive implant: a content analysis. J Fam Plann Reprod Health Care. 2017 Jul;43(3):195-200. doi: 10.1136/jfprhc-2016-101593. Epub 2017 Jan 20. PMID: 28108504. *Impact factor 2.151, Times cited 15; Role: Developed study concept and design, defined intellectual content, manuscript preparation, editing and review.*

21. **Boraas CM**, Achilles SL, Cremer ML, Chappell CA, Lim SE, Chen BA. Synthetic osmotic dilators with adjunctive misoprostol for same-day dilation and evacuation: a randomized controlled trial. Contraception. 2016 Nov;94(5):467-472. PMID: 27241895.

Impact factor 2.335; Times cited 11; Role: Developed study concept and design, defined intellectual content, conducted literature search, data acquisition, manuscript preparation, editing and review.

22. Rapkin RB, Achilles SL, Schwarz EB, Meyn L, Cremer M, **Boraas CM**, Chen BA. Self-Administered Lidocaine Gel for Intrauterine Device Insertion in Nulliparous Women: A Randomized Controlled Trial. Obstet Gynecol. 2016 Sep;128(3):621-8. doi: 10.1097/ACOG.0000000000001596. PMID: 27500351. *Impact factor 4.982; Times cited 30; Role: Defined intellectual content, data acquisition, manuscript preparation, editing and review.*

23. Akinsete OO, Sides T, Hirigoyen D, Cartwright C, **Boraas C**, Davey C, Pessoa-Brandao L, McLaughlin M, Kane E, Hall J, Henry K. Demographic, clinical, and virologic characteristics of African-born persons with HIV/AIDS in a Minnesota hospital. AIDS Patient Care STDS. 2007 May;21(5):356-65. PMID: 17518528.
Impact factor 5.944; Times cited 37; Role: Data acquisition, manuscript preparation, editing and review.

Non-Peer-Reviewed Publications

1. Martins SL*, **Boraas CM.** Contraceptive counseling: an essential travel medicine service. J Travel Med. 2020 Jul 14;27(4):taaa023. doi: 10.1093/jtm/taaa023
Role: Commentary preparation, editing and review.

2. Miller KK*, Gewirtz O'Brien JR*, Sajady M, Argo T*, Chaisson N, **Boraas C.** Long Acting Reversible Contraception (LARCs): Beyond Birth Control. Minnesota Pediatrician monthly newsletter, February 2020. Available at: http://www.mnaap.org/long-acting-reversible-contraceptives-larcs-beyond-birth-control/
Role: Manuscript preparation, editing and review.

3. **Boraas CM**, Schwarz EB. Contraceptive Choice for Women with Obesity. Gynecology Forum. 2012 May;17(4):20-3.
Role: Developed review design, conducted literature search, manuscript preparation, editing and review.

Chapters in Books

1. Ralph JA and **Boraas CM.** Surgical Abortion Complications. In Press. Major Complications of Female Pelvic Surgery: A Multidisciplinary Approach. Hoffman M, Bochner B, and Hull T, eds., Springer Nature Publishing, Berlin, Germany.
Role: Author

2. **Boraas CM.** A 32-Year-Old HIV-positive woman requesting IUD. 2019. *Office Gynecology: A Case-Based Approach, First Edition;* Chelmow D, Karjane N, Ricciotti H, Young A, eds., Cambridge University Press, New York, NY.
Role: Author

3. **Boraas CM** and Keder LM. Intrauterine Contraception Insertion and Removal. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh W and Kim K, eds., McGraw Hill Professional, New York, NY.

Role: Author

4. **Boraas CM** and Keder LM. Contraceptive Implant Insertion and Removal. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh, W. and Kim, K., eds, McGraw Hill Professional, New York, NY.
Role: Author

5. **Boraas CM** and Keder LM. Female Sterilization. In Press. *Atlas of Pelvic Surgery and Anatomy, First Edition*; Huh, W. and Kim, K., eds, McGraw Hill Professional, New York, NY.
Role: Author

Presentations

Invited Oral Presentations at International Professional Meetings, Conferences, etc.

1. **Boraas CM,** Nardos R, Ghebre R, Pace S, Chojnacki M. Obstetrics and Gynecology Medicine Panel. University of Minnesota Global Health Course. May 6, 2021. Virtual.
2. **Boraas CM.** Current Contraception Overview. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.
3. **Boraas CM.** Long-Acting Reversible Contraception – Implants. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.
4. **Boraas CM.** Long-Acting Reversible Contraception - Intrauterine Devices. American Refugee Committee Staff Development Conference. March 18-26, 2013. Sangkhlaburi, Thailand.

Invited Oral Presentations at National Professional Meetings, Conferences, etc.

1. **Boraas CM.** Asynchronous Medication Abortion: The MA-ASAP Research Study. Planned Parenthood Federation of America Maximizing Abortion Access Meeting. April 4, 2023. Minneapolis, MN.
2. **Boraas CM.** Asynchronous Medication Abortion: The MA-ASAP Research Study. Planned Parenthood Federation of America Medical Directors Council Annual Meeting. November 11, 2022. Tuscon, AZ.
3. **Boraas CM**, Ojanen-Goldsmith A, Torgrimson-Rojerio B, Hassan A*. Time for Action: The impact of tear gas used by law enforcement on reproductive health. Society of Family Planning Annual Meeting. October 12, 2021. Virtual.
4. **Boraas CM**. Merck Nexplanon Extension Trial, Site Tips and Tricks. MK-8415-060 Lessons Learned – Recruitment and Retention Meeting. May 5, 2021. Virtual.
5. **Boraas CM** and Rapkin RB. Surgical Miscarriage Management in the Office: You Can Do It. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.
6. **Boraas CM**, Kaneshiro B, Raymond E, Grant M. No Test Medical Abortion. Society of Family Planning Webinar. January 6, 2021. Virtual.

7. Borchert K, Wipf H*, Roeske E*, Clure C*, Traxler S, **Boraas CM.** Pregnancy of Unknown Location in Abortion Care: Management and Outcomes. National Abortion Federation Conference. April 2018. Seattle, WA.

8. **Boraas CM.** Interviewing Basics. Fellowship in Family Planning Career Development Workshop. July 23-24, 2017. Chicago, IL.

9. **Boraas CM.** Searching for a Position. Fellowship in Family Planning Career Development Workshop. July 23-24, 2017. Chicago, IL.

10. **Boraas CM** and Rapkin RB. Surgical Miscarriage Management in the Office: You Can Do It. ACOG Annual Clinical Meeting. May 7, 2017. San Diego, CA.

Invited Oral Presentations at Local and Regional Professional Meetings, Conferences, etc.

1. **Boraas, CM.** Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. November 13, 2023. Minneapolis, MN.
2. **Boraas, CM.** Satin, D. Janoski, E. Clinician responsibilities and vulnerabilities in the face of ethical and legal controversy. University of Minnesota Law 6854 Law, Biomedicine & Bioethics course. November 7, 2023. Minneapolis, MN.

3. **Boraas CM,** Hutto SL**.** Reproductive Health Skills Workshop. Simulation. University of Minnesota Medical School Obstetrics and Gynecology and Family Medicine Interest Groups Skills Night. March 20, 2023. Minneapolis, MN.

4. **Boraas CM,** Ruud M, Hassan A. Navigating and Innovating Women's Health Services, Policies and Access Issues. 17th Annual University of Minnesota Women's Health Research Conference. February 23, 2023. Virtual.

5. **Boraas CM** and Ralph JA. Post-Roe Implications for Reproductive Health Care and Beyond. University of Minnesota Department of Medicine Grand Rounds. December 8, 2022. Virtual.

6. **Boraas CM,** Hasday J, Walker S. Abortion Access After Dobbs. University of Minnesota Center on Women, Gender and Public Policy Hybrid Event. November 8, 2022. Minneapolis, MN.

7. **Boraas, CM.** Satin, D. Janoski, E. Clinician responsibilities and vulnerabilities in the face of ethical and legal controversy. University of Minnesota Law 6854 Law, Biomedicine & Bioethics course. November 8, 2022. Minneapolis, MN.

8. **Boraas, CM.** Trauma-informed Gyn and Pregnancy Care: How we use Language in the Exam Room. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 14, 2022. Minneapolis, MN.

9. **Boraas, CM.** Contraception for the Medically Complex Patient. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference, February 14, 2022. Minneapolis, MN.

10. **Boraas, CM.** Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. December 13, 2021. Minneapolis, MN.

11. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. September 17, 2021. Minneapolis, MN

12. **Boraas CM.** Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 21, 2021. St. Paul, MN.

13. **Boraas, CM.** Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. December 14, 2020. Minneapolis, MN.

14. **Boraas, CM.** Breastfeeding Basics for the Ob/Gyn Resident. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. December 28, 2020. Minneapolis, MN.

15. **Boraas CM.** Introduction to Family Planning. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 22, 2020. St. Paul, MN.

16. **Boraas CM.** Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 22, 2020. St. Paul, MN.

17. **Boraas CM.** Ectopic Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. June 22, 2020. Minneapolis, MN.

18. **Boraas CM.** Pregnancy of Unknown Location and Early Pregnancy Loss. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. May 4, 2020. Minneapolis, MN.

19. Wise M*, **Boraas CM.** Veracept Phase II Trial. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Journal Club. May 4, 2020. Minneapolis, MN.

20. **Boraas CM.** Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 24, 2020. Minneapolis, MN.

21. **Boraas, CM.** Global Maternal Mortality. University of Minnesota Global Pediatrics Education Presentation. February 6, 2020. Minneapolis, MN.

22. **Boraas CM.** Important Conversations – Challenging Patients, Language, Race and Racism. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 27, 2020. Minneapolis, MN.

23. **Boraas CM,** Pacala K**.** Dilation and Curettage Papaya Workshop. Simulation. University of Minnesota Medical School Obstetrics and Gynecology Interest Group Skills Night. February 27, 2020. Minneapolis, MN.

24. **Boraas CM**, Finn K, McKegney C, Ball C. Highlighting work as an abortion provider. Lunch Lecture. Medical Students for Choice. University of Minnesota Medical School. January 13, 2020. Minneapolis, MN.

25. Gerwitz-O'Brien J*, Donlon T*, **Boraas, CM.** Advocacy in Action. Becoming a Doctor Course. University of Minnesota Medical School. January 8, 2020. Minneapolis, MN.

26. **Boraas, CM.** Contraception for Endocrine Fellows. University of Minnesota Endocrinology Fellows Education Presentation. November 21, 2019. Minneapolis, MN.

27. **Boraas, CM.** Induced Abortion for Genetic Counselors. University of Minnesota Genetic Counselor Graduate Student Education Presentation. November 18, 2019. Minneapolis, MN.

28. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. September 13, 2019. Minneapolis, MN.

29. **Boraas CM.** Adolescent Gynecology. University of Minnesota Department of Pediatrics Resident Block Education Conference. August 9, 2019. Minneapolis, MN.

30. **Boraas CM.** Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 18, 2019. Minneapolis, MN.

31. **Boraas CM.** LARC Tips and Tricks. University of Minnesota Department of Obstetrics. Gynecology and Women's Health Resident Curriculum Conference. February 11, 2019. Minneapolis, MN.

32. Kummer L, **Boraas CM**, Chomilo N. Making an Impact through Advocacy. Becoming a Doctor Course. University of Minnesota Medical School. January 9, 2019. Minneapolis, MN.

33. **Boraas CM** and Flanagan S**.** Uterine Artery Embolization in Obstetric Hemorrhage. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Grand Rounds. December 18, 2018. Minneapolis, MN.

34. **Boraas CM.** Termination of Pregnancy in the Second Trimester. Fetal Diagnosis and Treatment Center. University of Minnesota Medical School. December 6, 2018. Minneapolis, MN.

35. **Boraas CM.** Contraception Overview. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 19, 2018. Minneapolis, MN.

36. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 19, 2018. Minneapolis, MN.

37. **Boraas CM.** Cesarean Scar Pregnancy. Fairview Infusion Center Continuing Medical Education. May 25, 2018. Minneapolis, MN.

38. **Boraas CM.** Abortion Cervical Preparation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 26, 2018. Minneapolis, MN.

39. **Boraas CM.** Dilation and Evacuation versus Induction of Labor for Termination of Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 26, 2018. Minneapolis, MN.

40. **Boraas, CM.** Ectopic pregnancy and induced abortion. University of Minnesota Womens' Health Nurse Practitioner and Nurse Midwifery Education Presentation. December 1, 2017. Minneapolis, MN.

41. **Boraas, CM.** Global Maternal Mortality: Focus on Delivery. University of Minnesota Department of Pediatrics Residency Block Education Presentation. Hennepin County Medical Center. November 17, 2017. Minneapolis, MN.

42. **Boraas CM.** Challenging Patient Encounters. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. October 30, 2017. Minneapolis, MN.

43. **Boraas, CM,** Terrell, CA, Hutto, SL. Abortion Care at UMMC. University of Minnesota Medical Center ER Department Grand Rounds. September 28, 2017. Minneapolis, MN.

44. **Boraas, CM.** Contraception for Patients with Medical Conditions. Continuing Education Presentation. Planned Parenthood MN-ND-SD. August 8 and 12, 2017. St. Paul, MN.

45. **Boraas, CM**, Terrell, CA, Hutto, SL. Abortion Care at UMMC. UMMC Peri-operative Education Meeting. April 11, 2017. Minneapolis, MN.

46. **Boraas CM.** Mifepristone: Politics and Science in Practice, University of Minnesota Department of Obstetrics, Gynecology and Women's Health Grand Rounds. February 21, 2017. Minneapolis, MN.

47. **Boraas CM.** Breech Vaginal Delivery. Simulation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. February 6, 2017. Minneapolis, MN.

48. **Boraas CM** and Ball CE**.** Family Planning Questions and Answers, Planned Parenthood MN-ND-SD Clinician Days. January 6, 2017. St. Paul, MN.

49. **Boraas CM.** Abortion Policy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.

50. **Boraas CM.** Abortion Cervical Preparation. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.

51. **Boraas CM.** Dilation and Evacuation versus Induction of Labor for Termination of Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. September 12, 2016. Minneapolis, MN.

52. **Boraas CM.** Challenging Patient Encounters. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. August 29, 2016. Minneapolis, MN.

53. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 20, 2016. Minneapolis, MN.

54. **Boraas CM.** Family Planning Update. University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Autumn Seminar. November 20, 2015. Minneapolis, MN.

55. **Boraas CM.** Introduction to Abortion. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Bootcamp. June 23, 2015. Minneapolis, MN.

56. **Boraas CM** and Ball CE**.** Family Planning Questions and Answers. Planned Parenthood MN-ND-SD Clinician Days. October 1, 2014. St. Paul, MN.

57. **Boraas CM** and Eggleston K**.** Family Planning Questions and Answers. Planned Parenthood MN-ND-SD Clinician Days. September 30, 2014. St. Paul, MN.

58. **Boraas CM.** Family Planning in Conflict Settings. University of Pittsburgh Global Health and Underserved Lecture Series. February 10, 2014. Pittsburgh, PA.

59. **Boraas CM.** Why Women 'Wait': Abortion in the Second Trimester. University of Illinois at Chicago Department of Obstetrics and Gynecology Grand Rounds. January 31, 2014. Chicago, IL.

60. **Boraas CM.** Abortion and Long-Term Health Outcomes: Examining the Evidence. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. January 6, 2014. Pittsburgh, PA.

61. **Boraas CM.** Misoprostol in Gynecologic Practice. Magee-Womens Hospital Gynecology Conference. University of Pittsburgh. November 11, 2013. Pittsburgh, PA.

62. **Boraas CM.** Towards Equity: Reproductive Health along the Thai-Burma Border. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. July 8, 2013. Pittsburgh, PA.

63. **Boraas CM.** Fit to be Tied: Sterilization in the USA. University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. February 22, 2013. Pittsburgh, PA.

64. **Boraas CM.** Health Reform 101: What's in it for Women? University of Pittsburgh Medical School Medical Students for Choice Lecture Series. November 2, 2012. Pittsburgh, PA.

65. **Boraas CM.** Health Reform 101: What's in it for Women? University of Pittsburgh Department of Obstetrics, Gynecology and Reproductive Sciences Gynecology Conference. October 22, 2012. Pittsburgh, PA.

66. **Boraas CM.** Maternal Mortality: The Promise of Progress. The Ohio State University Department of Obstetrics and Gynecology Grand Rounds. May 17, 2012. Columbus, OH.

67. **Boraas CM.** Current Contraception Overview. Kilimanjaro Christian Medical College Department of Obstetrics and Gynecology Grand Rounds. March 10, 2011. Moshi, Tanzania.

68. **Boraas CM.** Morbidity and Mortality Report – Case of the Lost IUD. The Ohio State University Department of Obstetrics and Gynecology Grand Rounds. September 2, 2010. Columbus, OH.

69. **Boraas CM.** Malaria in Pregnancy. University of Minnesota Department of Obstetrics, Gynecology and Women's Health Resident Curriculum Conference. August 27, 2010. Minneapolis, MN.

Peer-Reviewed Oral Presentations at National Professional Meetings, Conferences, etc.

1. Gawron LM, Roe AH, **Boraas CM,** Bernard C, Westhoff CL, Culwell K, Turok DK. Bleeding and pain over time with a novel low-dose copper intrauteirne device with a flexible nitinol frame. Society of Family Planning Meeting. October 28-30, 2023.

2. Faherty E*, Smith K, **Boraas C**, Lofgren S, Rothenberger M, and Enns E. Using mixed methods to identify and evaluate strategies to improve uptake of Expedited Partner Therapy for *chlamydia trachomatis* infection in Minnesota. Society for Medical Decision Making Virtual Meeting, October 18-20, 2021.

3. Martins SL* and **Boraas CM**. Willingness to use the 'male' birth control pill: Demographic and reproductive health correlates among a community-based sample of U.S. men. Annual Meeting of the Society for Pediatric and Perinatal Epidemiologic Research. June 21-22, 2021. Virtual.

4. Upadhyay U, Raymond E, Koenig L, Coplon L, Gold M, Kaneshiro B, **Boraas C**, Winikoff B. Safety and Efficacy of No-test Medication Abortion: A Retrospective Multi-Site Study. National Abortion Federation Meeting. May 11-12, 2021. Virtual.

5. Anger H, Raymond E, Chong E, Haskell S, Grant M, **Boraas C**, Tocce K, Banks J, Coplon L, Shochet T, Platais I. Comparison of clinical outcomes among patients who did and did not have a screening ultrasound or pelvic exam prior to obtaining medciaion abortion services via direct-to-patient telemedicine. National Abortion Federation Meeting, May 11-12, 2021. Virtual

6. Sayarath M*, Gerwitz O'Brien J*, Shramko M*, Argo T*, Brown E, Mishra P, **Boraas CM** McRee, A. Assessing the Gap in Sexual and Reproductive Health Services among Hospitalized Adolescents. Works in Progress Session. Society of Adolescent Medicine Conference, March 11, 2020. San Diego, CA. Due to COVID-19 related conference cancellation, this invited presentation was not given.

7. Borchert K, Wipf K*, Roeske E*, Clure C*, Traxler S, **Boraas CM**. Pregnancy of Unknown Location in Abortion Care: Management and Outcomes. National Abortion Federation Conference, April 23, 2018. Seattle, WA.

8. **Boraas CM**, Thompson I, Turok DK, Baldauf E, Borrero S, Schwarz EB, Sanders JN. Extending the window for insertion of the intrauterine device. American Society for Reproductive Medicine Scientific Congress, October 19, 2016. Salt Lake City, UT.

9. **Boraas CM**, Isley MM. Chlamydia and gonococcal infections and screening in women receiving intrauterine devices in a resident obstetrics and gynecology clinic. The Ohio State Department of Obstetrics and Gynecology Resident Research Day. October 2011. Columbus, OH.

Poster Abstract Presentations at National Professional Meetings, Conferences, etc.

1. Carroll AL, Strauss AM, Philipps, NM, Kaczmarczik KD, Shakur Z, Ramirez G, Klc TR, Tessier KM, **Boraas CM.** Concurrent administration of depot medroxyprogesterone acetate with mifepristone may decrease medication abortion efficacy: A retrospective cohort study. Society of Family Planning Meeting. October 28-30, 2023.

2. Carroll AL, Strauss AM, Philipps, NM, Kaczmarczik KD, Shakur Z, Ramirez G, Klc TR, Tessier KM, **Boraas CM.** Concurrent placement of an etonogestrel implant with mifepristone does not decrease medication abortion efficacy: A retrospective cohort study. Society of Family Planning Meeting. October 28-30, 2023.

3. Mahoney M, Ojanen-Goldsmith A, Hassan A, **Boraas CM**. I waited years for an option other than vasectomy": Interest in new contraceptive methods for sperm among people with vasectomies. 2023 IAPHS Annual Meeting. October 2-5, 2023. Baltimore, MD.

4. Raymond EG, Frye LJ, **Boraas CM**, Tocce K, Gingras S, Firstenberg BS, Almquist A, ORtega C, Mahoney M, Hernandez K, Blumenthal P, Winikoff B. "MA-ASAP": Asynchronous, Web-Based Provision of Medication Abortion. National Abortion Federation Annual Meeting. April 30-May 2, 2023. Denver, CO.

5. **Boraas CM**, Wise M, Miller J, Jafari N, Martins S. New male contraception: Yea or Nay? Correlates of supportive attitudes in a community-based sample of men and women. University of Minnesota Annual Women's Health Research Conference. February 23, 2023. Virtual.

6. Groene E*, **Boraas C**, Smith K, Lofgren S, Rothenberger M, Enns E. Offering Expedited Partner Therapy: a mixed methods study of Minnesota health providers. 2022 STD Prevention Conference. September 19-22, 2022. Virtual.

7. Keonig LR, Raymond EG, Gold M, **Boraas C**, Kaneshiro B, Winikoff B, Coplon L, Upadhyay UD. Time to Care Among Patients Who Receive Medication Abortion with History-Based Screening in the United States. Population Association of America Annual Meeting. April 6-9, 2022. Atlanta, GA.

8. Creinin M, Gawron L, Westhoff C, **Boraas CM,** Blumenthal P, Turok D. Phase 3 data of a novel low-dose copper intrauterine device with a nitinol frame: 1-year outcomes. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.

9. Martins S*, Miller JJ*, Wise M*, Jafari N*, **Boraas CM.** Willingness to Use Novel Reversible Male-Controlled Contraceptive Methods in a Community-Based Sample of Adult Men. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.

10. Wise M*, Martins S*, Tessier K, Traxler SA, **Boraas CM.** Success of Intrauterine Device Placement in Adolescents at Planned Parenthood. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.

11. Miller JJ*, Martins S*, Mahoney MA*, Tessier K, Traxler SA, **Boraas CM**. Correlates of long acting reversible contraception uptake at 30 days following medication abortion. ACOG Annual Clinical Meeting. April 30-May 2, 2021. Virtual.

12. Faherty E*, **Boraas CM,** Smith K, Lofgren S, Rothenberger M, and Enns E. Expedited Partner Therapy for Sexually Transmitted Infections in Minnesota: A Mixed-Methods Review of Current Practices and Barriers to Implementation. ISPOR 2021, May 17-20, 2021. Virtual.

13. Gerwitz O'Brien J*, Shramko M*, Sayarath M*, Brown E, Argo T*, **Boraas CM,** McRee A. Missed Opportunities to Provide Comprehensive Sexual and Reproductive Healthcare among Hospitalized Adolescents. Society for Adolescent Health and Medicine Annual Meeting. March 10-12, 2021. Due to COVID-19 related conference cancellation, this peer-reviewed poster was presented in electronic format.

14. Henke L*, Martins S*, Bangdiwala A, **Boraas CM**. Barriers to Obtaining Long-Acting Reversible Contraception Among Low-Income Women. ACOG Annual Clinical Meeting, April 24-27, 2020, Seattle, WA. Due to COVID-19 related conference cancellation, this peer-reviewed poster was presented in electronic format.

15. Gerwitz O'Brien J*, Shramko M*, Sayarath M*, Argo T*, Brown E, Mishra P, **Boraas CM** McRee A. Missed Opportunities to Provide Comprehensive Sexual and Reproductive Healthcare among Hospitalized Adolescents. Pediatric Research, Education and Scholarship Symposium. April 24, 2020. Minneapolis, MN.

16. Argo T*, Gerwitz O'Brien J*, Miller KK*, Prince A, Bahr T*, **Boraas CM**, Chaisson N, Borman-Shoap E. No Missed Opportunities: A trainee-driven long acting reversible contraceptive workshop for pediatric primary care clinicians. Society of Adolescent Medicine Conference. March 11, 2020. San Diego, CA.

17. Argo T*, Miller KK*, Bahr T*, Prince A, **Boraas CM**, Chaisson N, Borman-Shoap E, Gerwitz O'Brien J*. No Missed Opportunities: A trainee-driven long acting reversible contraceptive workshop for pediatric primary care clinicians. Minnesota American Academy of Pediatrics Conference. May 3, 2019. Minneapolis, MN.

18. Borchert K, Wipf K*, Roeske E*, Clure C*, Traxler S, **Boraas CM**. Pregnancy of Unknown Location in Abortion Care: Expectant Management and Ectopic Pregnancy Outcomes. National Abortion Federation Conference. May 6, 2019. Chicago, IL.

19. Raymond E, Tan Y, Comendant R, Sagaidac I, Platais I, Grant M, Sanhueza P, Van Pratt E, Bousiequez M, Gillespie G, **Boraas CM**, Weaver M. Simplified Medical Abortion Screening: A Pilot Study. National Abortion Federation Conference. April 23, 2017. Montreal, Canada.

20. Paul J*, Duvet M, **Boraas CM**. YouTube and the contraceptive implant: a content analysis. North American Forum on Family Planning. October 11, 2014. Miami, FL.

21. Lewis L*, **Boraas CM**, Dunn SA, Krans EE. Postpartum contraceptive intention and initiation among opioid dependent women. North American Forum on Family Planning. October 11, 2014. Miami, FL.

22. **Boraas CM**, Achilles SL, Cremer ML, Chappell CA, Chen BA. Dilapan-S with adjunctive misoprostol for same-day dilation and evacuation: a randomized controlled trial. North American Forum on Family Planning. October 11, 2014. Miami, FL.

23. Rapkin RB, Achilles SL, **Boraas C**, Cremer M, Schwarz EB, Chen BA. Self-administered lidocaine gel for intrauterine device insertion in nulliparous women: a randomized controlled trial. ACOG Annual Clinical Meeting. April 28, 2014. Chicago, IL.

24. **Boraas CM**, Isley MM. Chlamydia and gonococcal infections and screening in women receiving intrauterine devices in a resident obstetrics and gynecology clinic. North American Forum on Family Planning. October 23, 2012. Denver, CO.

25. **Boraas CM**. Emergency contraception knowledge, attitudes and practices – A survey of future providers in Minnesota and Guatemala. Global Health Council Conference. 2006. Washington, DC.

26. **Boraas CM**, Asante L, Heloo B. Female condom knowledge, attitudes and practices in Ghana's highest HIV prevalence regions. Global Health Education Consortium.

TEACHING AND CURRICULUM DEVELOPMENT

University of Minnesota

Course List

Undergraduate Courses

Annual speaker, The Future Physician II: The Life and Work of a Physician 2016-2020

Professional Medical Courses

Becoming a Doctor II: Making an Impact Through Advocacy Facilitator 2019-present

Obstetrics and Gynecology Core Clerkship Problem-Based Learning Facilitator 2018-present

Obstetrics and Gynecology Preceptor, Rural Physicians Associate Program 2017-present

Obstetrics and Gynecology Core Clerkship Attending Physician 2017-present

Participation two times per academic year (4 week rotation) as a faculty problem-based learning mentor for the third-year students during the clerkship in Obstetrics and Gynecology. I also present a one-hour lecture on the clinical aspects of abortion and contraception approximately four times per year to the entire clerkship. Additionally, students can spend one day with me on at Planned Parenthood MN-ND-SD or Whole Woman's Health learning about reproductive choice and counseling, medical and surgical abortion, and contraceptive counseling.

Advanced Family Planning Elective Attending Physician 2015-present

The purpose of this elective is to learn more about the subspecialty of family planning. During the two-four week elective, students will be present in several clinical settings, including Planned Parenthood MN-ND-SD, Whole Woman's Health, Women's Health Specialists clinic, and the operating room for D&E procedures. The student also makes a presentation on a topic from the current medical literature to the family planning faculty and staff.

Curriculum Development

Post Graduate Medical Education

Global Pediatrics Curriculum 2019-present

Developed lectures for pediatrics providers about maternal morbidity and mortality.

Global Obstetrics Simulation for Pediatrics Residents 2017-present

Developed a yearly simulation curriculum for delivery of a baby in the case of emergency for Pediatrics residents.

Fellowship in Family Planning, Director 2016-present

I serve as the future director of the family planning fellowship for graduated obstetrics and gynecology residents. This position has involved developing clinical, research and advocacy curriculum, which was approved by the University of Minnesota Board of Regents in Fall 2016. Application is currently under review by the national office of the Fellowship in Family Planning.

Ryan Residency in Abortion and Family Planning, Director 2015-present

I serve as the director of the family planning rotation for second year residents. This involves teaching and supervising the resident at Planned Parenthood in performing surgical abortions up to 23 6/7 weeks and medical abortions up to 10 0/7 weeks and in the operating room for D&E procedures up to 23 6/7 weeks. I also supervise office hysteroscopic sterilization and OR laparoscopic and hysteroscopic sterilization procedures. For residents who choose not to perform abortions, their education includes learning about early pregnancy counseling and decision making as well as performing ultrasounds for pregnancy dating.

Undergraduate Medical Education

Consultant, Endocrine and Reproductive Health Course	2021-present
Consultant, Diversity, Equity and Inclusion Thread	2021-present

Nationally Available Published Curricula

Boraas, CM. Invited Lecturer *Obstetric Emergencies: Focus on Delivery.* Clinical Tropical Medicine & Online Global Health Curriculum. Editors Kristina Krohn, Brett Hendel-Paterson, and William Stauffer. Available at https://med.umn.edu/dom/education/global-medicine/courses-certificates/online/global-health-curriculum. The entire curriculum consists of 7 modules with over 180 hours of online material, including reviews and assessments. Pair with the in-person course, the curriculum qualifies participants to sit for the CTropMed and DTMH. With over 1300 unique enrollees from 47 states and over 28 countries, this curriculum helps providers learn how to address health disparities across the globe. Curriculum originally launched 2006, converted to online in 2010, and last updated in 2021.

Boraas, CM. *Maternal Mortality.* GPEDS (Global Pediatric Education Series) for Medical Students. Clerkship Directors: Winter J, Danich E, Howard C. This Virtual Medical Student Clerkship consists of 4 modules (approximately 25 hours) of online content covering topics in global child health. Available for enrollment September 2020.

Boraas, CM. *Maternal Mortality.* GPEDS 2.0 (Global Pediatric Education Series). Editors Winter J, Danich E, Howard C. Available at globalpeds.umn.edu/gpeds. Curriculum consists of 4 modules (approximately 25 hours) of online content on global child health that serves as the primary global health curriculum for pediatric residents at multiple institutions. The content is also available to individual subscribers for CME credit. Curriculum originally launched May 2014, Updated November 1, 2019.

ADVISING AND MENTORING

Undergraduate Student Activities

Research Mentor, B.A. Candidate	01/2021-06/2023

Graduate Student Activities

PhD Candidate	06/2022-present
MPH Candidate	06/2022-6/2023
MPH Candidate	06/2022-6/2023
TRACT TL1 Program Mentor, PhD Candidate	07/2020-06/2022

Master's Theses Directed

MS in Medical Device Innovation Candidate	06/2022-12/2022
MPH Candidate	09/2015-12/2015

Professional Student Activities

Twin Cities Medical Society Public Health Advocacy Fellowship Mentee	Jun 2020-2021
Medical student research advisees	Jul 2015-2018
Medical student advisees	Jul 2015-2018

Clinical Supervision

3rd year medical students on Education in Pediatrics Along the Curriculum, 2017-present
3rd and 4th year medical students on OB/GYN clerkship rotations at Women's Health Specialists, 2015 – present
3rd and 4th year medical students on family planning elective rotations at Women's Health Specialists and community sites, 2015 – present

Residents Supervised

Clinical Supervision, 1st year residents on general gynecology rotations at Women's Health Specialists, 2015 – present

Clinical Supervision, 4th year residents on general gynecology rotations at Women's Health Specialists, 2015 – present

Clinical Supervision, 2nd year residents on general obstetrics rotations at UMMC L&D (The Birthplace), 2015 – present

Clinical Supervision, 3rd year residents on general obstetrics rotations at UMMC L&D (The Birthplace), 2015 – present

Clinical Supervision, 2nd year residents on family planning rotation at Planned Parenthood Minnesota, North Dakota, South Dakota, 2014 – present

Post Doctoral Fellows Supervised

Adolescent Health Fellowship	September 2018 - June 2021
Post-doctoral Fellowship	May 2019 - May 2020

Other Mentoring Activities

Faculty Advisor University of Minnesota Obstetrics and Gynecology Interest Group	2016-present
Faculty Advisor University of Minnesota Medical Students for Choice	2016-present

CLINICAL SERVICE

Clinical Leadership Accomplishments

Associate Medical Director, Planned Parenthood MN-ND-SD	2014-present

Clinical Service Responsibilities

Obstetrics, Gynecology, Midwifery and Family Planning Division 2015-present
Attending Physician
Consulting Physician
Clinics: 2 half days per week, 2015-present
OR: 1 half day per week, 2015-present

Planned Parenthood MN-ND-SD 2014-present
Clinics: 2 half days per week, 2016-present; 3 half days per week, 2015-2016; 4 half days per week 2014-2015

Whole Woman's Health 2014-present
Clinics: 2 half days per week, 2016-present; 1 half day per week, 2015-2016; 3 half days per week, 2014-2015

PROFESSIONAL SERVICE AND PUBLIC OUTREACH

Service To The Discipline/Profession/Interdisciplinary Area(s)

Editorships/Journal Reviewer Experience

Journal Reviewer, Obstetrics and Gynecology 2017-present
Recognized as Top 10% Peer Reviewer 2020
Journal Reviewer, Contraception 2013-present

Organization of conferences, workshops, panels, symposia

Member, University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Joint Autumn Seminar Planning Committee 2016
Role: Organized educational themes and curricula, recruited speakers.

Member, University of Minnesota Department of Obstetrics, Gynecology and Women's Health and MN ACOG Joint Autumn Seminar Planning Committee 2015
Role: Organized educational themes and curricula, recruited speakers.

National Committee Memberships

Member, Society of Family Planning Finance Committee 2021-present
Member, Society of Family Planning Research Implementation Interest Group 2021-present
Member, M-POWER Advisory Committee 2021-present
Member, No Test Medication Abortion Safety and Outcomes Working Group 2021-2023
Member, Complex Family Planning Fellowship Core Education Working Group 2021-2023
Member, Complex Family Planning Fellowship Education Committee 2020-2021
Member, Society of Family Planning Program Committee 2019-2020
Member, North American Forum on Family Planning Scientific Committee 2018-2020
Member, Society of Family Planning Audit Committee 2016-2018
Member, ACOG Online Learning in Ob-Gyn Advisory Committee 2014-2022
Member, ACOG Global Health Committee 2015-present
Member, Fellowship in Family Planning Guide to Learning Revision Subcommittee, 2016-2018

State Committee Memberships

Member, Minnesota Medical Association Health Equity Task Force 2020
Member, Minnesota PRAMS Advisory Committee 2017-present

Member, Reproductive Health Access Project, MN cluster	2017-present
Member, MN ACOG Advisory Council	2016-present
Member, MN ACOG Legislative Committee	2015-present

Public Advocacy

Physician Advocate, Minnesota ACOG Day at the Capitol	3/8/2022
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/4/2020
Member, Minnesota Doctors for Health Equity	2018-present
Physician Advocate, Minnesota Medical Association Day at the Capitol	2/13/2019
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/14/2018
Physician Advocate, Minnesota Medical Association Day at the Capitol	2/15/2017
Speaker, Press Conference on MN H.F. 411/S.F. 281, Physician's Integrity Act	1/23/2017
Physician Advocate, Minnesota Medical Association Day at the Capitol	3/23/2016

Service to the University/Medical School/Department

University of Minnesota

University-wide Service

Member, Medical School Faculty Advisory Committee	2022-present
Judge, Global Health Case Competition	2022
Faculty, Walter H. Judd Fellowships Selection Committee	2018
Faculty, Center for Global Health and Social Responsibility	2016-present
Chair, Students' International Health Committee	2002-2008
Representative, Center for Health Interprofessional Programs	2002-2004
Vice President, Student Senate, University of Minnesota School of Public Health,	2003

Medical School Service and Intercollegiate Service

Participant, Master Mentor Program	2017-present
Member, Medical School Admissions Committee	2007-2008, 2018-present
Member, Learning Environment Rounds	2017-present
Member, Essentials of Modern Medicine Curriculum Initiative	2007-2008
Member, Med2010 Education Initiative	2007-2008
Representative, Student Council	2004-2008
Representative, Education Council	2004-2008

Department/Unit Service

Member, ARTS Committee	2020-present
Member, Residency Program Evaluation Committee	2016-present
Member, Clinical Competency Committee	2016-present
Member, Education Council	2016-present
Member, Residency Interview Committee	2016-present
Moderator, Research Day	2016, 2019

M Health Fairview Service

Member, UMMC Obstetric Case Review Committee	2022-present
Member, Perinatal Loss Policy Committee	2021-present
Member, Termination of Pregnancy Policy Committee	2020-present

University of Pittsburgh

Medical School Service and Intercollegiate Service

Fellow Advisor, Medical Students for Choice	2012-2014

The Ohio State University

Department/Unit Service

Resident Supervisor, Columbus Free Clinic	2010-2012
Resident Advisor, Obstetrics and Gynecology Interest Group	2009-2012

St. Olaf College, Northfield, MN

University-wide service

Co-Founder, Helping Overcome Poverty through Education (H.O.P.E.)	2000-2001

Community Outreach Activities

Family Planning Consultant, Teen Annex Clinic	2021-present
Family Planning Consultant, Alight	2019-present
Mentor, Upward Bound, St. Paul, MN	2004-2008
Global Health Volunteer, Mano a Mano Organization, St. Paul, MN	2004-2008

Exhibit 2

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**

EXPERT REPORT OF MONIQUE CHIREAU WUBBENHORST, M.D., M.P.H.

I, Monique Chireau Wubbenhorst, M.D., M.P.H., pursuant to 28 U.S.C. section 1746 and Federal Rule of Civil Procedure 26(a)(2), do hereby declare as follows:

I. Background and Qualifications

1. I am a practicing board-certified obstetrician-gynecologist with over 30 years of experience in patient care, teaching, research, health policy, public health,

global health, and bioethics. I provide obstetrical care at St. Joseph's Regional Medical Center in Mishawaka, Indiana. I am also a consultant at Tenwek Mission Hospital in Bomet, Kenya.

2. I graduated from Mount Holyoke College in 1981 with a B.A. in Biological Sciences. I received my M.D. from Brown University concurrently with a master's degree in public health from Harvard University in 1991. I completed my residency in obstetrics and gynecology at Yale-New Haven Hospital in 1995. Subsequently, I joined the Department of Obstetrics and Gynecology at the Beth Israel-Deaconess Medical Center in Boston, Massachusetts, and was an Instructor at Harvard Medical School. I was also a member of the departments of Obstetrics and Gynecology at St. Elizabeth's Hospital and Mount Auburn Hospital.

3. I completed my postdoctoral fellowship in health services research at the Sheps Center for Health Services Research at the University of North Carolina-Chapel Hill in 2003 and was on the faculty of the Department of Obstetrics and Gynecology at Duke University School of Medicine from 2003 to 2018. I was a member of the Duke University Institutional Review Board for 15 years and was an attending physician at the Durham VA Medical Center, caring for women veterans. I joined the Bureau for Global Health at the United States Agency for International Development, where I served as Senior Deputy Assistant Administrator until 2021. I have worked at more than 25 hospitals and health facilities during my career. Currently I am a Senior Research Fellow at the Center for Ethics and Culture, University of Notre Dame.

4. My clinical career has focused on caring for women in underserved and disadvantaged populations, especially African American and Native American communities in the United States, 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, Native American reservations in the United States, and in India, the Philippines, Kazakhstan, Ghana, South Sudan, Nepal, Cameroon, and Kenya.

5. 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 multiple 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, demographics and epidemiology, and ethics in epidemiology and reproductive health.

6. A full list of my publications is set forth in my curriculum vitae, attached hereto as Exhibit A.

7. I am being compensated for my testimony at a rate of $700 per hour.

II. Summary of Opinions

8. I understand that Plaintiffs Planned Parenthood South Atlantic ("PPSAT") and Dr. Beverly Gray are seeking to block two components of North Carolina Session Law 2023-14 ("S.B. 20") (codified as amended by Session Law 2023-65 ("H.B. 190") at N.C. Gen. Stat. art. 1I, ch. 90 (the "Act")), which restricts abortion after twelve weeks of pregnancy with certain exceptions.

9. Specifically, I understand that the Act allows abortions in the case of rape or incest through 20 weeks of pregnancy, and abortions in the case of a "life-limiting anomaly" through 24 weeks of pregnancy, and that these abortions must be performed in a hospital, not an outpatient clinic (the "Hospitalization Requirement"). I understand that abortion providers will be required to comply with these rules if the Act takes effect.

10. I also understand that the Act requires that a physician who provides an "abortion-inducing drug" must "[d]ocument in the woman's medical chart the . . . existence of an intrauterine pregnancy" (the "IUP Documentation Requirement"). This provision would require abortion providers to confirm that a woman is pregnant (using pregnancy testing) and confirm the location of her pregnancy (using ultrasound), prior to prescribing mifepristone and misoprostol (medication abortion). This testing would be done to rule out ectopic pregnancy and protect women from its consequences. If the location of a woman's pregnancy could not be established (a pregnancy of unknown location), abortion providers would need to wait until the pregnancy is visible via ultrasound.

11. I have been asked to opine on whether there is a medical justification for these provisions of the Act and their impact on women's health and safety in North Carolina. The answer is yes. In my opinion, both the Hospitalization Requirement and the IUP Documentation requirement serve to protect women's health and are medically justified to help ensure patient safety and avoid exposure to unnecessary interventions.

12. If allowed to take effect, the Hospitalization Requirement will have a positive effect on North Carolinians because it will help protect women from the complications of second-trimester abortions performed in facilities that are not equipped to handle serious complications. Based upon a reasonable degree of medical probability, there are good medical reasons to require that all abortions after twelve weeks of pregnancy be performed in hospitals, considering evidence that these abortions are less safe when they are performed in abortion clinics, and that patient safety is improved when they are performed in hospitals.

13. If allowed to take effect, the IUP Requirement will have a positive effect on North Carolinians because it will help protect women from the complications of undiagnosed ectopic pregnancy. It will also protect women from being exposed to the medically unnecessary administration of mifepristone and misoprostol if they are in the process of having a miscarriage when they are seen for abortion. Based upon a reasonable degree of medical probability, there are good medical reasons to require that prior to medical abortion, the location of a woman's pregnancy should be documented with ultrasound. This is standard medical practice in obstetrics and

gynecology because it prevents a woman from suffering the complications of undiagnosed ectopic pregnancy. Diagnosis of intrauterine pregnancy in women prior to medical abortion, will not only protect the patient from the complications of ectopic pregnancy, but will also help serve the public health goal of reducing the morbidity and mortality from ectopic pregnancy, the leading cause of early pregnancy death.

III. Expert Opinions and Reasons for Them

A. The safety of abortion is difficult to ascertain because US abortion data is incomplete.

14. 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 2020 Abortion Surveillance, "Data from 30 reporting areas; excludes 22 reporting areas (California, Colorado, Hawaii, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nebraska, New Hampshire, New Jersey, New York City, New York State, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Washington, and Wisconsin) that did not report, did not report by race or ethnicity, or did not meet reporting standards.[1]

15. 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.[2] The lack of abortion reporting from some of

[1] Including Asian (Indian, Chinese, Filipino, Japanese, Korean, Vietnamese, or other Asian), Pacific (Abortion Surveillance — United States, 2020 | MMWR (cdc.gov)).
[2] *Id.*

the most populous states makes it difficult to arrive at accurate estimates of the number of abortions performed in the United States.

16. 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."[3]

17. It is my understanding from the available data that 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.[4] Only 54% of deaths were reported in both systems.[5]

18. 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]."[6] Data collected by the Alan Guttmacher Institute

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[3] 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.
[4] 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.
[5] *Id.*
[6] Abortion Surveillance — United States, 2020 | MMWR (cdc.gov).

(AGI) are also limited because AGI relies on surveys rather than collection of case data.[7]

19. It is my understanding that 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 are not possible. Estimates of abortion related mortality are likewise inaccurate because deaths from abortion appear to be underreported.[8]

20. 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. However, there are very few studies on longer-term follow up. ACOG notes that "[i]n practice, attendance at abortion follow up visits is usually low, generally about 50%. Studies of first trimester aspiration abortion noted that 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%" (Grossman D, Ellertson C, Grimes D, Walker D. The American College of

[7] For a description of their methodology, see https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.

[8] *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).

Obstetrician-Gynecologists Current Commentary: Routine Follow up Visits After First-Trimester Induced Abortion *Obstetrics & Gynecology*).

21. This may be due in part to the instructions given to patients after their procedures. For example, Summit Medical Centers, which operate abortion clinics in Atlanta and Detroit, explicitly state on their website that "[y]ou do not need to return to Summit Medical for a follow-up visit after your abortion."[9]

22. It is a principle of medical practice that physicians must follow up with their patients after treatment or arrange such follow up. Yet 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 because they are not trained to do so.. 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.

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

[9] https://www.summitcenters.com/after-your-abortion/.

24. There are significant risks to woman associated with the use of mifepristone. The FDA report states that 26 women in the United States and 12 women in foreign countries have been reported to have died following the use of mifepristone for first trimester abortion. The report also notes that 97 women were diagnosed with ectopic pregnancies (see table below). These are likely underestimates.

25. 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.

26. "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 chemical 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 chemical abortion."[10]

27. 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.

28. 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."

B. Abortion Epidemiology in North Carolina

29. Based on North Carolina Department of Health data, 24,694 abortions were performed in North Carolina in 2020 on state residents. PPSAT performs an estimated 11,084 abortions per year, or 45% of abortions in NC. In NC in 2020, 88% of all abortions were performed at 13 weeks or less. 37.4% of abortions were surgical

[10] Advancing New Statndards in Reprod. Health, *Safety of Miscarriage Treatment in Hospitals, ASCs, and Office-Based Settings*, Univ. of Cal. S.F. 1, (2018), https://www.ansirh.org/sites/default/files/publications/files/safety–of–miscarriage–treatment–jps2.pdf.

abortions and 59.1% were chemical abortions. For surgical abortions, 33.8% were performed at less than 13 weeks and 6.3% were performed at greater than 13 weeks. For chemical abortions, 56.9% were performed at less than or equal to 9 weeks, and 2.6% were performed at more than 9 weeks' gestation.[11]

30. Based on CDC data, 29,636 abortions were performed in NC in 2020. 38.2% of abortions (11,320) were performed at less than or equal to 6 weeks, 41.6% (12,328) at 7–9 weeks, 13.9% (4,119) at 10–13 weeks, 2.9% (859) at 14–16 weeks, 1.7% (503) at 16–17 weeks, 1.6% (474) at 18–20 weeks, and 0.2% (59) at > 21 weeks. In other words, 6.2% of abortions (1,837) were performed in the second trimester.[12]

31. The current epidemiology of abortion in NC based on the data above suggests several trends. First, even before the Act was made law, women were readily accessing abortion early in pregnancy; 93% of abortions were performed at or before 13 weeks, and 96% are performed before 16 weeks.

C. Abortion Safety

32. The allegation that abortion is healthcare appears throughout Dr. Farris's and Dr. Boraas's expert disclosures, including in the phrases "abortion care," "safe and critical health care," and "desperately needed healthcare." 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.

[11] https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2020/abortioncharacteristics.pdf.
[12] https://schs.dph.ncdhhs.gov/data/vital/pregnancies/2020/abortioncharacteristics.pdf.

33. Abortion is not "critical health care". As noted above, since a small and decreasing percentage of OB/GYNs perform abortions, abortion cannot be considered "critical health care".

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

35. Abortion, including medication abortion, and first and second trimester surgical abortion, is associated with significant risks to the mother and is always lethal to a developing child.

36. First trimester chemical 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.[13] 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.[14] As a result, it is free of methodological problems and bias that plague other studies of abortion, including those conducted in the United States.

37. In the study by Niinimaki et al, 20% of women underwent chemical abortion, and 5.6% underwent surgical abortion.[15] The authors note that "[t]he overall incidence of adverse events was fourfold higher in the medical compared with

[13] 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.
[14] *Id.*
[15] *Id.*

the surgical abortion cohort. The risk of hemorrhage with chemical abortion was 15.6%, and 2.1% with surgical abortion. The risk of incomplete abortion with chemical abortion was 6.7%, and 1.6% with surgical abortion. The risk of emergency surgery with chemical abortion was 5.9% with chemical abortion, and 1.8% with surgical abortion."[16]

38. Therefore, in this study, women undergoing chemical 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 chemical abortion. As noted, the strength of this study was its ability to completely ascertain all abortions and all associated complications.

39. Multiple statements from plaintiffs' experts that rates of complications from abortion are low miss an important epidemiological point. When a large number of individuals undergo a procedure, even rare complications will result in a large absolute number of those individuals suffering morbidity and mortality. In the case of abortion, even if the estimated (and demonstrably inaccurate, as noted below) complication and mortality rates are low, given the high rates of abortion the numbers of women who are likely to suffer complications is significant. As an example, translating the numbers from the Niimaki study to North Carolina, an

[16] *Id.*

estimated 2,775 women per year would suffer hemorrhage following first trimester medication abortion.

40. There are other risks associated with the use of mifepristone, such as infection and blood clotting problems. 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.[17]

41. 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.

42. A study by Ashok *et al.* noted rates of hemorrhage to be higher with late first trimester medical abortion compared with surgical abortion (2.0% vs 0.8%). Rates of pelvic infection following surgical abortion were double those following medical abortion (8.2% vs. 4.4%). Pelvic infection is strongly associated with future risk for infertility.[18]

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[17] https://www.operationrescue.org/wp-content/uploads/2018/07/Autopsy-Report-DiamondWilliams.pdf.

[18] Ashok P, Kidd A, Flett GMM, Fitzmaurice A, Graham W, Templeton A. A randomized comparison of medical abortion and surgical vacuum aspiration at 10-13 weeks gestation. Hum Reprod 17:1, pp. 92-98, 2002.

43. The risks of abortion increase with gestational age. As Turok *et al.* note, "[t]he 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."[19]

44. Grimes and Cates used data from approximately 243,000 D&E procedures from 1972–78 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 gestation.[20]

45. In the same study, the mortality rate for dilation and curettage procedures at < 12 weeks gestation 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.[21] The authors note that "because the risk of death from D&E is directly related to gestational age, the death 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)."[22]

46. Many studies have quantified the association between increasing gestational age and increasing risk for maternal mortality, specifically in second trimester abortions. The same study by Cates and Grimes cited above shows that

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[19] 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.
[20] Grimes D and Cates W. Deaths from Second Trimester Abortion by Dilatation and Evacuation: Causes, Prevention, Facilities. Obstetrics & Gynecology 58(4):p 401-408, October 1981.
[21] *Id.*
[22] *Id.*

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.[23]

47. 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.[24]

48. Rates of complications associated with second trimester abortion are higher than for first trimester abortion. For example, Turok *et al.* studied differences in complications between second trimester abortions performed in 475 women, in hospitals vs. free-standing clinics.[25] 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.[26]

49. Other complications included: need for readmission, need for curettage after abortion for retained placenta and/or fetal parts, infection of the fetal

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[23] *Id.*
[24] Suzanne Zane, Andreea A. Creanga, Cynthia J. Berg, Karen Pazol, Danielle B. Suchdev, Denise J. Jamieson, William M. Callaghan. Abortion-Related Mortality in the United States 1998–2010. Obstet Gynecol. 2015 August ; 126(2): 258–26.
[25] 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.
[26] *Id.*

membranes after initiation of the procedure, and uterine infection.[27] The authors also note that complications may have been underreported due to loss to follow-up.[28]

50. Edlow *et al.* 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."[29]

51. Lederle *et al.*[30] found a 30% increased risk for complications with each additional week of gestation.

52. African American women also have 2–3 times higher mortality rate from abortion compared with white women. Bartlett *et al.* found that "[t]he 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."[31]

53. 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

[27] *Id.*
[28] *Id.*
[29] 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.
[30] 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.
[31] 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.

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."[32]

54. Dr. Farris cites the study by the National Academies of Science as supporting the safety of abortion.[33] The NAS report has very significant flaws. The NAS 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.
>
> 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'.
>
> 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.
>
> 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 chemical 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

[32] Zane *et al.*, *supra* n.30.
[33] 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.

abortionists do not maintain hospital admitting privileges or care for their own complications.[34]

55. The studies cited by Dr. Farris and Dr. Boraas by Upadhyay *et al.* are unreliable.[35] For example, the 2015 study has many limitations, 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 did not engage with the medical system.[36] As with many studies of this type, no charts were reviewed.[37] There was very limited follow up.[38] The authors acknowledge some of these issues.[39] They also note that 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.[40]

56. For the 2018 study by Upadhyay *et al.*, a national sample was used, but this study also had issues.[41] For example, it included only about 15.7% of hospitals.[42] It under-sampled some regions (West and South) and oversampled others.[43] Significantly, the authors note that "Most visits were to non-trauma or trauma level

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[34] AAPLOG Practice Guideline Number 8 (February 2020).
[35] Farris Report ¶¶ 31 n.13, 51 n.40, 61 n.41; Boraas Report ¶¶ 3 n.1, 21 ns.11 & 13, 24 ns.23 & 29, 28 n.38, 49 n.45, 50 n.46.
[36] 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.
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *Id.*
[41] Upadhyay U, Johns NE, 1, Barron R, Cartwright AF, Tapé C, Mierjeski A, McGregor AJ. Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample. BMC Medicine (2018) 16:88.
[42] *Id.*
[43] *Id.*

III hospitals (62.8%) and most were to hospitals in urban locations (92.3%)."[44] Similar to other retrospective administrative database research studies, other 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.[45] Gestational age at the time of abortion, race-ethnicity and abortion method were not ascertained for this study.[46] As with many studies of this type, no charts were reviewed.[47]

57. However, it is noteworthy that one-third of patients in the 2018 study by Upadhyay et al required suction curettage for bleeding and presumed retained fetal parts, placenta and membranes, and that 15 patients in the sample had ED visits ending in the patient's death. [48]Per Upadhyay et al, "the major incident rate may have been slightly underestimated . . . Likewise, *this study may miss abortion-related incidents that were inaccurately coded as a miscarriage* [emphasis added]".[49]

58. The study by Upadhyay et al (2002), cited by Dr Boraas, actually admits that not all patients who might have ectopic pregnancy would be diagnosed before abortion.[50] Yet the study authors disregard this fact in this statement. Rather, they

[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] Ushma D. Upadhyay, Christy M. Boraas et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study,* 182 J. Am. Med. Ass'n Internal Med. 482, 488 (2022).

state that a higher emphasis should be put on "expanded access, increased convenience, and earlier treatment" than "identification of ectopic pregnancies."[51]

59. The study by Upadhyay et al (2022) also has serious flaws related to ascertainment of outcomes, missing data and loss to follow up. This was a "retrospective cohort study assessing the effectiveness and safety of using history - based screening alone for chemical abortion."[52] The study was designed to estimate the safety and effectiveness of no-test chemical abortion (i.e., no hCG testing was performed, nor was ultrasound or Rh testing done). chemical abortion pills were dispensed through telemedicine and through the mail.[53] Dispensing abortion pills without seeing a patient, assessing gestational age or Rh status, evaluating for ectopic pregnancy, or screening for coercion, abuse or trafficking is not clinically appropriate.

60. 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.[54] Abortions were classified as complete based on laboratory or ultrasound findings, or a symptom checklist or patient report.[55] Some records were recoded as complete if notes in the chart indicated that "the treating clinician had no

[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*

concern that the abortion was incomplete after phone, text, or email follow-up contact with the patient."[56] Some of these definitions were not consistent or objective.

61. 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.[57] In the final sample, slightly less than 2/3 (63%) of patients had abortion outcome data.[58] Four patients were treated for ectopic pregnancy.[59] The authors note that "we may have failed to identify some additional interventions and adverse events."[60] 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.

62. 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.

63. Dr. Boraas 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."[61]

64. In evaluating the risks of childbirth vs abortion, the NAS report compared mortality from abortion to mortality from childbirth and several surgical

[56] *Id.*
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] Boraas Report ¶ 24.

procedures.[62] There are multiple problems with the data sets used, as well as mortality data which were not evaluated in the report.

65. 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.[63] 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.

66. U.S. maternal mortality data are also incomplete. Based on my understanding of the data, 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.[64]

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[62] *See National Academies*, *supra* n.40.

[63] 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.

[64] 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.

67. As noted above, U.S. abortion data are incomplete. Because of these severe data deficiencies, the U.S. did not report a maternal mortality ratio to the world from 2007–16.

68. 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.

69. Many pregnancy outcomes are never reported, for example women who miscarry and never engage with the health system. 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).

70. 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.[65]

[65] 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.

71. 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."[66]

72. Assertions that abortion is safer than childbirth also do not take into consideration the biology of pregnancy. Based on my understanding of 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.

D. An abortion procedure is not the same as a procedure to manage miscarriage

73. Dr. Farris states that "the process of medication abortion very closely approximates the process of miscarriage."[67] This is a medically and ethically inaccurate statement.

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[66] 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.

[67] Farris Report ¶ 17.

74. Abortion and miscarriage are quite different, and abortion is neither ethically nor medically identical to miscarriage. 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 (dilation and suction curettage) to remove the fetus, placenta and membranes. There are important moral and ethical differences between the two procedures.

75. Surgical treatment. There are three surgical methods for treating miscarriage. These are dilation and sharp curettage (D&C), dilation and suction curettage (suction D&C), and manual vacuum aspiration (MVA). With dilation and sharp curettage, the patient is given sedation and pain medicine. Next the cervix is grasped with a clamp. A local anesthetic (such as lidocaine) is injected into the cervix to reduce pain. The cervix is dilated using plastic or metal cone-shaped dilators, then a curette (a loop-shaped stainless-steel instrument) is passed into the uterus and used to remove the uterine contents – the demised fetus along with the placenta and membranes.

76. With suction D&C, as above the patient is given sedation and pain medicine, the cervix is grasped with a clamp, a local anesthetic is injected into the cervix, and the cervix is dilated. A plastic suction curette is then passed into the uterus. The curette is attached to an electric device which creates a vacuum. A combination of suction and curettage removes the uterine contents. Suction and sharp curettage has replaced sharp curettage because it is faster, safer and less painful.

77. With manual vacuum aspiration (MVA), a plastic curette is attached to a handheld syringe. A vacuum, generated manually, provides suction, which removes the embryo or fetus, amniotic fluid, and membranes.

78. Suction D&C has been used in hospitals for decades to treat first and second trimester miscarriages where there is hemorrhage, or retained placenta and fetal parts.

79. However, MVAs were originally not designed for the United States. Beginning in the late 1980s and early 1990s, manual vacuum aspiration began to be used in developing countries for treatment of bleeding and retained fetal parts or placenta following miscarriage.[68] Unlike suction D&C, the use of MVA is limited to miscarriages up to about 9 weeks because the cannula and syringe are too small to treat later miscarriages. In contrast, it is my understanding that suction D&C can be used up to about 14–16 weeks' gestation.

80. Dr. Farris states, without providing any references, that "[a]bortion providers have used MVAs in aspiration abortion for decades, but because MVAs are associated with abortion, hospitals were reluctant to use them for miscarriage management."[69] Here Dr. Farris has conflated the treatment of first trimester miscarriage using MVA—which can readily be performed in an outpatient setting with the management of second trimester miscarriage—which is best performed in a hospital and for which the use of MVA is an adjunct. The question in this case is not

[68] Johnson B, Benson J, Bradley J, Rabago Ordonez A. Costs and resource utilization for the treatment of incomplete abortion in Kenya and Mexico. Soc). . Sci. Med. Vol. 36. No. Il. pp. 1443-1453, 1993.
[69] Farris Report ¶ 39.

whether first trimester procedures should be performed in a hospital, but whether second trimester ones—either for miscarriage management or abortion—should be.

81. Dr. Farris states, without supporting statistics, that D&E for second trimester miscarriage are routinely performed in inpatient and outpatient settings.[70] In my experience, working in more than 20 hospitals (7 in NC), over 33 years of clinical practice, I have noted that OB/GYNs manage second trimester miscarriages in the hospital setting. In fact, Dr. Boraas agrees with this, stating that "miscarriage management more typically happens in hospitals or ambulatory surgical centers."[71] She goes on to state, without any supporting data, that "usually there is no medical or scientific reason for that—it is simply that abortion care has been stigmatized and siloed."[72]

82. But second trimester miscarriage is typically managed in the hospital precisely because there are good clinical reasons to do so, such as the risk of severe or life-threatening hemorrhage, retained placenta, cervical laceration, DIC, and pain control. Hemorrhage, for example, can be unpredictable, can occur quickly and can be difficult to control. In the hospital, IV fluids, blood and staff including anesthesia staff are immediately available. Epidural anesthesia is also an option for pain control in-hospital.

83. Dr. Boraas claims that "[g]eneral anesthesia or deep sedation are not necessary for most second trimester abortion patients."[73] But research suggests that

[70] *Id.* ¶ 45.
[71] Boraas Report ¶ 19.
[72] *Id.*
[73] Boraas Report ¶ 36.

for patients undergoing second trimester abortion, pain control is often suboptimal and problematic and that such pain affects patients' experience of the procedure.[74]

84. 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. Additionally, Dr. Boraas states that "doctors are willing to provide miscarriage management, but they may lack . . . support or fear threats of violence when it comes to abortion care,"[75] without any data to support these assertions. As noted above, a small percentage of OB/GYNs perform abortions and this number has been decreasing for decades. Most OB/GYNs choose to care for patients with miscarriage, but do not choose to perform abortions.

85. Dr. Farris states in her report that "the rates of miscarriage-treatment-related complications are higher than documented rates of abortion-related complications."[76] She references a publication, Advancing New Standards in Reprod. Health, Safety of Miscarriage Treatment in Hospitals, ASCs [ambulatory surgical centers], and Office-Based Settings to support her claim.[77] This issue brief states, "This study used a private insurance claims database with a large, national sample to compare the safety of miscarriage treatment in different facilities: hospitals, ASCs, and office-based settings. . . . Researchers reviewed 97,374 miscarriages treated in

[74] 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.
[75] *Id.*
[76] Farris Report ¶ 36.
[77] *Id.* ¶ 36 &n.26.

hospitals, ASCs or office-based settings and identified miscarriage-treatment-related complications."[78] However, the publication gives no citation for this assertion. Reviewing the references for this article, only 2 out of 7 citations focus on miscarriage and neither "used a large national sample to compare the safety of miscarriage treatment in different facilities." Dr. Farris has therefore not provided any data to support her assertion that "rates of miscarriage-treatment-related complications are *higher* than documented rates of abortion-related complications."[79]

86. In a study comparing outcomes for women undergoing D&E for second trimester abortion or fetal death, Kerns *et al*. noted that "possible complications can include cervical laceration, uterine perforation, infection and hemorrhage. Disseminated intravascular coagulation (DIC) is of particular concern due to the possibility of excessive and uncontrolled blood loss, possibly requiring a transfusion or in extreme cases resulting in maternal death."[80] DIC occurs when the mother's blood loses the ability to coagulate, resulting in a cascading series of complications that require transfusions and intensive care.

87. Dr. Farris cites Kerns *et al*. regarding increased risk for D&E performed for miscarriage vs. abortion, stating that "[n]otably, the risk of complications from a

[78] Advancing New Statndards in Reprod. Health, *Safety of Miscarriage Treatment in Hospitals, ASCs, and Office-Based Settings*, Univ. of Cal. S.F. 1, (2018), https://www.ansirh.org/sites/default/files/publications/files/safety–of–miscarriage–treatment–jps2.pdf.
[79] Farris Report ¶ 36.
[80] Kerns J, Ti A, Aksel S, Lederle L, Sokoloff A, Steinauer J. Disseminated Intravascular Coagulation and Hemorrhage After Dilation and Evacuation Abortion for Fetal Death. Obstet Gynecol 2019;134:708-713.

D&E to manage . . . a miscarriage . . . later in the second trimester can be higher than the risk of complications from a D&E for abortion at the same gestational age."[81]

88. In this study, major complications occurred in 2% of patients, with no difference between patients undergoing D&E for abortion vs. D&E for miscarriage.[82] Rates of major hemorrhage, retained products of conception and cervical laceration did not differ between the 2 groups. DIC occurred more commonly in patients with fetal death than in those undergoing abortion (2% and 0.2% of procedures respectively).[83] The authors acknowledge, however, that their results may have been confounded by the lack of data on the length of time the fetus was dead.[84] The longer a fetus has been deceased, the more likely it is that a woman will develop coagulation abnormalities.[85] As Kerns et al note, "For most cases, we did not have documentation of the time since fetal death, limiting any analysis of complication incidence by duration of fetal retention after fetal death."[86] They note "the association between prolonged fetal retention after fetal death and coagulopathy [coagulation abnormalities]" and note that further research is needed.[87] Without knowing the length of time a fetus had been dead, there is uncertainty about the conclusion that rates of DIC were higher in women undergoing D&E for miscarriage vs. abortion.

[81] Farris Report ¶ 28 & n.10.
[82] Jennifer L. Kerns et al., *Society of Family Planning Clinical Recommendation: Management of Hemorrhage at the Time of Abortion*, Contraception, 3 (2023).
[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*

These findings do not support Dr. Farris' statement that the risk of complications from D&E for miscarriage is higher than that for D&E for abortion.

89. Research has shown that the risk of complications following first trimester chemical 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 first trimester miscarriage with misoprostol experienced excessive bleeding and 3% of patients were diagnosed with infection.[88]

90. 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.[89] Rates of bleeding and infection were therefore higher for medical and surgical abortion than for treatment of miscarriage.[90]

91. Some studies have examined the mortality associated with miscarriage. Berman *et al.* (1985) found that the miscarriage mortality ratio (deaths per 1,000,000 miscarriages) increased up to 16 to 19 weeks, then declined.[91] Suraiya *et al.* (1999) found that the rate of increase of the miscarriage mortality ratio began to decline after 19 weeks.[92] See chart below for table of results.

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[88] J Trinder, P Brocklehurst, R Porter, M Read, S Vyas, L Smith. Management of miscarriage: expectant, medical, or surgical? Results of randomised controlled trial (miscarriage treatment (MIST) trial). BMJ, doi:10.1136/bmj.38828.593125.55.

[89] 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] *Id.*

[91] Berman *et al.*, *supra* n.70.

[92] Saraiya M, Green C, Berg C, Hopkins F, Koonin L, Atrash H. Spontaneous Abortion–Related Deaths Among Women in the United States—1981–1991.Obstet Gynecol 1999;94:172– 6.

Table 1. Mortality rates for miscarriage at different gestational ages

Berman et al, 1985		Suraiya et al, 1999	
Weeks of gestation	Mortality ratio (deaths per 1,000,000 miscarriages)	Weeks of gestation	Mortality ratio (deaths per 100,000 miscarriages)
0-7 weeks	0.14	---	---
8-11 weeks	0.68	0-12 weeks	0.3
12-15 weeks	5	13-15 weeks	1.5
16-19 weeks	5	16-19 weeks	4.1
20-24 weeks	2.2	---	---

92. For comparison, Bartlett *et al.* found that that the risk of a woman dying from abortion increased 38% for each week of gestational age. Based on their data, at higher gestational ages, rates of death from abortion are much higher than those from miscarriage.

93. These rates of deaths from miscarriage are lower than for induced abortion. In fact, they are likely to be markedly lower that what was noted in the study for two reasons.

94. First, many miscarriages are never documented as they occur very early in pregnancy. Women may not realize they are pregnant or may not seek care. The denominators of total estimated miscarriages in the study by both Suraiya *et al.* and Berman *et al.* are likely to be lower than the true number of miscarriages, and the authors would have therefore overestimated the ratio of deaths to miscarriages. They

acknowledge this, stating that "[b]ecause we limited our estimates to clinically recognized pregnancies, we underestimated the total number of pregnancy losses."[93]

95. Second, a number of miscarriages are "complete"—that is, the demised fetus passes in his or her entirety. Women with complete miscarriages do not undergo any medical interventions. Women undergoing abortion, on the other hand, are always exposed to both anesthesia and procedural risks, whereas women who suffer complete miscarriage are not exposed to these risks and therefore have a lower risk for death. Berman *et al.* note this, stating that "[m]any women who spontaneously abort never undergo any medical procedure and thus are not exposed to any risk of anesthesia. By contrast, all women who have an induced abortion have an operation and typically undergo some form of anesthesia."[94]

96. 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.[95]

97. In my opinion, and based on the above data, 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

[93] Berman *et al.*, *supra* n.70; *id.*
[94] Berman *et al.*, *supra* n.70.
[95] Lanska J, Lanska A, Rimm A. Mortality from abortion and childbirth. J of American Medical Association 1983;250:361.

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 first trimester of pregnancy. Abortions are mostly performed before the time in gestation when most of the maternal deaths in the maternal mortality statistics occur.

98. 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]."[96] These authors found that the risk of a woman dying from abortion increased 38% for each week of gestational age.[97] Abortions performed past 21 weeks had a mortality rate 76 times greater than abortions done in the first trimester.[98] Based on their data, during the 2nd and 3rd trimesters, the abortion related mortality equals and then exceeds that of childbirth.[99]

99. A Finnish study in 1997 as noted found death rates 4 times higher after abortion compared to childbirth up to 1 year.[100] Subsequent studies in Finland

[96] 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.
[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] 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.

showed maternal mortality-childbirth 28.2/100,000, while abortion mortality was 83.1/100,000 or 3 times higher.[101] The risk of suicide was 6 times higher following abortion.

100. 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.[102]

101. It can be concluded from the above that childbirth is safer than abortion at comparable gestational ages.

E. Aspiration & D&E abortions are surgery.

102. Dr. Farris claims that "[a]lthough aspiration abortion and D&E are both sometimes referred to as 'surgical,' they are not what is commonly understood to be surgery."[103] This statement is medically inaccurate.

103. "Aspiration abortion" is more accurately described as suction abortion with curettage, as Dr. Farris states in her own declaration, in Paragraph 21, where she states that "Aspiration abortion" is "also known as suction curettage or dilation & curettage." Both suction abortion with curettage and D&E are types of surgical abortion and are surgical procedures. They are described as such and coded, billed, and reimbursed as such.

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[101] (Gissler M, Ber C, Bouvier-Coll M, Buekins P. Pregnancy-associated mortality after birth, spontaneous abortion, or induced abortion in Finland 1987-2000).
[102] 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.
[103] Farris Report ¶ 15.

104. "Surgical abortion is a procedure that ends an undesired pregnancy by removing the fetus and placenta from the mother's womb (uterus)... Surgical abortion involves dilating the opening to the uterus (cervix) and placing a small suction tube into the uterus. Suction is used to remove the fetus and related pregnancy material from the uterus."[104]

105. "A person can have an abortion by taking medication or undergoing surgery."[105]

106. "Surgical abortion, also known as suction aspiration abortion, can be performed in a one-day procedure if less than 14 weeks have passed since the first day of your last menstrual period."[106]

107. First and second trimester surgical abortion, which are surgical procedures, are not comparable to vasectomy or contraceptive implant removals, which are minimally invasive, do not enter into viscera, and do not result in the death of a human being. Surgical abortion requires surgical training distinct from other types of training. It requires standard surgical operative sterile technique. 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. Curettage is essentially a linear incision through the lining of the uterus. These incisions are associated with surgical complications.

[104] Abortion - surgical: MedlinePlus Medical Encyclopedia.
[105] https://www.medicalnewstoday.com/articles/325582.
[106] Surgical Abortion (First Trimester) | Conditions & Treatments | UCSF Health.

108. "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."[107] Per Santamaria *et al.* (2018), "15–20% of patients receiving curettage due to an induced or spontaneous abortion . . . develop IUA [intrauterine adhesions]."[108]

109. Abnormal placental attachment occurs as a result of damage to the lining of the uterus with curettage.[109] Such damage may lead to premature separation of the placenta (abruption) or invasion (accreta). 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. Baldwin *et al.* note that in 1950, pre-*Roe*, abnormal placental attachment occurred in 1:30,000 deliveries.[110] In 2016 it occurred in 1:272 deliveries, a 110-fold increase.[111]

110. 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.

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[107] 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.
[108] *Id.*
[109] 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.
[110] *Id.*
[111] *Id.*

111. 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.

112. Dr. Farris states that "[d]ilation and evacuation . . . uses a combination of gentle suction and additional instruments . . . to evacuate the pregnancy contents from the uterus."[112] This statement is medically and ethically inaccurate. Even by abortionists' accounts, D&E is anything but gentle. In fact, it is a demonstrably brutal procedure that kills an unborn child in a way that would not be countenanced for an animal. D&E involves the cutting up, tearing apart, and crushing of the fetus, and is therefore a destructive feticidal surgical procedure.

113. Abortion is not comparable to the other surgical procedures listed in Dr. Farris's report.[113]

a. Vasectomy: The incisions made during vasectomy are superficial. Bleeding is usually minimal. Moderate sedation or general anesthesia are not used. In fact, the paper cited by Dr. Farris, by Adams and Wald, 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."[114] It does not mention damage to bowel or bladder, sepsis, embolism, coagulation

[112] Farris Report ¶ 25.
[113] *Id.* ¶ 33.
[114] Christopher E. Adams & Moshe Wald, Risks and Complications of Vasectomy, 36 Urologic Clinics N. Am. 331, 331 (2009).

problems, hemorrhage or other complications that are associated with abortion.[115]

b. Colonoscopy: Colonoscopy involves no forcible dilation or scraping of viscera. Deeper levels of sedation or general anesthesia are not used. The paper cited by Dr. Farris does not focus on colonoscopy complications.[116] 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.[117] This paper cannot answer the question of whether colonoscopy is associated with fewer complications than abortion.

c. Wisdom tooth extraction: Wisdom tooth extraction involves no entry into viscera. Moderate sedation or general anesthesia are not used. The study cited by Dr. Farris focuses on impacted wisdom teeth, not non-impacted wisdom teeth.[118] 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.

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[115] *Id.*

[116] Ranasinghe I, Parzynski C, Searfoss R, Montague J, Lin Z, Allen J, Vender R, Kanchana B, Ross J, Bernheim S, Krumholz H, Drye E. Differences in Colonoscopy Quality Among Facilities: Development of a Post-Colonoscopy Risk-Standardized Rate of Unplanned Hospital Visits, 150 Gastroenterology 103, 109 (2016).

[117] *Id.*

[118] Francois Blondeau & Nach G. Daniel, Extraction of Impacted Mandibular Third Molars: Postoperative Complications and their Risk Factors, 73 J. Canadian Dental Ass'n 325, 325b (2007).

Farris does, that the stated complication rate for removal of impacted wisdom teeth is the same as for removal of all wisdom teeth. Further, the complication rate quoted by Dr. Farris comes from the below table, listing 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.

d. Tonsillectomy: Tonsillectomy involves no entry into viscera. The paper cited by Dr. Farris is a randomized controlled trial to assess whether tonsillectomy, adenotonsillectomy or nonsurgical management is better in children.[119] Its goal was to assess whether surgery offers benefit over nonsurgical management of children with repeated episodes of throat infection.[120] The authors concluded, that "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."[121] 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.

114. In contrast, first trimester surgical abortion carries immediate risks of hemorrhage, infection, continuing pregnancy, death, perforation of the uterus,

[119] Blondeau F and Daniel Nach. Extraction of impacted mandibular third molars: postoperative complications and their risk factors. JCDA May 2007, Vol. 73, No. 4.
[120] *Id.*
[121] *Id.*

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.*[122]

115. 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	0.1-0.2% (39-800)	*ACOG Practice Bulletin #135*, 2013

[122] 2020_CPGs.pdf (prochoice.org).

Amniotic fluid embolus‡	0.000125 - 0.001% (<1-<1)	
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

116. As noted, first and second trimester abortions are very different in terms of morbidity, mortality, and complications. 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.[123] 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.

[123] CDC, *supra* n.7.

117. Dr. Farris's allegation also overlooks the fact that the frequency of complications associated with a procedure is not the same as the magnitude and severity of complications.[124] 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. The papers cited above 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.

F. Second-trimester abortion is better performed in a hospital.

118. There are very limited data on whether it is safer to perform second-trimester abortion in hospitals or in clinics. However, available data, as well as patient experience and my personal experience, suggest that not only is the safety of second-trimester abortions performed in clinics overrated, but there are also excellent reasons for these abortions to be performed in hospitals.

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

[124] Farris Report ¶ 13.

120. The ACOG paper cited does not discuss the question of whether abortions should be performed in hospitals vs clinics.[125]

121. The APHA citation is a 2008 policy statement that does not discuss the question of whether abortions should be performed in hospitals vs clinics.[126]

122. 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.[127]

123. 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.[128]

124. The U.S. 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.[129]

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[125] Comm. on Health Care for Underserved Women, ACOG Committee Opinion No. 815: Increasing Access to Abortion, 136 Obstetrics & Gynecology e107, e109 (2020).
[126] 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.
[127] Barbara S. Levy et al., Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology, 133 Obstetrics & Gynecology 255 (2019).
[128] 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).
[129] 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-

125. Moreover, multiple women's deaths from abortions performed in clinics have been documented.[130]

126. 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.[131] 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.

127. These documented deaths and complications from abortion 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.

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low-volumehospitals#:~:text=These%20large%20numbers%20of%20low,similar%20patients%20rather%20than%20by.

[130] *See, e.g.*, https://www.nydailynews.com/news/queens-clinic-a1-medicine-probed-alexandra-nunez-fatally-injured-undergoing-abortion-article-1.460728; https://abortiondocs.org/wp-content/uploads/2018/01/2011-Washington-Surgi-Clinic.pdf; https://www.nytimes.com/2016/10/12/nyregion/queens-doctor-is-charged-for-womans-death-after-abortion-procedure.html.

[131] *See, e.g.*, https://www.youtube.com/watch?v=tDwBL9tlzzU; https://www.operationrescue.org/archives/abortion-injuries-on-the-rise-at-chapel-hill-planned-parenthood/; https://www.operationrescue.org/archives/abortion-injuries-on-the-rise-at-chapel-hill-planned-parenthood/.

128. Dr. Farris alleges (based on the paper by Jones *et al*.) that 3% (total 2810) of abortions are performed in hospitals.[132] There are methodological problems inherent in this Guttmacher Institute abortion report, which include:

a. The use of surveys rather than patient-level data (47% response rate).[133]

b. Estimation of "caseloads at facilities that accounted for 12% of abortions and used state health department data for the remaining 4% of abortions.[134] This problem was particularly pronounced in six states, including larger ones such as New York (30%), Florida (33%), and New Jersey (40%)."[135]

c. 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."[136] In other words, the authors made estimates for a substantial number of caseloads, using

[132] Farris Report ¶ 40.
[133] 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.
[134] *Id.*
[135] *Id.*
[136] *Id.*

sources such as media stories, which weakens the validity of their study.

d. The study did not appear to collect or did not report data on race/ethnicity.[137]

e. The study did not appear to collect or did not report data on gestational age at the time of abortion.[138]

129. Dr. Farris also does not address the fact that most abortions in the Jones *et al.* report, 492,210 (53%) were chemical abortions, performed in the first trimester, which at the present time are not done in hospitals.[139] Recalculating the true percent of abortions done in hospitals as a fraction of non-chemical abortions provides an estimate of 6.4%.

130. 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 North Carolina are required to report the complications they are aware of, but since abortionists practicing in clinics do not always manage their own complications, they are not always aware of them.

131. Many OB/GYN physicians, including myself, have cared for critically ill patients with serious complications from abortion because abortionists have refused

[137] *Id.*
[138] *Id.*
[139] *Id.*

to manage their complications. 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 sepsis, uterine perforation, and damage to her large bowel. She was hospitalized for 10 days and required 2 procedures.

132. Other colleagues report similar experiences. Dr. Kathy Aultman, a former abortionist, stated "As a gynecologist on call in the emergency room, I personally treated women experiencing severe complications, including life-threatening hemorrhage and infection from abortions, because no one at the abortion clinic had admitting privileges. No abortion clinic personnel ever called to give me information on a patient they were sending to the ER. This is not a safe way to practice medicine."[140]

133. An AAPLOG practice bulletin notes that "abortionists do not maintain hospital admitting privileges or care for their own complications."[141]

134. In medicine, physicians are often referred to according to their clinical activities. For example, physicians who work primarily in a hospital setting are referred to as hospitalists, regardless of specialty. OB/GYNs who work primarily on the labor floor of hospitals are called "laborists." Similarly, the term abortionist refers to the clinical activity of abortion providers. It is also used in the biomedical literature, including as a title by which abortionists refer to themselves.[142]

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[140] Former abortionist: Clinic safety takes a back seat to abortion rights (usatoday.com).
[141] AAPLOG Practice Guideline No. 8, 2020.
[142] *See, e.g.*, Michaels, M. O., Michaels, F. I., & Otto, S. (2023). Inception of Life on the Pendulum of Death: Common Paradigms and Uncommon Narratives on the Polemics between Birthers and Abortionists. Sociology Mind, 13, 95-115; Matthew Lee Anderson, Anti-abortionist Action Theory and the Asymmetry between Spontaneous and Induced Abortions. The Journal of Medicine and

135. 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. It is not appropriate for emergency rooms and hospitals to backstop for clinicians who do not wish to manage their own complications when these procedures could be performed more safely in a hospital. It is an axiom in medicine that physicians should not perform procedures if they are not able to manage their complications.

136. Dr. Farris claims that "licensed abortion clinics like PPSAT's [are safer] for most patients than most hospitals, many of which do not routinely provide abortion care."[143] Again, Dr. Farris conflates organizations offering abortion with clinicians providing abortion.

137. 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. For this reason, clinicians often perform abortions which they feel to be higher risk in hospitals.

138. Dr. Farris alleges that "[i]n fact, at least one study demonstrated that second-trimester terminations of pregnancy by D&E in appropriate patients in a

Philosophy: A Forum for Bioethics and Philosophy of Medicine, 2023, 48, 209–224; Barbara Baird, "Happy Abortionists": Considering the Place of Doctors in the Practice of Abortion in Australia since the Early 1990s. Australian Feminist Studies Volume 29, 2014 - Issue 82).

[143] Farris Report ¶ 42.

dedicated outpatient facility can be safer and less expensive than hospital-based D&E or induction of labor."[144]

139. But 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. Retrospective studies are very vulnerable to bias and confounding.[145] 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).[146]

140. 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.[147]

141. The authors also note that complications may have been underreported due to loss to follow-up in the clinic patients: "In our cohort . . . [i]t 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-

[144] Farris Report ¶ 42.
[145] Turok *et al.*, *supra* n.21.
[146] *Id.*
[147] *Id.*

related complications, have undergone a prior cesarean section and have had prior early pregnancy failure."[148]

142. Turok *et al.* go on to note that "[a]s 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."[149]

143. This study lacks data on race-ethnicity and Medicaid status.[150] There are also significant differences between the populations studied.[151] The authors also chose to combine cases of D&E for abortion with cases of *in utero* fetal death.[152] It is highly possible that these issues were associated with residual confounding and bias of the results.

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

145. Dr. Farris claims that "[t]he features that differentiate hospitals from abortion clinics include systems operations requirements, staffing requirements, and

[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] *Id.*

building construction requirements. Not only are these features irrelevant and unnecessary in the context of abortion care, they also provide no medical benefit."[153]

146. 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.

147. In fact, during one of the emergency calls by PPSAT Chapel Hill, the physician requests that paramedics come in through a side door stated, "The side door is important. We would prefer that you come there . . . a broader doorway."[154]

148. Abortion clinics are also not open 24 hours per day to address urgent complications which may arise after business hours and on weekends. Dr. Farris's statement that "PPSAT sometimes has clinic days on which, for staffing reasons, it is able to offer chemical abortion but not procedural abortion"[155] 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.

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[153] Farris Report ¶ 39.

[154] https://www.operationrescue.org/archives/abortion-injuries-on-the-rise-at-chapel-hill-planned-parenthood/.

[155] Farris Report ¶ 62.

149. While PPSAT may claim that it has adequate safety protocols and experienced abortion providers on staff, it is not the only abortion facility in North Carolina. In fact, fewer than half of abortion facilities in North Carolina are Planned Parenthood affiliates. Therefore, it cannot attest to the capabilities of other abortion organizations or their clinical protocols related to second trimester abortion. The risks of second trimester abortion are inherent to the procedure and are serious and not infrequent. Requiring that these procedures be done in the hospital helps protect women from poor outcomes.

150. In 2016, Americans United for Life published data collected from 32 states over 8 years on abortion clinic health and safety violations.[156] More than 1,400 clinic health and safety violations were documented in the report. The top 10 violations were:

a. Failure to ensure a safe and sanitary environment and failure to follow infection control protocols;

b. Failure to accurately document patient records and keep patient information confidential;

c. Failure to ensure staff were properly trained for duties;

d. Unlicensed/unqualified/untrained staff providing patient care;

e. Expired medications and medical supplies;

f. Failure to purchase and maintain required equipment;

[156] Unsafe: How the public health crisis in America's abortion clinics endangers women. Americans United for Life, 2016.

g. Failure to adopt, follow and/or periodically review health and safety protocols;

h. Failure to properly handle medications:

i. Failure to comply with physical plant standards;

j. Failure to monitor patient vital signs.

151. A report on inspections of North Carolina abortion facilities shows that over the past 5 years, several clinics have been cited for similar deficiencies. 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 were cited for deficiencies.[157] 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.

152. The above data indicate a history of 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 documented problems in abortion clinics (as noted above), there is no mechanism other than biannual inspection by the Department to verify the safety of clinical activities, and no accrediting body promulgating standards of care to which abortion clinics may be held accountable.

[157] *See* NC DHSR AHCLCS: Reports of Surveys for Abortion Clinics, ncdhhs.gov.

153. The fact that abortion clinics cannot meet minimal state-mandated standards of safety and hygiene raises concerns that they can safely perform second trimester abortion procedures.

154. 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.

155. In addition to state and federal inspections, many hospitals choose to go through voluntary accreditation by an independent nonprofit accrediting organization, the Joint Commission On Accreditation of Health Organizations. 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.

156. The Centers for Medicare and Medicaid Studies 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.

157. Hospitals are required to maintain complete, comprehensive and accurate medical records. They also 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.

158. 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.

159. 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. In contrast, in outpatient abortion clinics, anesthesia is administered by the abortionist performing the procedure, who is not an anesthesiologist.[158]

160. Dr. Farris states that "only 3% of abortions are performed in hospitals"[159] However, given that there were approximately 600,000 to 700,000 abortions in the United States in 2020,[160] this means that 18,000 to 21,000 abortions were performed in hospitals.

161. In North Carolina in 2020, an estimated 1,894 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.[161]

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[158] Farris Report ¶¶ 23, 26.
[159] *Id.* ¶ 92.
[160] Abortion Surveillance — United States, 2020 | MMWR (cdc.gov).
[161] *Id.*

162. 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.[162] For example, Dr. Beverly Gray, one of the plaintiffs in the case, "provides abortion both in a hospital setting and in outpatient clinics."[163]

E. The Hospitalization Requirement benefits, not burdens, women in crisis relationships.

163. 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.[164]

164. The paper by L.G. Ward *et al*, cited by Dr. Farris, notes positively the possible benefits of trauma-informed care for patients who carry to term.[165] Nowhere in this paper is abortion mentioned as a positive alternative to carrying a baby to term.

165. The *Roberts et al.* study[166] cited by Dr. Farris[167] is problematic for two reasons. First, many abortions are coerced. [168] Yet this question was not addressed in

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[162] *See* https://obgyn.duke.edu/education-training/fellowship-programs/complex-family-planning and Complex Family Planning Procedures Clinic - UNC Department of Obstetrics & Gynecology.
[163] Compl. ¶ 24.
[164] Mahkorn Sandra (1979) Pregnancy and Sexual Assault. In: Mall, Watts, The Psychological Aspects of Abortion. University Publications of America,Washington, D.C, 55-69.
[165] L. G. Ward, *Trauma-Informed Perinatal Healthcare for Survivors of Sexual Violence*, 34 J. Perinatal & Neonatal Nursing 199 (2020).
[166] Sarah C.M. Roberts et al., *Risk of Violence From the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, 12 BMC Med. 1, 5 (2014).
[167] Farris Report ¶ 84.
[168] 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; Moore A, Frohwirth L, Miller E.

the study. Second, it is 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).

166. For comparison, a systematic review and meta-analysis of worldwide data on intimate partner violence by Román-Gálvez *et al.* noted that "[d]ue 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."[169]

167. In my opinion, a false equivalence has been set up, which is 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. 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, helping her avoid the physical and psychological risk of abortion, supporting her through her pregnancy, and ensuring she and her child are protected from the perpetrator.

168. 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 they can provide resources to assist women in crisis while

Male reproductive control of women who have experienced intimate partner violence in the United States. Soc Sci Med 2010 Jun;70(11):1737-44.

[169] Rosario M. Román-Gálvez RM, Martín-Peláez S, Fernández-Félix BM, Zamora J, Khan KS, Bueno-Cavanillas A. Worldwide Prevalence of Intimate Partner Violence in Pregnancy. A Systematic Review and Meta-Analysis. Front. Public Health, 30 August 2021.

engaging law enforcement.[170] To the best of my knowledge, such resources are not available at abortion clinics.

169. 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. Dr. Farris presents no evidence that this is routinely done at PPSAT. Without this evidence, it is more difficult to prosecute abusers and rapists.

170. Therefore, the Hospitalization Requirement offers needed protection to vulnerable women and children.

F. The Hospitalization Requirement benefits, not burdens, the parents of unborn children with fetal anomalies have other options.

171. 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.[171]

172. 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

[170] *See, e.g.*, Three steps every hospital can take to implement human trafficking prevention programs | AHA News; How Nurses Can Recognize And Report Human Trafficking | NurseJournal; . Identifying and Assisting Victims of Human Trafficking | AHA.

[171] 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; Nora Sullivan & Eoghan de Faoite, Psychological Impact of Abortion due to Fetal Anomaly: A Review of Published Research, 32 Issues L. & MED. 19 2017.

and other care can improve both the quality and length of life for the newborn as well as psychological outcomes for the parents.[172]

173. 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. Between 40–85% of women will typically choose perinatal hospice or palliative care for a fatal fetal anomaly, if given the option.[173]

174. Hospitals are often associated with a perinatal hospice program. In contrast, based on a review of the literature there is no evidence that absent legal requirements, perinatal hospice is offered by abortion clinics.

175. Dr. Farris states that "[p]atients 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

[172] C. Malloy, M. Chireau Wubbenhorst, T. Sander Lee, The Perinatal Revolution, Issues in L. & Med. 26 Vol. 34 no. 1 (2019), page 15, 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); 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.

[173] 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).

risk from clinicians who provide abortion care infrequently."[174] But she provides no data are provided to support this statement and it is therefore speculative. On the contrary, the University of North Carolina Memorial Hospital has performed hundreds of abortions over the last few years.[175]

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

176. Dr. Farris claims that "[m]ifepristone and misoprostol are safe—substantially safer than Tylenol and Viagra, for example."[176] The report cited by Dr. Farris to support this allegation does not accurately report the data from the FDA report on post-marketing events in women who had taken mifepristone.[177] The FDA report is shown below.

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).

[174] Farris Report ¶ 72.
[175] *See* 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.").
[176] Farris Report ¶ 18.
[177] See Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,"* Univ. of Cal. S.F. (2019), https://www.ansirh.org /sites/default/files/publications/files/mifepristone_ safety_4-23-2019.pdf.

177. The report also states inaccurately that "13 cases appear to be unrelated to the abortion."[178] This is not only false, but it also implies that FDA came to this conclusion, when such a conclusion appears nowhere in the FDA report.

178. The report also states that "[b]ecause 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 chemical abortion."[179]

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

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

[178] *Id.*
[179] *Id.*

181. As noted by Drugwatch, "[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].[180]

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

[180] https://www.drugwatch.com/fda/black-box-warnings/.

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)

183. 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)

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

185. Per Dailymed's data on acetaminophen, "[m]ost 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."[181]

186. Dr. Farris states that "[a]ccording to the FDA, serious adverse events . . . are 'exceedingly rare, generally far below 0.1% for any individual adverse event.'"[182] However, her citation links to an approval letter for Danco's supplemental new drug application, which says nothing about safety or the incidence of adverse events associated with mifepristone.[183]

187. 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.

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[181] https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=511536b2-6cbd-463e-b2db-6feec474cf6b.

[182] Farris Report ¶ 18 & n.7 (citing Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Medical Review(s)*, FDA, 47 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf).

[183] *Id.*

188. An updated 2022 FDA complete post-marketing report for mifepristone is shown 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 - 06/30/22[‡]
Cases with any adverse event	2740	1473
Hospitalized, excluding deaths	768	280
*Experienced blood loss requiring transfusions [§]	416	188
Infections [||] (*Severe infections [¶])	308 (57)	106 (14)

[†] 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.

189. 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 chemical abortion is for the

most part an elective procedure, deaths and serious complications from mifepristone represent an unacceptable level of risk.

190. In a study cited by Dr. Boraas, Barnhart *et al*. noted that 15% of patients undergoing chemical abortion required subsequent surgical abortion to complete the procedure.[184]

H. Diagnosis of Pregnancy

191. Dr. Farris alleges that "preserving patients' access to this very early abortion care is all the more important given North Carolina's twelve-week ban."[185] Yet Dr. Farris presents no data on the percent of women in her clinic (or any of PPSAT's clinics) with a pregnancy of unknown location who undergo abortion before a pregnancy can be visualized.

192. Pregnancy is suspected from signs such as absent menstrual cycles and signs of pregnancy. It is diagnosed using tests for human chorionic gonadotropin (hCG), a hormone produced by the placenta, and ultrasound.

193. Very sensitive blood tests can detect a pregnancy within days of conception. As home pregnancy test technology has progressed, most home pregnancy tests are now sensitive enough to detect a pregnancy at about 4 weeks' gestation (i.e., an average hCG level of 100 mIU/mL) and some can potentially detect pregnancy earlier. For example, a review of over-the-counter home pregnancy tests showed a

[184] Kurt Barnhart et al., *Pregnancy of Unknown Location: A Consensus Statement of Nomenclature, Definitions, and Outcome*, 95 Fertility & Sterility 3 (2011).
[185] Farris Report ¶ 9.

range of sensitivities from 2.8 mIU/mL to 25.7 mIU/mL.[186] The below chart shows reference ranges for hCG by weeks of gestation.

Week of gestation	hCG level
3	6 - 71
4	10 - 750
5	217 - 7138
6	158 - 31795
7	3697 - 163563
8	32065 - 149571
9	63803 - 151410
10	46509 - 186977

194. According to *Radiopaedia*, "[t]he gestational sac is the first sign of early pregnancy on ultrasound and can be seen with endovaginal [transvaginal] ultrasound at approximately 3–5 weeks gestation when the mean sac diameter (MSD) would approximately measure 2–3 mm in diameter.[187]

195. 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."[188]

196. At about 6 weeks, 2 days' gestation using transvaginal ultrasound, and 6 weeks, 4 days' gestation using transabdominal ultrasound, "the embryo appears, which has also been designated as the embryonic pole or embryonic disc," also known

[186] Minkin, M., Embryonic development and pregnancy test sensitivity: the importance of earlier pregnancy detection, Women's Health 2009; 5(6), 659-667.
[187] https://radiopaedia.org/articles/gestational-sac?lang=us.
[188] *Id.*

as the fetal pole.[189] The fetal pole is the earliest sonographic manifestation of the developing embryo (that is, the first sign of the body of the unborn child).[190]

197. In my opinion, based on the above articles, cardiac activity is present in the embryo before the pregnancy can even be detected by ultrasound imaging and can be seen as early as 5 weeks gestation, depending on characteristics of the patient's body and the skill of the sonographer. On ultrasound at that stage, fetal cardiac activity looks like a faint twinkle within the embryo. Since the widespread use of ultrasound began in the 1980s, these ultrasound findings have been used to visualize the developing child.

198. Edwards *et al.* noted that "[s]ensitive urine pregnancy tests, transvaginal ultrasonography, and quantitative serum ß-hCG measurements have moved the diagnosis of normal and ectopic pregnancy well into the first six gestational weeks."[191] These authors used surgical abortion to evaluate for intrauterine pregnancy in women without a gestational sac or other evidence of IUP.[192] Most intrauterine pregnancies are visible by 8 weeks, which is well within NC's legal limit.

I. Ectopic pregnancy

199. Ectopic pregnancy occurs when an embryo implants outside the uterine cavity. Sites of implantation can include the Fallopian tube, the lateral part of the

[189] Hamza et al., 2016, Diagnostic Methods of Ectopic Pregnancy and Early Pregnancy Loss: a Review of the Literature, Geburtshilfe Frauenheilkd 2016 Apr.; 76(4): 377-382.
[190] Radiopaedia, https://radiopaedia.org/articles/fetal-pole.
[191] Edwards J. and Carson, S., New technologies permit safe abortion at less than six weeks' gestation and provide timely detection of ectopic gestation, Am J. Obstet Gynecol 1997; 176:1101-6.
[192] *Id.*

uterus, the abdomen, the cervix or the ovary. The Fallopian tube is the most common site of abnormal implantation, accounting for 96% of ectopic pregnancies.[193]

200. Because the Fallopian tube is a flexible thin-walled structure it will support the growth of the embryo to a certain point. Lacking the special characteristics of the uterine lining, however, it eventually becomes distended and ruptures. Because the tube has a rich blood supply, when it ruptures, hemorrhage into the abdomen occurs. Although diagnostic methods have led to earlier detection and treatment of ectopic pregnancy, it remains the leading cause of first-trimester maternal mortality. 4–6% of all pregnancy-related deaths are attributed to ectopic pregnancy.[194]

201. In a retrospective study of 2,026 pregnant patients who presented to the emergency department with first-trimester vaginal bleeding and/or abdominal pain, 376 (18 percent) were diagnosed with ectopic pregnancy.[195] Of these 376 patients, 76 percent had vaginal bleeding and 66 percent had abdominal pain.[196]

202. In another study, a population-based registry of ectopic pregnancy from France, the incidence of rupture was 18 percent.[197]

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[193] Bouyer J, Coste J, Fernandez H, Pouly JL, Job-Spira N. Sites of ectopic pregnancy: a 10 year population based study of 1800 cases. Hum Reprod 2003:17(12):3224.
[194] Anderson FW, Hogan JG, Ansbacher R. Sudden death: ectopic pregnancy mortality. Obstet Gynecol. 2004;103(6):1218.
[195] Casanova B, Sammel M, Chittams J, Timbers K, Kulp J, Barnhart K. Prediction of outcome in women with symptomatic first-trimester pregnancy: focus on intrauterine rather than ectopic gestation. J Women's Hlth 18(2), 2009, pp 199-200.
[196] *Id.*
[197] Job-Spira, Fernandez H, Bouer J, Pouly JL, Germain E, Coste J. Ruptured tubal ectopic pregnancy: risk factors and reproductive outcome: results of a population-based study in France. AJOG 1999;190(4):938).

203. The diagnosis of ectopic pregnancy should be **suspected** in a pregnant patient with no evidence of an intrauterine pregnancy on transvaginal ultrasound (TVUS) and **any** of the following:

a. "Visualization of a complex inhomogeneous extraovarian adnexal mass, an extraovarian adnexal mass containing an empty gestational sac, or intraperitoneal bleeding on TVUS.[198]

b. "A serum human chorionic gonadotropin (hCG) that is rising abnormally <35 percent over two days."[199]

c. Abdominal pain and/or vaginal bleeding, especially in those patients with risk factors for ectopic pregnancy…including prior ectopic pregnancy, prior tubal pathology or surgery (*e.g.*, pelvic inflammatory disease or tubal ligation), current use of an intrauterine device, and in vitro fertilization (IVF). However, over 50 percent of patients do not have an identifiable risk factor for ectopic pregnancy.[200]

204. The diagnosis of ectopic pregnancy can be **confirmed** when any of the following are present:

a. A gestational sac outside the uterus with a yolk sac or embryo (with or without a heartbeat) on transvaginal ultrasound.[201]

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[198] Tulandi T. Ectopic pregnancy: Clinical manifestations and diagnosis. UpToDate, July 31, 2023.
[199] *Id.*
[200] Stovall TG, Kellerman AL, Ling FW, Buster JE. Emergency department diagnosis of ectopic pregnancy. Ann Emerg Med. 1990;19(10):1098.
[201] Tulandi, *supra* n.200.

b. A positive serum hCG and no products of conception on uterine aspiration with subsequent rising or plateauing hCG levels.[202]

c. Visualization at surgery with histologic confirmation following resection of ectopic pregnancy tissue.[203]

205. For evaluation of possible ectopic pregnancy, "[t]ransvaginal ultrasound (TVUS) is the most useful imaging test for determining the location of a pregnancy. . . . It is not possible to determine whether a pregnancy is normal from a single hCG level because there is a wide range of normal levels at each week of pregnancy."[204]

206. Estimated rates of ectopic pregnancy range from 6.4 to 20.7 per 1000 pregnancies.[205]

207. Studies suggest that rates of morbidity and mortality are higher among African Americans than among European Americans.[206] Rates of ectopic pregnancy were also observed to have increased from 2006 to 2013, to 13.7 per 1000 live births, in a study using data from emergency departments.[207]

208. Rates of ectopic pregnancy appear to be rising concurrent with an increase in rates of pelvic inflammatory disease (PID). PID is a major risk factor for

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[202] *Id.*
[203] *Id.*
[204] *Id.*
[205] Zane, SB et al 2002; Van Den Eeden SK et al, 2005; Hoover KW et al 2010; Stulberg DB et al 2014; Casadio et al, 2020.
[206] Stuhlberg DB, Cain L, Dahlquist IH, Lauderdale DS. Ectopic pregnancy morbidity and mortality in low-income womenet al, 2004-2008. Hum Reprod 2016;31:666; 2016; Creanga AA, Shapiro-Mendoza CK, Bish CL, et al. Trends in ectopic pregnancy mortality in the United States:1980-2007. Obstet Gynecol et al, 2011;117:837.
[207] Mann LM, Kreisel K, Llaa E, Hong J, Torrone EA. Trends in ectopic pregnancy diagnoses in United States emergency departments. Matern Child Health J. et al 2020; 24(2):213.

ectopic pregnancy; women who have had PID are at three time the risk for ectopic pregnancy compared with women who have not had PID.[208]

209. In addition, some contraceptive methods are associated with increased risk for ectopic pregnancy if they fail. While patients using hormonal contraception or an intrauterine device (IUD) are at lower risk for conceiving, if they conceive while using these methods the risk for ectopic pregnancy is higher than for women who conceive while not using contraception. This risk has been quantified; among intrauterine device (IUD) users, the risk is 1 in 2, to 1 in 16 pregnancies. Li et al (2015) found that "current use of most contraceptives was significantly correlated with the incidence of EP following contraceptive failure, and the risk varied across the different contraceptive methods"; oral contraceptives tripled the risk for ectopic pregnancy, emergency contraception (Plan B) increased the risk more than 4-fold, and IUDs increased the risk 16 times (Furlong LA. Ectopic risk when contraception fails.[209] Research indicates that 51% of women who undergo abortion were using contraception the month they became pregnant, and that "[t]here was a statistically significant increase in the proportion of abortion patients who reported using long-acting reversible methods in the month they got pregnant."[210]

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[208] Bouyer J, Coste J, Fernandez H, Job-Spira N. Sites of ectopic pregnancy: a 10 year population based study of 1800 cases. Hum Reprod 2002;17(12):3224; Li C, Zhao WH, Zhu Q, Cao SJ, Ping H, Xi X, Wuin GJ, Yan MX, Zhang D, Qiu J, Zhang J. Risk factors for ectopic pregnancy: a multi-center case-control study. BMC Pregnancy Childbirth 2015;15:187.

[209] A review. J Reprod Med 2002;47:881; Li C et al. Contraceptive use and the risk of ectopic pregnancy: A multicenter case-control study. PLoS One 2014;9e115031.

[210] Jones R. Reported contraceptive use in the month of becoming pregnant among U.S. abortion patients in 2000 and 2014. Contraception 97 (2018)309-312.

210. Because this is precisely the population of women who are likely to seek abortion (women who are using contraception, who become pregnant), the population of women seeking abortion is likely to be at higher risk for ectopic pregnancy.

211. There does not appear to be data on rates of ectopic pregnancy in North Carolina. However, ectopic pregnancy occurs in approximately 1–2% of pregnancies in the United States. Extrapolating this data to North Carolina—where there were an estimated 142,529 pregnancies (abortions, live births, fetal deaths) in 2020[211]—there were possibly as many as 1425–2850 ectopic pregnancies in 2020. This is probably an underestimate since miscarriages are not included in this annual total number of pregnancies in NC.

212. According to Barnhart *et al.* (2010), "[e]ctopic 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."[212] In other words, the symptoms of ectopic pregnancy do not assist in making a reliable diagnosis because they can occur in a number of other situations, including miscarriage and following induced abortion (surgical or chemical abortion). As noted above, vaginal bleeding and abdominal pain are extremely common following induced abortion.

[211] Version 9.4 SAS System Output (ncdhhs.gov).
[212] Barnhart *et al.*, *supra* n.186.

213. The authors go on to note that "[p]ractice 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."[213] They note that serial hCG measurements, that is, measurements of blood levels of hCG over 48 hours or more, are needed to diagnose or rule out ectopic pregnancy.[214] In fact, they state that "[t]here is worldwide consensus regarding the utility of transvaginal ultrasound (TVS) and (serial) . . . hCG concentrations in the diagnosis of EP."[215] Therefore, evidence-based literature and consensus are clear that serial hCG levels and transvaginal ultrasound are the standard of care for diagnosis of ectopic pregnancy.[216]

214. Similar statements regarding the importance of diagnosing ectopic pregnancy and the necessity to use serial hCG levels and transvaginal ultrasound are reported in the literature.[217]

215. Barnhart *et al.* go on to note that "Diagnosis can be straightforward when TVS definitively identifies an intrauterine pregnancy (IUP) or 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),

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[213] *Id.*
[214] *Id.*
[215] *Id.*
[216] *Id.*
[217] *See, e.g.*, Condous G, Timmerman D, Goldstein S, Valentin L, Jurkovic D, Bourne T. Pregnancies of unknown location: consensus statement. Ultrasound Obstet Gynecol 2006;28:121-122 ("The initial serum human chorionic gonadotropin (hCG) level is not predictive of PUL outcome. . . . A single-visit approach to the management of PULs is not appropriate, because it may result in an unacceptably large proportion of clinically significant ectopic pregnancies being missed.").

necessitating further diagnostic tests and follow-up to achieve a final diagnosis" [emphasis added].[218]

J. Pregnancy of unknown location

216. Pregnancy of unknown location (PUL) refers to a clinical situation where a woman with a positive pregnancy test, who then undergoes transvaginal ultrasound, is not found to have either an intrauterine pregnancy or an ectopic pregnancy.

217. Among PULs, the distribution of final diagnoses is as follows[219]:

a. Ectopic pregnancy, 6 to 20 percent.[220]

b. Intrauterine pregnancy (IUP), live or nonviable, 30 to 47 percent.[221]

c. Pregnancies where the location is never confirmed, 50 to 70 percent.[222]

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[218] Barnhart *et al.*, *supra* n.186.
[219] *Id.*
[220] Hahlin M, Thorburn J, Bryman I. The expectant management of early pregnancies of uncertain site. Hum Reprod 1995; 10:1223;.Banerjee S, Aslam N, Zosmer N, et al. The expectant management of women with early pregnancy of unknown location. Ultrasound Obstet Gynecol 1999; 14:231; Banerjee S, Aslam N, Woelfer B, et al. Expectant management of early pregnancies of unknown location: a prospective evaluation of methods to predict spontaneous resolution of pregnancy. BJOG 2001; 108:158; Kirk E, Condous G, Van Calster B, et al. Rationalizing the follow-up of pregnancies of unknown location. Hum Reprod 2007; 22:1744; Condous G, Van Calster B, Kirk E, et al. Prediction of ectopic pregnancy in women with a pregnancy of unknown location. Ultrasound Obstet Gynecol 2007; 29:680.
[221] Kirk E, Condous G, Van Calster B, et al. Rationalizing the follow-up of pregnancies of unknown location. Hum Reprod 2007; 22:1744; Condous G, Van Calster B, Kirk E, et al. Prediction of ectopic pregnancy in women with a pregnancy of unknown location. Ultrasound Obstet Gynecol 2007; 29:680; Kirk E, Condous G, Haider Z, et al. The practical application of a mathematical model to predict the outcome of pregnancies of unknown location. Ultrasound Obstet Gynecol 2006; 27:311; Bignardi T, Condous G, Kirk E, et al. Viability of intrauterine pregnancy in women with pregnancy of unknown location: prediction using human chorionic gonadotropin ratio vs. progesterone. Ultrasound Obstet Gynecol 2010; 35:656.
[222] Banerjee S, Aslam N, Zosmer N, et al. The expectant management of women with early pregnancy of unknown location. Ultrasound Obstet Gynecol 1999; 14:231; Condous G, Timmerman D, Goldstein S, et al. Pregnancies of unknown location: consensus statement. Ultrasound Obstet Gynecol 2006; 28:121.

218. Pregnancies of unknown location must be evaluated, diagnosed, and treated appropriately. Evaluation typically begins with a history and physical examination, including querying the patient about her last menstrual period. Physical examination is performed to evaluate for findings suggestive of ectopic pregnancy or miscarriage.

219. Barnhart *et al.* proposed in their consensus statement that PULs could be classified as follows:

a. Category 1: Definite ectopic pregnancy – Extrauterine gestational sac with yolk sac and/or embryo (with or without cardiac activity);

b. Category 2: Probable ectopic pregnancy – Inhomogeneous adnexal mass or extrauterine sac-like structure;

c. Category 3: PUL – No signs of either ectopic pregnancy or IUP;

d. Category 4: Probable IUP – Intrauterine echogenic sac-like structure;

e. Category 5: IUP – Intrauterine gestational sac with yolk sac and/or embryo (with or without cardiac activity).[223]

220. Barnhart et al (2023) note that "[i]f given the classification of categories 1 or 5, a definitive diagnosis is made and PUL is excluded. By contrast, if given the classification of categories 2, 3, or 4", further clinical and laboratory assessment is required."[224]

[223] Barnhart *et al.*, *supra* n.186.
[224] *Id.*

221. According to consensus statements and clinical guidelines, following the initial hCG testing, serial hCG measurements are obtained every 48 hours to assess if a pregnancy is normal (that is, a living intrauterine pregnancy) or abnormal (that is, a miscarriage or ectopic pregnancy).[225] Barnhart et al note "However, serial hCG values alone (without TVUS) cannot confirm the location of a pregnancy…In all cases, continued frequent re-evaluation and assessment should occur throughout management as patients may quickly progress from stable to unstable, necessitating a timely change in patient management."[226]

222. For women with a desired pregnancy, these authors recommend assessment with hCG every 48 hours "and periodic transvaginal ultrasound assessment provided the patient remains stable (*i.e.*, has stable vital signs) and until a final pregnancy outcome (*i.e.*, ectopic pregnancy, IUP, treated PUL, resolved PUL) is confirmed."[227]

223. Importantly, Barnhart *et al.* comment on the use of mifepristone and misoprostol in the setting of PUL. They note that while surgical abortion has been described as part of the management of PUL, because it can provide tissue documenting an IUP, "immediate management with mifepristone and misoprostol has been described,"[228] referring to the study by Goldberg *et al.*[229] They go on to say

[225] Condous G, Timmerman D, Goldstein S, et al. Pregnancies of unknown location: consensus statement. Ultrasound Obstet Gynecol 2006; 28:121; Barnhart K, Bollig K. Approach to the patient with pregnancy of unknown location. UpToDate April 24, 2023.
[226] Barnhart *et al.*, *supra* n.186.
[227] *Id.*
[228] *Id.*
[229] Goldberg A, Fulcher I, Fortin J, Hofer R, Cottrill A, Dethier D, Gilbert A, Janiak E, Roncari D. Mifepristone and misoprostol for undesired pregnancy of unknown location. Obstet Gynecol 2022;139:771-80.

that "However, further studies are needed, and we do not routinely use mifepristone and misoprostol for management of PUL in our practice. Patients with an undesired pregnancy undergoing expectant management are managed the same as for those with desired pregnancy (above)."[230]

224. From the above studies it is clear that prescribing mifepristone and misoprostol exposes women to harms including undiagnosed ectopic pregnancy and unnecessary medical interventions in the case of a nonviable pregnancy.

225. The Act requires abortion providers to exercise their due diligence in pursuing a diagnosis in patients with PUL—the same due diligence that would be exercised by any OB/GYN caring for a woman with a PUL, as outlined in the consensus statements and papers listed above. To state that a woman is "at low risk for ectopic pregnancy" is not meaningful without proper diagnostic tests that will rule out ectopic pregnancy or miscarriage. Given the stakes (severe illness and injury, or death) associated with untreated ectopic pregnancy, patients deserve to receive a definitive diagnosis. It is appropriate to delay abortion until a patient with a PUL is given a diagnosis of ectopic pregnancy, intrauterine pregnancy or miscarriage. Such a diagnosis can be made within 48–72 hours.

226. Contrary to Dr. Farris' allegations, there are three important reasons for the requirement that an intrauterine pregnancy be seen before abortion can be performed, that is, that chemical abortion should not be performed in a woman with a PUL.

[230] Barnhart *et al.*, *supra* n.186.

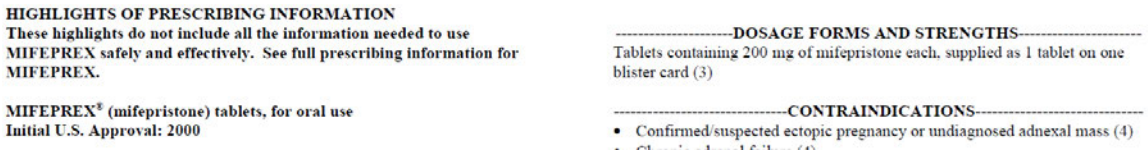
227. First, some proportion of women seeking abortion with a PUL will be in the process of having a miscarriage. Using chemical abortion in a woman with a miscarriage would unnecessarily expose her to mifepristone and misoprostol. and result in patients being charged a fee for no reason.

228. Second, another proportion of women seeking abortion with a PUL will have an ectopic pregnancy. 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. As noted above 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.[231]

229. Third, the patient may not return for follow up. If she has an ectopic pregnancy that has not been ruled out, she is at risk for tubal rupture and death.

230. Ectopic pregnancy is a contraindication to chemical abortion, based on mifepristone product labeling. The reason for this is that mifepristone does not treat ectopic pregnancy, and its use in this setting is not appropriate because a woman might take must be ruled out before using mifepristone in pregnancy. Practitioners who do not rule out ectopic pregnancy before using mifepristone for chemical abortion are ignoring clear warnings associated with the use of this drug.

[231] Mann *et al.*, *supra* n.209.



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)

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

232. 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.[232]

233. 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.

234. Because most abortions at this gestational age are elective, there must be a high bar for patient safety. Missing any ectopic pregnancy that could have been reasonably diagnosed is a failed interaction with the medical system that puts patients' lives at risk.

[232] Farris Report ¶ 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.").

235. Dr. Farris states that "[i]f . . . the patient's hCG levels are sufficiently high . . . this may be evidence of ectopic pregnancy."[233] 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 chemical 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.

236. Dr. Farris alleges that "[i]f a low-ectopic-risk patient with a pregnancy of unknown location were referred to a hospital for ectopic evaluation instead of receiving a chemical 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 chemical abortion."[234] This statement is misleading.

237. First, as noted, ectopic pregnancy cannot always be diagnosed in the setting of PUL with one hCG value and one ultrasound evaluation. While it is true that a patient with PUL who is referred to a hospital for definitive diagnosis before chemical abortion would likely receive serial hCG testing similar to what she would receive at PPSAT, she would also receive serial ultrasounds to establish a diagnosis of intrauterine pregnancy, ectopic pregnancy or miscarriage. However, this fragmented care is associated with worse outcomes.

[233] *Id.* ¶ 64.
[234] Farris Report ¶ 59.

238. The PPSAT protocol does not mention follow up ultrasound.[235] Instead, 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.

239. 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.

240. Dr. Boraas relies on a study that she co-authored to claim that PPSAT's protocol is safe and effective.[236] But that study has several limitations.

241. First, 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.[237]

242. Second, the median time to diagnose pregnancy location was 3 days in the delay-for-diagnosis group, 4 days for the immediate treatment chemical abortion group, and 2 days in the immediate treatment surgical abortion group.[238] 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

[235] *Id.* ¶ 55.
[236] Boraas ¶ 44 & n.43 (citing Karen Borchert, Christy M. Boraas et al., *Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study*, 122 Contraception 109980, at 6 (2023)).
[237] *See* Borchet *et al.*
[238] *Id.*

second group, and 17% in the third group).[239] This is higher than the national average (1–2% of pregnancies).[240]

243. Third, rates of loss to follow up were very high in this study.[241] With a high loss to follow up rate, no conclusions can be drawn related to risk for complications. There were significant differences between groups which were likely to have affected the results of the study.[242] In the other groups, however, rates of miscarriage could not be assessed.[243]

244. Of note, it took 4 days to diagnose ectopic pregnancies in the first group, 7.5 days to diagnose ectopic pregnancies in the chemical abortion group, and 4.5 days to diagnose ectopic pregnancies in the surgical aspiration group.[244] Rates of failed treatment for chemical abortion were 15% (patients required follow up surgical abortion) and 2.5% for the surgical abortion group.

245. What this study implies is that:

a. Patients with ectopic pregnancies were not evaluated and treated in a timely fashion;[245]

b. A high percentage of patients were lost to follow up, and their outcomes could not be ascertained;[246]

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[239] *Id.*
[240] *Id.*
[241] *Id.*
[242] *Id.*
[243] *Id.*
[244] *Id.*
[245] *Id.*
[246] *Id.*

c. 15% of patients in the chemical abortion group required surgical abortion;[247]

d. 5–7% of patients received unnecessary interventions (medication or surgical abortion) because they had ectopic pregnancies;[248]

e. Some percentage of patients in the medical and surgical abortion groups probably received unnecessary interventions because they were miscarrying;[249]

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 chemical abortion group, and 97.6% for the surgical abortion group).[250]

246. 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 not only can be made is safer, but it is associated with likely improved efficacy of abortion.

247. The studies cited by Dr. Farris[251] also do not prove that chemical abortion in the setting of PUL is safe.

248. 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

[247] *Id.*
[248] *Id.*
[249] *Id.*
[250] *Id.*
[251] *Id.* ¶ 60.

need for vacuum aspiration for incomplete termination."[252] However, the study never explains how this was determined, *i.e.*, ultrasound or hCG. The authors note that "[t]he lack of more specific definitions regarding outcomes . . . is troublesome."[253]

249. 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."[254]

250. The study by Goldstone *et al.* found that women with PUL who underwent chemical abortion were "significantly more likely to have EMA [early chemical abortion] failure or continuing pregnancy after EMA than women with a confirmed IUGS [intrauterine gestational sac]."[255]

251. Dr. Farris claims that "banning medication abortion, but not procedural abortion, for . . . patients with pregnancies of unknown location is arbitrary and unnecessary."[256] 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. In contrast, where such evaluation is not provided for chemical abortion.

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[252] I. Bizjak et al., *Efficacy and Safety of Very Early Medical Termination of Pregnancy: A Cohort Study*, 124 BJOG: Int'l J. Obstetrics & Gynaecology 1993 (2017).
[253] *Id.*
[254] *Id.*
[255] Philip Goldstone et al., *Effectiveness of Early Medical Abortion Using Low-Dose Mifepristone and Buccal Misoprostol in Women With No Defined Intrauterine Gestational Sac*, 87 Contraception 855 (2013).
[256] Farris Report ¶ 61.

K. The IUP Documentation Requirement

252. Dr. Farris alleges that "[n]ot only is it safe and evidence-based to provide chemical abortion to patients whose pregnancies are too early to see by ultrasound and who are at low risk for ectopic."[257] But there are significant safety and efficacy concerns with chemical abortion.

253. The integrity of some of the literature on chemical abortion in early pregnancy and abortion in general can be questioned.

254. The rate of complications was four times higher in medical than in surgical abortions.[258] Another Finnish study of 18,000 women found an 8% rate of surgery for chemical abortion failures in the first trimester, and almost 40% surgery rate in the second trimester.[259]

255. A recent article in the *New England Journal of Medicine* indirectly highlights the dangers of medication abortion in the setting of PUL.[260] According to the article, a woman

> who was at 5 weeks 4 days' gestation on the basis of the last menstrual period presented to the emergency department with severe abdominal pain; 6 days earlier, the patient had used mifepristone and misoprostol that had been procured on the internet to end the pregnancy. A pelvic ultrasound showed an empty uterus and small-volume hemoperitoneum. *Given the history of medication-induced abortion and the presumption that the pregnancy had been resolved, the presentation was attributed to hemorrhagic cyst rupture* [emphasis added]. The

[257] *Id.* ¶ 9.
[258] 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.
[259] 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.
[260] Harris L and Grossman D. Complications of unsafe and self-managed abortion. N Engl J Med 2020;382:1029-40.

> patient returned 6 days later with increased pain. Diagnostic laparoscopy revealed a ruptured right tubal ectopic pregnancy.[261]

256. The significance of this case is not that she patient attempted self-abortion, as opposed to medication abortion in the setting of PUL. It is the fact that because the patient had a history of having undergone abortion, emergency department clinicians did not pursue a diagnosis of ectopic pregnancy and attributed her symptoms to ruptured ovarian cyst. As a result, this patient was at very high risk for a fatal outcome. Similarly, a patient who has undergone medical abortion in the setting of a PUL with an undiagnosed ectopic pregnancy might present to an emergency department with abdominal pain, thinking that she was no longer pregnant. Like the clinicians in this scenario, those caring for her could be led to a wrong diagnosis, with potentially catastrophic results.

IV. Conclusion

257. In conclusion there are good medical reasons to require that all abortions after twelve weeks of pregnancy be performed in hospitals. Evidence indicates that these abortions are less safe when they are performed in abortion clinics and that patient safety is improved when they are performed in hospitals.

258. Similarly, there are good medical reasons to require that the location of a woman's pregnancy should be documented with ultrasound prior to chemical abortion. This is standard medical practice in obstetrics and gynecology because it prevents a woman from suffering the complications of undiagnosed ectopic

[261] *Id.*

pregnancy. Diagnosis of intrauterine pregnancy in women prior to chemical abortion will not only protect the patient from the complications of ectopic pregnancy but also will help serve the public health goal of reducing the morbidity and mortality from ectopic pregnancy, the leading cause of early pregnancy death. It will also prevent women from receiving a medically unnecessary intervention (medication abortion) if they are already in the process of having a miscarriage.

259. Women deserve to undergo thorough evaluation before abortion and careful management during and after abortion to prevent morbidity and mortality, and the Hospitalization Requirement and the IUP Documentation Requirement improve patient safety by helping to achieve those goals.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 12, 2023.

Monique Chireau Wubbenhorst

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

Exhibit A

CURRICULUM VITAE

Updated: 09-07-2023

Name: Monique Chireau Wubbenhorst, MD, MPH, FACOG, FAHA
Flanner Hall
Notre Dame, IN 46656

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: Africa Renewal Medical Advisory Committee.

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 -

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
Leominster Memorial Hospital 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
Moses Cone Hospital	Staff obstetrician-gynecologist (*locum tenens*)	2005

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 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**

EXPERT REPORT OF CATHERINE J. WHEELER, M.D.

I, Catherine J. Wheeler, M.D., pursuant to 28 U.S.C. section 1746 and Federal Rule of Civil Procedure 26(a)(2), do hereby declare as follows:

I. Background and Qualifications

1. I completed my Bachelor of Science in Human Nutrition at Colorado State University in Fort Collins, Colorado, in 1981. I began a Ph.D. program in

Nutrition at Cornell University in 1981, but then I changed my path to pursue a career in medicine.

2. I completed medical school at Tulane University School of Medicine in New Orleans, Louisiana, in 1987. I completed Ob-Gyn residency at the University of Utah, Salt Lake City, Utah, in 1991. In addition to general Ob-Gyn training, my residency at the University of Utah included training in second-trimester abortions for the indication of fetuses with genetic syndromes and severe fetal anomalies.

3. I am a board-certified obstetrician-gynecologist (Ob-Gyn) licensed to practice medicine in Utah. I practiced as an Ob-Gyn in Salt Lake City, UT, for 24 years from 1991 through 2015. Early in my private practice, I performed second-trimester abortions for my established patients who requested induced abortion for fetuses with genetic syndromes and severe fetal anomalies.

4. I was among the founding partners of a private Ob/Gyn practice, Millcreek Women's Center in Salt Lake City, Utah, from 1991 to 2008. I was also on the medical staff at St. Mark's Hospital, and my primary outpatient surgical centers were St. Mark's Outpatient Surgical Center and St. Mark's Hospital Surgery Center at 45th. In approximately 2008, I stopped practicing obstetrics due to a health condition but continued practicing office and surgical gynecology.

5. I became a full-time faculty member of the Ob-Gyn Department at the University of Utah from 2008 to 2012. My primary role was development of a multidisciplinary comprehensive Women's Midlife Health Clinic. Additionally, I

developed menopause and midlife health teaching curricula for the Ob/Gyn residents and provided gynecological care and surgery.

6. In 2012, I was employed by HCA St. Mark's Gynecology, a newly developed gynecology clinic, and I worked there until that clinic closed in 2015. During my tenure at St. Mark's Gynecology, I provided office gynecology care and gynecologic surgery. In 2015, I stopped practicing medicine due to my health condition.

7. I have maintained my license to practice medicine in Utah and my board certification (ABOG), and I am an ACOG Life Fellow. My current CV is attached to this report as Exhibit A. I have not previously offered testimony as an expert witness.

8. I am offering my opinions in this matter pro bono.

II. Summary of Opinions

9. Intervenor-Defendants have asked me to provide my expert opinion in this case as to the following topics:

- The differences between abortion and miscarriage;
- The diagnosis and risks of ectopic pregnancy;
- The risk of chemical abortion in a patient with a pregnancy of unknown location; and
- The medical benefits of performing second-trimester surgical abortions in a hospital, as opposed to an outpatient clinic.

10. My expert testimony is based on my education, training, clinical and personal experience, and continuing education as board-certified Ob-Gyn physician, as well a review of the current literature.

III. Expert Opinions and Reasons for Them

A. Induced Abortion and Spontaneous Abortion

11. Spontaneous abortion refers to a nonviable intrauterine pregnancy with either an empty gestational sac (no embryo), or an embryo/fetus without cardiac activity.[1] In other words, there was a spontaneous demise of the developing embryo/fetus.

12. Induced abortion—which is colloquially referred to as simply "abortion"—is the direct termination of a pregnancy and necessarily involves the intentional death of a living embryo or fetus. There are essentially three methods of surgical abortion: Dilation and Curettage (D&C), also called suction or aspiration abortion, Dilation and Evacuation (D&E), and Induction Abortion (induction of labor with or without direct feticide).[2] Rarely, a woman will require a uterotomy (incision in the uterus through the abdomen) or hysterectomy for failed D&E or induction labor, or for complications.[3] The method chosen usually depends on the gestational age and size of the embryo or fetus, which determines the feasibility of extracting the fetus through the dilated cervix. Additionally, chemical abortion is FDA-approved for use until 10 weeks of gestation.

[1] Early Pregnancy Loss, ACOG, 2018 November, Practice Bulletin 200.
[2] Second Trimester Abortion. ACOG, 2013 June, Practice Bulletin 135.
[3] *Id.*

13. Prior to 13-weeks gestation, the surgical technique for induced abortion is a suction (or aspiration) dilation and curettage (D&C). This procedure can be performed with local anesthesia as a cervical block and often sedation, or general anesthesia, as desired. It is typically performed in an outpatient surgical center but can be performed in a hospital. It is commonly performed in outpatient surgery centers and in clinics that focus on performing abortions. Using sterile technique, the cervix is progressively dilated with blunt metal dilators (Hegar dilators), to accommodate the size of the cannula, which is estimated by the uterine size and gestational age. Once in place, the cannula is attached to negative pressure ("suction device"), with pressures typically 400-500 mm Hg (mercury).[4] In her Expert Witness Report, Katherine Farris, MD, referred to the suction employed in D&C and D&E as "gentle."[5] The typical suction required for these procedures, at 400–500 mm Hg, is not gentle. Physicians are trained to use the curette gently and purposely from the uterine fundus toward the cervix, with as few passes of the instruments as possible, to attempt to minimize the risk of uterine perforation. Trauma to the endometrial cavity can result in adhesions, which can impact future fertility or cause placenta accreta syndrome in a subsequent pregnancy. Similarly, trauma to the cervix can result in preterm birth or an incompetent cervix in a subsequent pregnancy.

14. Between approximately 13-weeks gestation and 22 to 24-weeks gestation, the most common abortion procedure is a dilation and evacuation (D&E)

[4] Sun L, Yu Y, QI X. Short-Term Effects of Catheter Pressure and Time Control in Vacuum Aspiration Abortion for Early High-Risk Pregnancies. Iran J Public Health. 2017 May; 46(5):634-639.
[5] K Farris, Expert Witness Report, p. 11.

surgery. Based on my clinical experience and on the literature, these procedures are much more complex and technically difficult than D&Cs. According to Warren Hern, a prominent late term abortionist in Colorado, "[u]nlike first-trimester abortion[,] . . . midtrimester abortion is beset with numerous technical problems that are considerably more difficult to solve" because "[t]he uterus is larger and requires special instruments for vaginal termination, and getting these instruments past the cervix without damaging it is more difficult."[6] Similarly, "[t]he fetus is larger and more difficult to get through the cervix either with induction or with instruments," and "[t]he cervix is not as ready for induction of labor and delivery as it is at term."[7] Thus, "[t]he uterus does not respond to oxytocics as well as it does at term induction,"[8] meaning that the risk of hemorrhage is higher, and the uterus does not respond as well to typical medications to cause uterine contraction to decrease the risk of bleeding.

B. Second-Trimester D&E Abortions

15. While the technical performance of the procedure of first trimester D&C or second-trimester D&E may be similar for management of miscarriage (spontaneous abortion), and induced abortion, the reality is that with miscarriage, the developing human embryo or fetus has already died, as opposed to abortion, which has the purpose of causing the demise of a living human embryo or fetus. It is the intentional taking of life that makes these completely different procedures, just as

[6] Hern, WM, *Abortion Practice*. J.B. Alpenglo Graphics, Inc., Boulder, CO, 1990, p. 123.
[7] *Id.*
[8] *Id.*

administering anesthesia for a surgery with the goal of treatment for a patient's benefit is completely distinct from administering the same drugs for capital punishment to induce the death of a human being convicted and sentenced to death for a capital crime. Even authors who are opposed to conscientious objection (CO) of physicians to abortion recognize that "one should never be forced to kill in situations where one is convinced this killing is morally wrong,[9] and one who researched reasons for physician CO quoted an objector, "The fetus is my patient, too[10]."

16. The overwhelming majority of Ob-Gyns in the United States do not provide abortion services. One study used the American Medical Association (AMA) Physician Masterfile, a data base maintained by the AMA intending to include all practicing physicians in the United States, to conduct a cross-sectional national survey of Ob-Gyns in private practice, asking "Did you do any abortions?"[11] Overall, 7% of physicians answered "yes."[12] Of those who did, 42% only provided surgery, 25% only medication, and 33% provided both.[13] The study did not query for gestational ages of abortions performed.

17. Another survey of Ob-Gyns using the AMA Physician Masterfile queried, "Do you provide abortion services?"[14] That study found that 14.4% of the

[9] Myskja BK, Magelssen M. Conscientious Objection to Intentional Killing: An argument for toleration. BMC Medical Ethics, 2018 19: 82.
[10] Fink LR, Stanhope KK, Rochat RW, Bernal OA. "The Fetus Is My Patient, Too": Attitudes Toward Abortion and Referral Among Physician. Conscientious Objectors in Bogota, Colombia. Int Perspec Sex Reprod, 2016; 42(2):71-80.
[11] Desai S, Jones RK, Castle K. Estimating Abortion Provision and Abortion Referrals Among United States Obstetrician-Gynecologists in Private Practice. Contraception 2018 April; 97(4): 297-302.
[12] *Id.*
[13] *Id.*
[14] Stulberg DB, Dude AM, Dahlquist I, Curlin FA. Abortion Provision Among Practicing Obstetrician-Gynecologists. Obstet Gynecol, 2011; 118: 609-614.

physicians provided abortions.[15] A third survey employed the American College of Obstetricians and Gynecologists (ACOG) Collaborative Ambulatory Research Network, a collection of members who volunteer to participate in research.[16] While the study randomly selected members of this group, a significant limitation of this study is potential self-selection bias of ACOG members volunteering to participate in research surveys.[17] Their results indicated that 24% of respondents performed any type of induced abortion in the prior year, with 9.4% performing only surgery, 4.0% only medication, and 10.4% both.[18]

18. In my clinical experience, most physicians who do provide abortions limit themselves to performing them in the first trimester due in part to the increased difficulty and risks of second-trimester abortion for their patients. A survey of all U.S. Ob-Gyn residency directors found that only 22% of residency directors reported that their graduation residents were fully competent to perform D&E up to 17 weeks 6 days gestation, on average only performing 4 D&E surgeries.[19]

19. Additionally, Warren Hern, who primarily performs abortions in the second and third trimesters, described the reaction of his staff to late-term abortions as "emotional trauma" and noted several psychological defenses to handle the more destructive parts of the procedure.[20] Hern concluded that the "most challenging part

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[15] *Id.*
[16] Grossman D, Grindlay K, Altshuler AL, Schulkiun J. Induced Abortion Provision Among a National Sample of Obstetric-Gynecologists. Obstet Gynecol, 2019; 133:477-483.
[17] *Id.*
[18] *Id.*
[19] Steinauer JE, Turk JT, Pomerantz T, Simonson K, Learman LA, Landy U. Abortion Training in U.S. Obstetrics and Gynecology Residency Programs. Am J Obstet Gynecol 2018; 219:86,e1-6.
[20] Hern WM, Corrigan B. What About Us? Staff Reactions to D&E. Advances in Planned Parenthood, 1980. 15(1).

of the procedure is how we feel about doing it."[21] He further explained that "[n]o one who has not performed a D&E can know what it is like, or what it means . . . there is no possibility of denying an act of destruction. It is before one's eyes. The sensations of dismemberment flow through the forceps."[22] He found that with second trimester abortions, his staff feared complications, visualizing the fetus, and the violence of the D&E.[23]

20. Having performed D&Es, I agree with Hern's assessment. While concern for complications and lack of confidence from inadequate training are critical reasons Ob-Gyn physicians may not perform second trimester D&Es, in my experience and opinion, this "destruction" is the more significant reason that most Ob-Gyn physicians do not perform abortion and, in particular, abortions after the first trimester.

21. D&E is a surgical procedure. The AMA defines surgery by its invasive nature: "Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise

[21] *Id.*
[22] *Id.*
[23] *Id.*

altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel."[24]

22. Many surgeries do not include scalpels, such as endometrial biopsy, suturing wounds, orthopedic manipulations, endoscopic procedures, angioplasty, placement of central lines, and D&C (dilation and curettage) for gynecology indications. This is reflected in the inclusion of D&E and D&C codes in the surgical section of CPT (Current Procedural Terminology)[25], the uniform language health care professionals use to code medical services and procedures.

23. Performing second-trimester D&C and D&E in a clinic setting is an exception to the traditional norm of performing them in a surgical suite in a hospital. While these surgeries "can" be performed in other settings, from my clinical experience and review of the literature, the safest location for patients to undergo a D&E is in the hospital setting. due to the procedure's inherently greater risk to the

[24] AMA Definition of Surgery: H-475.983; https://policysearch.ama-assn.org/policyfinder/detail/surgery?uri=%2FAMADoc%2FHOD.xml-0-4317.xml, accessed 12/11/2023.
[25] CPT Overview and Code Approval; https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval, Accessed 12/11.2023.

patient and hospitals' enhanced ability to provide emergent care for potentially life-threatening complications.

24. All surgeries carry inherent risk. One does not know in advance of the procedure which patient will have a complication. For this reason, it is the physician's obligation in providing evidence-based and the best possible care to their patient, to not only consider the medical indication(s) for the recommended treatment or procedure, the alternatives, the patient's risk factors, the risks, and the benefits of the procedure, but also the safest location to provide the surgery. All complications and deaths related to induced abortion are iatrogenic (caused by the procedure or treatment, not a natural complication of an illness), which is only rarely indicated for a medical diagnosis. No surgery, or procedure, should be taken lightly.

25. The increased difficulty and risks of abortions after the first trimester led to the development of a two-year fellowship in "complex family planning" after the completion of four years residency of obstetrics and gynecology. The first fellowship was launched at UCSF in 1991, and board certification as a subspecialty of Ob-Gyn was first offered in 2020.[26]

26. To perform a D&E,[27] the cervix is first "prepared," typically with laminaria, which is a sterilized form of seaweed that is dried and rolled such that it appears similar to a stick. Usually, multiple laminaria are placed into the woman's cervix the day before the D&E, which gradually dilate and thin the cervix.

[26] Schreiber CA, Madden T. Complex Family Planning: A newly accredited, landmark fellowship. Contraception 2021 Jan; 103(1): 1-2.
[27] ACOG, Practice Bulletin 135, *op cit*.

Misoprostol, a prostaglandin, which causes uterine contractions and cervical softening,[28] may also be prescribed for cervical dilation. This minimizes the force required intra-operatively to dilate the cervix and, thereby, decreases the significant risk of perforation of the uterus. Significantly more dilation of the cervix is required in the second trimester due to the increased diameter of the fetal cranium, which grows more calcified with gestational age and, thus, more difficult to remove.

27. Once the chosen anesthetic has been administered and sterile preparations have been completed, the cervix is further dilated with surgical dilators as needed in the operative suite. Then, the amniotic sac ruptured, and instruments are repeatedly introduced through the dilated cervix to grasp, crush, disarticulate (pull apart), and remove the fetus in pieces, which causes fetal death. The placenta and membranes are removed as much as possible with the suction curette, followed by palpation with a curette (a long-handled instrument with the sharp metal loop to scrape, or curette, the placenta from the uterine wall) for remaining placental tissue. This process commonly requires 15 to 30 minutes of active surgery time, from the physician first placing vaginal instruments to assess the cervix, dilating the cervix, rupturing the amniotic membranes, removal of the fetus, and all the placental tissue. The fetal parts are collected and organized by the surgical assistant as they are sequentially removed from the uterus, and the physician evaluates to makes sure that all major fetal parts are accounted for.

[28] Medication Abortion Up to 70 Days. ACOG 2020 October, Practice Bulletin 225.

28. I performed D&E under ultrasound-guidance to observe the direction and location of operative instruments and avoid perforation of the uterus and to aid in grasping the fetal parts, especially the cranium, which can be notoriously difficult to remove. The ultrasound also aided to ascertain whether the fetus and pregnancy tissues had been completely removed. While ultrasound guidance is known to decrease risks of perforation and incomplete abortion, not all abortionists utilize ultrasound.

29. In my experience, first-trimester D&Cs are very different surgeries from second-trimester D&Es. Prior to 13 weeks, the uterus is within the bony pelvis, and much smaller. A first trimester D&C is usually rather quick—no more than 3 to 5 minutes of operating time—usually involves only a few passes of the instruments through the cervix and is rarely associated with heavy bleeding. D&Es, on the other hand, require considerable effort and time to remove all of the fetal body parts and the larger, more calcified cranium, which can be especially difficult to grasp. Thus, operating time is longer (typically 15–30 minutes in my experience), and a variety of instruments are required, along with many more passes of instruments through the cervix.

30. The ACOG Practice Bulletin on Second-Trimester Abortion[29] specifically lists the significant complications of D&E, including hemorrhage, cervical laceration, retained products of conception, infection, uterine perforation, abnormal placentation (placenta accrete syndrome, a placenta that has invaded deeper into the

[29] ACOG, Practice Bulletin 135, *op cit*.

uterine wall and that does not detach normally), disseminated intravascular coagulopathy (DIC, a life-threatening decreased ability to form clots due to copious hemorrhage), and embolism (a catostrophic complication in which amniotic fluid, fetal cells or hair enter the maternal circulation causing cardiovascular collapse[30]).

31. In the second trimester, the uterus has risen out of the bony pelvis and continues to grow cephalad (upward). Additionally, heavy and rapid bleeding commonly occurs. The development of the maternal-fetal interface of the endometrium and the placenta requires development of "highly dilated vessels (maternal spiral arterioles) with minimal smooth muscle, creating low-resistant vessels that deliver blood to the intervillous space at low velocities that prevent damage to the placental architecture."[31] When the placenta is sheared from the interface, either surgically or natural separation after a term delivery, there can be impressively brisk bleeding. Uterine contractions provide the pressure on these vessels to slow the bleeding. However, uterine atony is not uncommon with D&E procedures, and the uterus at this early gestation does not respond as well to oxytocics (to induce uterine contraction) as a term uterus does. Hemorrhage remains the top complication of all types of abortion and a primary contributor to abortion mortality.[32]

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[30] Kaur K, Bhardwaj M, Kumar P, Singhal S, Singh T, Hooda S. Amniotic Fluid Embolism. J. Anaesthesiol Clin Pharmacol, 2016 Apr-Jun; 32(2): 153-159.
[31] Greenbaum S, Averbukh I, Soon E, Rizzuto G, Baranski A, Greenwals NF, Kagal A, Bosse M, Jaswa EG, Khair Z, Kwok S, Warshawsky, S, Hadeesha Piyadasa, Goldston M, Spence A, Miller G. Schwartz M, Graf W, Van Valen D, Winn VD, Hollmann T, Keren L, van de Rijn M, Angelo M, A Spatially Resolved Timeline of the Human Maternal-Fetal Interface. Nature, 20223 July; 619: 595-605.
[32] Zane S, Creanga A, Berg C, Pazol K, Suchdey DB, Jamieson DJ, Callaghan WM. Abortion-Related Mortality in the United States 1998-2010. Obstet Gynecol 2015; 126(2): 258-265.

32. The complication rates of D&E are partially dependent on the physician's technical skills, experience, training, and on the location where the procedure is performed, including the skill and training of medical staff. Warren Hern states, "Abortion is a blind procedure that proceeds by touch, awareness of the nuances of sensations provided by instruments, honesty, and caution. While competent orientation in the performance of an abortion is essential, abortion, almost more than any other operation, demands experience to develop skill."[33] In a review of medication and surgical second trimester abortions in their facilities, Autry *et al.* found a 4% complication rate of D&E procedures.[34]

33. Our first and primary concern in medicine must be for the patient's safety and best interest, not abortion access. Patient safety is more important than not the relatively small inconveniences of performing abortion in a hospital.

34. Mortality of legal abortion increases with gestational age. Zane *et al.* reviewed abortion-related mortality in the United States between 1998 and 2010, finding that mortality increased with gestational age, from 0.3 per 100,000 procedures at 8 weeks or less gestation, to 6.7 per 100,000 procedures at 18 weeks gestation.[35]

35. Bartlett *et al.* reviewed abortion-related mortality in the U.S. between 1988 and 1997, finding that while the overall death rate for women having a legal induced abortion was 0.7 per 100,000 abortions, the risk of death exponentially

[33] Hern W, *op cit*, p. 103.
[34] Autry AA,, Hayes EC, Jacobson GF, Kirby RS. A Comparison of Medical Induction and Dilation and Evacuation for Second Trimester Abortion. Am J Obstet Gynecol 2002 Aug; 187(2): 393-397.
[35] Zane S, et al, *op cit*.

increased 38% each additional week after 8 weeks gestation.[36] Over 90% of abortions in the United States are performed in the first trimester, with significantly lower risk procedures than D&E's at later gestations. The strongest risk factor for abortion mortality was gestational age.[37] Mortality resulting from second trimester procedures was most commonly related to hemorrhage and infection, which accounted for approximately one fourth of abortion-related deaths[38]. Embolism, and anesthetic complications each contributed to 15% of the mortality.[39] The second most significant risk factor was race. At all gestational ages, women of black and other races were 2.4 times more likely to die of complications as white women. [40] The authors state: "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. The increased amount of fetal and placental tissue requires a greater degree of cervical dilation, the increased blood flow predisposes to hemorrhage, and the relaxed. Myometrium is more subject to mechanical perforation. The technical challenges of the procedure during the second trimester are different from those present in the first trimester, and the inherently greater risk of complications may be less amenable to prevention.[41]

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[36] Bartlett LA, Berg, CJ, Shulman HB, Zane SB, Green CA, Whitehead S, & Atrash HK. Risk Factors for Legal Induced Abortion-Related Mortality in the United States. Obstet Gynecol 2004; 103:729-737.
[37] *Id.*, p. 735.
[38] *Id.*
[39] *Id.,* p. 733.
[40] *Id.* p. 733.
[41] I*d.,* p. 735.

36. A global review found that induced abortions after 12 to 14 weeks of pregnancy account for a larger proportion of abortion-related serious complications.[42]

37. While "legal" and "safe" are often conjoined in common vernacular, "legal" does not mean "safe." Severe physical injuries may occur from surgical abortion, and the risk increases with gestational age. Even experienced abortionists can damage adjacent organs or major blood vessels as they insert suction curettes or grasping forceps into the soft, gravid uterus. Injury to adjacent major blood vessels and/or gynecologic, genitourinary, or gastrointestinal organs requires emergency abdominal surgical exploration to stop bleeding, bowel resection, bladder repair, hysterectomy, or perform other repairs. Death from induced abortion can occur due to hemorrhage, sepsis, thrombotic emboli, intravascular amniotic or air emboli, complications of anesthesia, and cardiac or cerebrovascular events.[43]

38. One retrospective study of uterine perforation during second trimester surgical abortion identified seven women from an outpatient local clinic, and 8 from other clinics who required treatment at the hospital for uterine perforation.[44] Six patients were hypotensive, 4 experienced hemorrhage, and in 4 women, bowel had been delivered through her cervix.[45] 2/3 of the patients suffered a bowel injury, 2 required a hysterectomy, 6 were complicated by post-operative infection.[46] Three

[42] Cohen MA, Kapp N, Edelman A. Abortion Care Beyond 13 Weeks Gestation: A global perspective. Clin Ob and Gyn 2021; 64(3): 460-474.
[43] Induced Abortion and the Increased Risk of Maternal Mortality. AAPLOG, 2019 August 13, Committee Opinion 6.
[44] Darney P, Atkinson E, Hirabayashi K. Uterine Perforation During Second Trimester Abortion by Cervical Dilation and Extraction: A review of 15 cases. Obstet Gynecol, 1990; 75:441.
[45] *Id.*
[46] *Id.*

women had a delay of more than 24 hours for exploratory surgery.[47] Uterine perforation in the second trimester procedures is more complicated due to the larger uterus, size of the fetus and required size of the instruments, and it "is always a serious complication."[48]

39. One significant consideration for location of a procedure must be the ability to minimize the pain and suffering of the patient. One of the most common questions a patient asks is "Will it hurt?" Having personally undergone D&Cs under paracervical blocks for two miscarriages, I can testify to the pain of first trimester D&Cs. The second trimester abortions I performed were completed under general anesthesia, specifically for adequate pain relief for my patients.

40. Renner, *et al*., completed a systemic review of pain management for first trimester abortion and found that local anesthesia (paracervical block, PCB) did not diminish abortion pain.[49] The study also found that conscious sedation still had significant procedural pain but decreased pain post-procedure.[50] General anesthesia (GA) provided pain relief during the procedure but required anti-inflammatories and opioids for post-procedure pain.[51] The study concluded: "Many patients still find first-trimester surgical abortion extremely uncomfortable due to pain with cervical dilation and aspiration, unless given GA. Given how widely PCB is used, the paucity of data supporting the benefit of a PCB as shown in this review is surprising and

[47] *Id.*
[48] *Id.*
[49] RM Renner, JT Jeffrey, MD Nichols, AB Edelman. Pain Control in First Trimester Surgical Abortion: A systemic review of randomized control trials. Contraception 2010; 81:372-388.
[50] *Id.*
[51] *Id.*

concerning. Although PCB appears relatively safe, no strong data exist regarding its effectiveness for pain control."[52]

41. Another study used a visual analogue score (0–100) to assess women's pain during an abortion at less than 63 days (9 weeks gestation) under local anesthesia.[53] 44.4% of the women experienced pain higher than "50" and 7.4% in the highest quartile.[54] Pain during a second-trimester abortion would be more pronounced, due to the size of the uterus (at the umbilicus at 20-weeks gestation), longer procedures, and need for multiple passes of instruments through the cervix and extensive intrauterine manipulations to grasp and remove the larger fetal parts and the much larger placenta. This level of pain would not be tolerated unnecessarily with patients undergoing other medical procedures.

42. Normally in obstetrics, doctors administering anesthesia to pregnant patients must take into account the safety of two patients: the mother and the unborn child. But with induced abortion, the physician can direct attention solely to the effectiveness and safety of anesthetics for the mother.[55] A pregnant woman exhibits large increases in respiratory and cardiovascular function. Plasma volume and cardiac output increase, peripheral vascular resistance decreases, by mid-gestation the gravid uterus may compress the aorta and vena cava and increase her risk of profound hypotension. Anatomic changes during pregnancy also make airway

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[52] *Id.*
[53] H Hamoda, GMM Flett, PW Ashok, A Templeton. Surgical Abortion Using Manual Vacuum Aspiration Under Local Anesthesia: A pilot study of feasibility and women's acceptability. J Fam Plann Reprod Health Care 2005 July; 35: 136-139.
[54] *Id.*
[55] MA Rosen, RB Weiskopf. Management of Anesthesia for the Pregnant Surgical Patient. Anesthesiology, 1999 Oct; 91(4): 1159.

management more technically difficult. Pregnancy also increases risk for aspiration, due to decreased gastroesophageal sphincter tone. Rosen recommended that elective procedures be deferred until after delivery due to the increased risks of anesthesia with pregnancy. Induced abortion is most commonly an elective surgery, and the risks of surgical procedures and anesthesia during pregnancy must be carefully considered as a risk factor during informed consent with the patient.

43. In Dr. Farris' Expert Witness Report, she states that "there is no scientific evidence indicating that abortions performed in a hospital are safer than those performed in an appropriate outpatient clinic or office-based setting." [56] She cites Roberts, et al, who compare induced abortion morbidities and adverse events in ambulatory care centers vs. clinic settings in women with private insurance.[57] The Journal of the American Medical Association (JAMA) editorial review of Roberts, et al's study, noted that the "analysis of hospital based care was explicitly outside the scope of this study" and "the results of hospital-based abortion care may be of interest because hospitals would be presumed to be simultaneously the safest sites, as well as the site caring for patients with more complex health needs or greater severity of illness."[58]

[56] Farris K, Expert Witness Report, p. 20.
[57] Roberts SCM, Upadhyay UD, Liu G, Kerns JL, Ba D, Beam N, Leslie DL. Association of Facility Type With Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions. JAMA, 2018; Jun 26; 319(24): 2497–2506.
[58] Westhoff CL, Davis AR. Abortion-Related Adverse Events by Facility Type: Reassurance From a National Analysis. JAMA, 2018 June 26; 319(24): 2481-2483.

44. Dr. Farris also cites[59] a 2008 study specifically comparing complications of second trimester induced abortions in a clinic setting compared to a hospital setting.[60] However, a thorough review of Turok, et al's study comparing second trimester termination of pregnancy by site and procedure type reveals that the patient population is non-comparable, and the complications in the hospital groups patients were most likely related to the medical conditions indicating the termination of the pregnancy, rather than the location or technical skill and experience of the physician.[61]

45. At the University of Utah, pregnancy terminations in the second trimester are performed for fetal anomalies, pregnancy complications and maternal medical indications that impose serious risks to the mother's life and health, and intrauterine fetal demise.[62] These health conditions greatly increase the risk to the pregnant woman for any medical procedure, including D&E. In contrast, 98% of the clinic D&E procedures were "elective." It is not surprising, given the women's coexisting medical conditions, that the hospital D&E and inductions resulted in major complication rates of 11% and 10%, respectively, defined as prolonged hospitalization, exploratory surgery, or transfusion.[63]

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[59] Farris K, Expert Witness Report, p. 20-21.
[60] DK Turok; SE Gurtcheff, MS Esplin, M Shah, SE Simonsen, J Trauscht-Van Horn, RM Silver. Second Trimester Termination of Pregnancy: A review by site and procedure type. Contraception 20008; 77(3): 155-161
[61] *Id.*
[62] *Id.*
[63] *Id.*

46. The clinic D&E procedures studied by Turok, et al,[64] carried a 1% risk of major complications: there were two women who experienced uterine perforation, both requiring an exploratory laparotomy and one requiring hysterectomy, one requiring transfusion. The third woman with a major complication required blood transfusion. When a uterine perforation occurs in a clinic setting, requiring transfer to a hospital, the woman has the increased risk of delay in urgent medical care. When a facility or physician is unable to manage a complication during a surgery, transfer of care to another facility would add the risk of necessitating a second anesthetic to manage the complication, as well as the risk of the delay of urgent management. Another risk for the patient is the risk of inadequate communication in the transfer of care to another physician. This is not quality medical care for women.

47. In Turok, et al's study,[65] the overall rate of reported complications from clinic D&E, with one abortion provider with 20 years of experience, was 6%, and included hemorrhage, retained products of conception, and infection. A review of the case details of the women with reported complications after hospital D&E included women with significant pregnancy complications or medical conditions, including HELLP Syndrome and failed induction, systemic lupus erythematosis and on renal dialysis who died of disease complications, placental abruption, intrauterine fetal demise (which often coexists with medical conditions and implications to the woman), previable preterm rupture of the membranes, and chorioamnionitis, in addition to fetal anomalies. One woman received a perforation of the uterus with placement of

[64] *Id.*
[65] *Id.*

laminaria and underwent a cesarian section and repair of uterine and pelvic sidewall injury.[66]

48. Warren Hern commented on reported higher mortality rates for hospital compared to clinic procedures, noting that there are "several reasons these differences may not reflect a true comparison: the numbers are small; there may have been selective underreporting of deaths from either kind of facility; the true denominators are not known (numbers of women having abortions); women who have their abortions in clinics may be healthier or different in other ways from those having their abortions in hospitals; D&E abortions performed in hospitals may occur later in pregnancy than those performed in clinics, resulting in higher complication rates on that basis alone; and physicians performing second trimester D&C abortions in clinics may be more experienced than those performing them in hospitals."[67] If the last factor is significant, it could be ameliorated by physicians with more experience performing second trimester D&E's obtaining hospital privileges to care for these very rare women who seek abortion due to rape, incest, fetal life-limiting diagnosis, or medical conditions that severely threaten the mother's health or life. While Dr. Hern addressed abortion mortality, severe maternal morbidity (SMM) affects a much larger proportion population, and is a risk for maternal mortality.[68] "SMM could be

[66] *Id.*
[67] Hern W, *op cit.* p. 34-35.
[68] Kern-Goldberger AR, Howell EA, Srinivas SK, Levine LD, What we Talk About When We Talk About Severe Maternal Morbidity: A call to action to critically review severe maternal morbidity as an outcome measure. Am J Obstet Gynecol MFM 2022; 5:100882.

thought of as "near miss" events for maternal death" and include complications that place a patient at significant risk for mortality.[69]

49. Second trimester abortions for indications of rape and incest, maternal health indications, and fetal anomalies are rare. In 2019, for states that report these statistics for all abortions, the reported incidences for rape and incest ranged from <0.01% to 1.9%; for maternal health 0.2 to 7.1%, and for fetal anomaly 0.3 to 2.3%.[70] Due to the severity of potential complications, it is in the patient's best interest to perform these procedures in the hospital setting.

50. I am not aware of any research directly comparing safety of D&C or D&E for indications of medical complications, such as spontaneous abortion or intrauterine fetal demise, to those performed electively. While technically the procedure is similar, underlying clinical conditions may alter the risks and difficulty of the procedure, as Turok's research indicates.[71]

> Based on the literature and my professional experience, it is my expert opinion that it is in the patient's best medical interest to perform second trimester D&E procedures in a hospital setting where anesthesia is available to appropriately attend to the patient's airway and anesthetic needs during the procedure, blood is available urgently for transfusion, and where life-threatening complications can be immediately managed without delay and transfer.

[69] *Id.*
[70] Wubbenhorst MC. Midtrimester Abortion Epidemiology, Indications and Mortality. Charlotte Lozier Institute, On Science, 2021 Oct; Issue 5.
[71] Turok, et al., *op cit.*

C. Early Chemical abortion, Pregnancy of Unknown Location, and Ectopic Pregnancy

51. Chemical abortion most often consists of two drugs. First, the woman takes mifepristone, which reversibly binds to the progesterone receptor, thereby blocking the effects of progesterone, which is necessary for maintenance and growth of the early pregnancy.[72] This causes necrosis, or break down, of the placental implantation site (decidua) and usually the death of the embryo or fetus. Second, 24 to 48 hours later, the woman takes misoprostol, a synthetic prostaglandin, which induces uterine contractions to expel the fetus or embryo and other pregnancy tissue.[73]

52. Mifepristone is currently approved by the FDA currently approves for use in chemical abortion through 70 days gestation (10 weeks).[74] The prescribing information includes a contraindication for use in known or suspected ectopic pregnancy, noting that mifepristone is not effective in treating ectopic pregnancies.[75] The FDA also specifically warns that the symptoms of chemical abortion (abdominal pain and bleeding) may be similar to symptoms of a ruptured ectopic pregnancy.[76]

53. ACOG provides patient information, or "FAQS" for patients regarding symptoms to expect with a chemical abortion[77] and possible symptoms of an ectopic pregnancy. These symptoms significantly overlap: abnormal vaginal bleeding,

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[72] ACOG, Practice Bulletin 225, *op cit.*
[73] *Id.*
[74] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf; accessed December 7, 2023.
[75] *Id.*
[76] *Id.*
[77] https://www.acog.org/womens-health/faqs/ectopic-pregnancy; accessed December 4, 2023.

abdominopelvic pain, and cramping.[78] When an ectopic pregnancy ruptures, the symptoms are sudden, severe abdominal pain, shoulder pain, weakness, dizziness, and fainting. However, dizziness also occurs in 28–39% of women during chemical abortion.[79]

54. Due to the similarity of symptoms of chemical abortion and of ectopic pregnancy, it is not possible for the patient to be able to discern what are normal symptoms of medical abortion and what symptoms require urgent attention for possible ectopic pregnancy. The National Academy of Science report on abortion states "some women still report high levels of pain [from chemical abortion], and pain is commonly reported as the worst feature of the method."[80] At least one side effect is reported by 85% of chemical abortion patients.

55. Dr. Farris claims that chemical abortion is safer than Tylenol.[81] This comparison relies on data including Tylenol deaths from overdose, which is not comparable to use of mifepristone at recommended doses.[82] There is no antidote for Tylenol toxicity, which has a good safety profile at therapeutic levels but can cause severe liver toxicity if taken in large amounts.[83] Tylenol is over the counter.

[78] https://www.acog.org/womens-health/faqs/induced-abortion; accessed December 7, 2023.
[79] ACOG Practice Bulletin 193, *op cit*.
[80] National Academies of Science, Engineering and Medicine, The Safety and Quality of Abortion Care in the U.S. National Academies Press 2018 Mar 16.
[81] Farris, K, Expert Witness Report, p.9.
[82] Skopf I. What is the Truth About the Alliance of Hippocratic Medicine v. U.S. Food and Drug Administration Lawsuit? Charlotte Lozier Institute, 2023 June 13; On Science, Issue 14.
[83] Agrawak S, Khazaeni B. Acetaminophen Toxicity. Statpearls, 2023 June 9.

Mifepristone requires a prescription and carries an FDA black box warning for risk "for serious and sometimes fatal infections and bleeding."[84]

56. The precise number of abortions performed in the United States and its complications are unknown due to lack of mandatory reporting. Finland is one of the few countries that is able to accurately determine abortion numbers and its immediate complications due to its ability to link the country's abortion registry, care registry for health institutions, and cause of death registry with its single payer health care payor data and thus identify pregnancy outcomes. Niimimaki's review of immediate complications of abortion at 63 days gestation or less revealed adverse events four-times higher for medical compared with surgical abortion (20.0% vs. 5.6%), with higher hemorrhage (15.6% vs. 2.1%, incomplete abortion (6.7% vs. 1.6%), and surgical (re)evaluation (5.9% vs. 1.8%), all statistically significant.[85] A second study by the same authors, comparing adverse events of adolescent and adult women undergoing chemical abortion, confirmed the significant rates of complications, including hemorrhage (15.1%), incomplete abortion (9.8%), and need for surgical evacuation (12.8%).[86]

57. Ectopic pregnancies have been among the most humbling experiences of my career due to the lack of identifiable risk factors in the majority of the patients.

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[84] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf; accessed December 7, 2023.

[85] Niimimaki M, Pouta A, Bloiju 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.

[86] Niinimaki M, Suhonen S, Mentula M, Hemminki E, Heikinheimo O, Gissler M. Comparison of Rates of Adverse Events in Adolescent and Adult Women Undergoing Medical Abortion: Population register based study. BMJ 2011; 342:d2111.

One patient presented non-classically only with worsening rectal pain. And another woman brought in by the ambulance in MAST trousers in hemorrhagic shock. Physicians truly cannot predict accurately which pregnant woman without an identifiable intrauterine pregnancy has an ectopic pregnancy and which will experience life-threatening acute tubal rupture.

58. The American College of Obstetrics and Gynecology defines an ectopic pregnancy as "a pregnancy that occurs outside of the uterine cavity," and estimates that ectopic pregnancies occur in about 2% of all pregnancies.[87] Between 2011 and 2013, ectopic pregnancies accounted for an estimated 2.7% of identifiable pregnancy-related maternal deaths.[88] The true incidence of ectopic pregnancy is not known, as most are treated medically in the clinic, rather than surgically[89] Ectopic pregnancy has been identified as the leading cause of pregnancy-related death during the first trimester of pregnancy.[90] The rates of ectopic pregnancy appear to be rising in the United States, according to one study which evaluated the rates of women with ectopic pregnancies treated in emergency departments between 2006–13.[91]

59. The Planned Parenthood chemical abortion protocol referred to in this Court's Order Granting Preliminary Injunction, screens patients with unknown pregnancy location for some of the ectopic risk factors and uses serum hCG trends to

[87] Tubal Ectopic Pregnancy, ACOG, 2018 March, Practice Bulletin 193.
[88] AA Creanga, Syverson C, Seed K, Callaghan WM. Pregnancy-Related Mortality in the United States, 2011-2013. Obstet Gynecol, 2017 Aug; 130(2): 366-373.
[89] LM Mann, K Kreisel, E Llata, J Hong, EA Torrone. Trends in Ectopic Pregnancies in U.S. Emergency Departments: 2006-2013. Matern Child Health J, 2020 Feb; 24(2): 213-221.
[90] Current Trends in Ectopic Pregnancy – United States, 1990-1992. MMWR Weekly 1995 Jan 27; 44(03): 46-48.
[91] Mann, et al, *op cit*.

follow the patients.[92] However, the American Association of Reproductive Medicine states that "[a]ny pregnant woman potentially can have an ectopic pregnancy."[93] There are risk factors that increase the risk of ectopic pregnancy,[94,95,96] but more than half of women with an ectopic pregnancy have no identifiable risk factors.[97]

60. According to Saxon *et al.*[98], the most prevalent risk factors for ectopic pregnancy were prior ectopic pregnancy, prior pelvic infection, and IUD. Only 43% of the women with an ectopic pregnancy had at least one risk factor. Having a risk factor also did not correlate with the risk for rupture, with only 1/3 of women having any risk factor. ACOG lists risk factors[99] as: prior ectopic pregnancy, damaged fallopian tube, history of ascending pelvic infection, prior pelvic or tubal surgery, assisted reproductive techniques, cigarette smoking, age greater than 35 years, and in situ IUD (failures of IUD are associated with up to 53% ectopic pregnancy rates).

61. Screening women with pregnancy of unknown location (PUL) for ectopic pregnancy based on risk factors is grossly ineffective. One study assessing immediate vs. delayed initiation of chemical abortion with PUL, found that of the women who were ultimately diagnosed with an ectopic pregnancy, only 12.9% had a "major ectopic

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[92] Court Order Granting Preliminary Injunction, Case 1:23-cv-480, pg. 14-15.
[93] Practice Committee of the American Society for Reproductive Medicine (ASRM). Medical Treatment of Ectopic Pregnancy: A Committee Opinion. Fertil Steril, 2013 Sept; 100(3): 638-644.
[94] *Ibid.*
[95] ACOG Practice Bulletin 193 *op cit*.
[96] D Saxon, T Falcone, EJ Mascha, T Marino, M Yao,, T Tulandi. A Study of Ruptured Ectopic Pregnancies. Obstet Gynecol 1997 July; 90(1): 46-49.
[97] ACOG Practice Bulletin 193 *op cit*.
[98] Saxon, et al, *op cit*.
[99] ACOG, Practice Bulletin 193, *op cit*.

risk factor," defined by the authors as a history of ectopic pregnancy, history of tubal surgery, or in situ IUD (currently within the uterine cavity).[100]

62. Diagnosis of an ectopic pregnancy when a pregnancy is not identified in the uterine cavity can be complex. In the typical clinical situation, a woman presents with abdominopelvic pain or vaginal bleeding in early pregnancy or has known significant risk factors for ectopic pregnancy. In the context of early medical abortion, the clinical situation is quite different, as the woman is primarily presenting to request a termination of her pregnancy, and not for medical symptoms that would indicate a possible ectopic pregnancy. Based on her ultrasound findings, she now faces the question of whether her pregnancy is viable (living), and whether her pregnancy is within the uterine cavity. For women with a possible ectopic pregnancy, it is critical to identify the location of the pregnancy, to allow early treatment with methotrexate, to avoid life-threatening ectopic rupture, and for the woman to know if she has an increased risk of ectopic pregnancy in future pregnancies.[101] The risk of recurrent ectopic is 10% if she has had one ectopic pregnancy, and 25% if she has had two.[102] Prior ectopic pregnancy is a high-risk factor which should trigger early ultrasound in future pregnancies, regardless of symptoms.[103]

63. The work-up to rule-out ectopic pregnancy typically begins with an ultrasound. The sequence of findings of a normal intrauterine pregnancy on vaginal

[100] Goldberg, Alisa B.; Fulcher, Isabel R.; Fortin, Jennifer; Hofer, Rebecca K.; Cottrill, Alex; Dethier, Divya; Gilbert, Allison; Janiak, Elizabeth; Roncari, Danielle. Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location. Obstet Gynecol, May 2022 139(5):771-780.
[101] ACOG Practice Bulletin 193, *op cit*.
[102] *Id.*
[103] *Id.*

ultrasound is gestational sac, yolk sac, fetal pole, and lastly cardiac motion. A gestational sac should be visible by transvaginal ultrasound between 5.5 and 6.0 weeks gestational age.[104] An intrauterine gestational sac may be visualized as early as 5 weeks gestation, but the definitive diagnosis by ultrasound includes a gestational sac with a yolk sac or an embryo.[105] A recent retrospective cohort study evaluated women with PUL, with abdominopelvic pain and/or bleeding, and followed them to either a definitive diagnosis or hCG < 5 mIU/mL.[106] Out of 1,236 women with PUL, those with no intrauterine fluid collection had a 26.7% ectopic pregnancy rate.[107] The authors noted that 10–16% of women with an ectopic pregnancy may have a pseudogestational sac, although the study rate was 2.2% ectopic pregnancy.[108] The study was limited by a 23% loss to follow-up.[109]

64. A pregnant woman typically experiences a missed menses at 4 weeks gestation. Chemical abortion is approved by the FDA through 70 days of gestation (10 weeks). There is no clinical urgency nor clinical benefit to treating a woman with PUL with chemical abortion. Nor is there quality scientific evidence to support proceeding with chemical abortion when there is a question of pregnancy location. The safest and most expedient means to resolve PUL in the setting of undesired pregnancy is aspiration abortion.

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[104] Practice Committee of ASRM, *op cit*.
[105] ACOG Practice Bulletin 193, *op cit*.
[106] Lee IT., Rubin ES, Wu J, Koelper N, Barnhart K. The Incidence and Importance of the Pseudogestational Sac Revisited. AJOG 2022 April; 226(4): 537.E1-537.E7.
[107] *Id.*
[108] *Id.*
[109] *Id.*

65. When an intrauterine pregnancy is not identified by transvaginal ultrasound, women at risk of ectopic pregnancy are followed by serial serum hCG levels, typically repeated at 48 hours, and then every 2 to 7 days, with recommendation to follow the levels until they reach non-pregnancy levels. "Serum hCG alone should not be used to diagnose an ectopic pregnancy."[110] In the past, there was believed to be a discriminatory level of hCG at which one must see an intrauterine pregnancy on ultrasound, typically 2000 mIU/mL. However, this has been found to be inaccurate. While ACOG no longer identifies a specific discriminatory level, it suggests if one is used, it should be "conservatively high, *e.g.*, as high as 3500 mIU/mL." [111]

66. The difficulties in following serial hCG include mis-categorizing ectopic pregnancies and the potential of interrupting a desired intrauterine pregnancy. A 2012 retrospective study evaluated the accuracy of serum hCG in identifying ectopic pregnancies.[112] It found that a minimal expected 2-day rise in hCG of 35% (for normal intrauterine pregnancies) or minimal drop of 36 to 47% (for failing intrauterine pregnancies) had only an 83% sensitivity and 70.8% specificity for ectopic pregnancy, and misclassified 16.8% of ectopic pregnancies and 7.7% of normal intrauterine pregnancies.[113]

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[110] ACOG Practice Bulletin 193, *op cit*.
[111] *Id.*
[112] Morse CB, Sammel MD, Allen-Taylor L, Oberfoell NL, Takacs P, Chung K, Barnhart KT. Performance of hCG Curve in Women at Hight Risk for Ectopic Pregnancy: Exceptions to the rule. Fertil Steril 2012 Jan; 97(1): 101-106.e2.
[113] *Id.*

67. The danger, morbidity, and mortality of ectopic pregnancies are significant. In Saxon *et al.*'s retrospective review, 17.5% of the women operated on for an ectopic pregnancy required blood transfusion.[114] 33.8% of the women with ectopic pregnancy experienced tubal rupture.[115] There are no randomized controlled trials regarding the safety of immediate chemical abortion vs. delaying chemical abortion until the diagnosis of pregnancy location is completed. A 2020 systemic review with meta-analysis found no randomized controlled trials regarding initiating abortion before definitive evidence of an intrauterine pregnancy, and only two retrospective studies that met criteria.[116] The authors noted that "the quality of the evidence was very low."[117]

68. A review of the literature on initiating chemical abortion when ultrasound does not reveal the pregnancy location, located only two retrospective studies reported the incidence of PUL in women presenting for induced abortion, with rates of 2.9%[118] and 8.0%.[119]

69. The high rate of loss to follow-up in these retrospective studies, is concerning, as the outcomes, are not known, and possibly significantly skew the reported results. Of particular concern in these retrospective studies was the large

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[114] Saxon, et al, *op cit*.
[115] *Id.*
[116] Schmidt-Hansen M, Cameron S, Lord J, Hasler E. Initiation of Abortion Before There is Definitive Evidence of Intrauterine Pregnancy: A systemic review with meta-analysis. Acta Obstet Gynecol Scandinavia 2020 April; 99(4): 451-458.
[117] *Id.*
[118] Borchert K, Thibodeau C, Varin P, Wipf H, Traxler S, Boraas CH. Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A retrospective cohort study. Contraception 2023; 122: 109980.
[119] Goldberg, et al, *op cit*.

"non-adherence" defined as no clinical follow-up for more than 60 days,[120] and loss to follow-up, ranging from 16%,[121] 17–38%[122] and 7.4–16.6% (including one woman with diagnosed ectopic pregnancy they were unable to contact and excluded from the study).[123] One retrospective study conducted at Planned Parenthood clinics in Massachusetts found that 20.4% of women with PUL at presentation for chemical abortion had no final diagnosis in the electronic health record at their last clinical contact.[124] Not all of the studies reported loss to follow-up.

70. One reasonable cause for loss to follow-up would be requiring emergent care in an emergency department. Planned Parenthood's protocols indicate that a woman with a possible ectopic pregnancy should be referred to an emergency provider[125]; in other words, Planned Parenthood's medical providers do not treat women with ectopic pregnancies.

71. Of the studies that included the outcome of ectopic pregnancy in women presenting with PUL, rates of ectopic pregnancy varied from 5.9%[126] and 10.8%[127] The Goldberg study included 4 women with ruptured ectopic pregnancies[128]. Bizjak's retrospective study on the safety and efficacy of very early medical termination of pregnancy excluded women with ectopic pregnancy from their final analysis, but did

[120] Borchert, et al. *op cit*.
[121] Goldberg, et al. *op cit*.
[122] Borchert, et al. *op cit*.
[123] Goldstone P, Michelson J, Williamson E. Effectiveness of Early Medical Abortion Using Low-Dose Mifepristone and Buccal Misoprostol in Women with No Defined Intrauterine Gestational Sac. Contraception 2013; 87(6):855-858.
[124] Goldberg, et al. *op cit*.
[125] Court Order Granting Preliminary Injunction, Case 1:23-cv-480, *op cit,* p. 14-15.
[126] Goldberg, et al, *op cit*.
[127] Borchert, et al. *op cit*.
[128] Goldberg, at al. op cit.

report 10 women diagnosed with ectopic pregnancies, two of whom experienced ectopic rupture.[129]

72. Proceeding with immediate chemical abortion in the clinical setting of PUL, rather than delaying for diagnosis of pregnancy location, resulted in unnecessary treatment, increased failure rates, and increased ongoing pregnancy rates. The majority of women in the delay-for-diagnoses group proceeded to spontaneous miscarriage (52% in Goldberg[130] and 79.3% in Borchert[131]), thus avoiding unnecessary chemical abortion medication. Borchert[132] found successful chemical abortion rates of the women immediately beginning chemical abortion were lower (85.4% vs. 96.7%), and rates of ongoing pregnancy higher (10.4% vs. 2.5%). Goldstone found that the odds of failure of chemical abortion in women with PUL compared women with documented intrauterine pregnancy was higher, with odds 2.7 times higher of failure, and the odds of a continuing pregnancy 12.72 times higher.[133] A retrospective study in Austria and Sweden did not confirm this differential.[134] However, in their sub-analysis of women whose uterus was empty on ultrasound, compared to women with a sac-like structure, successful termination decreased from 98.9% to 93.5%.[135]

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[129] Bizjak I, Fiola C, Berggren L, Hognert H, Saar I, Bring J, Gemzell-Danielsson K. Efficacy and Safety of Very Early Medical Termination of Pregnancy: A cohort study. BJOG 2017; 124:1993-1999.
[130] Goldberg, et al. *op cit*.
[131] Borchert, et al. *op cit*.
[132] *Id.*
[133] Goldstone, et al. *op cit*.
[134] Bizjak, et al. *op cit*.
[135] *Id.*

73. One study evaluated whether proceeding to immediate chemical abortion in situations of PUL and undesired pregnancy may lead to an earlier diagnosis of pregnancy location.[136] One study attempted to compare days to diagnosis, defined as resolution of the location of the pregnancy, in women receiving same-day chemical abortion vs. those with delay for diagnosis.[137] However, these groups were incomparable, as the method of "diagnosis" (ultrasound vs. implied by serial serum hCG testing) and timing of testing were different for the two treatment groups. Women in the "same day" group were presumed to have a completed chemical abortion if they experience a 50% decline in hCG from baseline at 2 to 3 days after medication.[138] However, this group may have included women with undiagnosed spontaneously resolving ectopic pregnancies, which would impact her future pregnancy risk of ectopic.[139] Women in the delayed treatment group were also followed with serial hCG levels, and an ultrasound was arranged after the level reached 2000 IU/L, per Planned Parenthood protocol.[140] Thus, evaluation for pregnancy location was not performed at the same time interval as the "same day" group.[141] The median days to diagnosis for the "delay" group was 3 days (2–10 days), and for "same day" group was 4 days (3–9 days), with significant overlap and without significant clinic difference in the groups.[142] This study also included the option of proceeding to aspiration D&C with evaluation for products of conception, an option

[136] Borchwert, et al. *op cit*.
[137] *Id.*
[138] *Id.*
[139] *Id.*
[140] *Id.*
[141] *Id.*
[142] *Id.*

recommended by ACOG for undesired pregnancies with PUL and risk for ectopic pregnancy.[143] This is the most expedient method, and the standard of care, for women with undesired pregnancy. Using very early chemical abortion for this indication is experimental and not consistent with evidence-based care, as well as carrying significant risk.

74. A retrospective study of women with PUL and symptoms of bleeding or pain found that there was no single pattern of hCG that could characterize an ectopic pregnancy, and there was significant overlap with spontaneous abortion and viable intrauterine pregnancy.[144]

75. There is no quality published evidence for the protocols utilizing serial hCG for monitoring completion of chemical abortion, nor for differentiating ectopic pregnancy from effective chemical abortion. In a 2023 study, Bharadwa followed hCG trends after chemical abortion in women with PUL.[145] The authors admitted that current hCG protocols after chemical abortion are "based on limited clinical evidence."[146] "Few studies examine chemical abortion with a PUL but some use a protocol requiring a >50% decline from the initial hCG value by 5 to 7 days after mifepristone initiated to confirm complete abortion. . . . The origin of these studies is unclear."[147] The authors rely on 2016 Planned Parenthood guidelines: a 50% decline

[143] ACOG Practice Bulletin 193, *op cit*.
[144] Cameron KE, Senapat S, Sammel MD, Chung K, Takacs P, Molinaro T, Barnhart K. Following Declining Human Chorionic Gonadotropin Values in Pregnancies of Unknown Location: When is it safe to stop? Fertil Steril, 2016 April; 105(4): 953-957.
[145] Bharadwa S, Fulcher I, Fortin J, Pocius KD, Goldberg AB. hCG Trends After Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location. Contraception, 2023 Nov; 25: 110343.
[146] *Id.*
[147] *Id.*

in hCG by day 4 to 5 (after mifepristone) or 80% decline by day 7.[148] The authors state "it is not clear which cutoffs apply to chemical abortion with PUL."[149] While the authors stated that no ectopic pregnancies were missed, there were four women who experienced a ruptured ectopic, and loss to follow up of the two study groups were 11% and 17%.[150] They found the trend lines of hCG "challenging to differentiate ectopic pregnancies from unsuccessful chemical abortion based on hCG trends alone," but felt the trends could flag women who required follow-up.[151]

76. ACOG notes that increasing hCG levels do not eliminate the possibility of an ectopic pregnancy, and declining hCG levels cannot differentiate an ectopic pregnancy.[152] Thus, ACOG recommends monitoring hCG levels until they reach non-pregnant levels, because "rupture of an ectopic pregnancy can occur while levels are decreasing or very low."[153]

77. Saxon's retrospective study on 693 women with ruptured ectopic pregnancies found that 11% of women had hcG levels < 100 mIU/mL at presentation.[154]

78. These studies in congregate provide evidence against the safety and effectiveness of current Planned Parenthood protocols prescribing early chemical abortion to women with PUL. It is my expert opinion that proceeding with early chemical abortion in the clinical situation of PUL is not supported by scientific

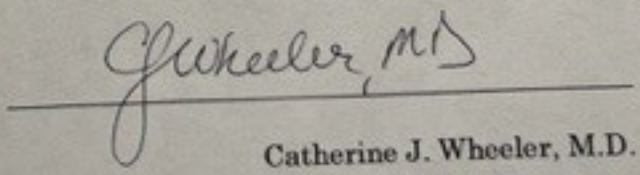
[148] *Id.*
[149] *Id.*
[150] *Id.*
[151] *Id.*
[152] ACOG, Practice Bulletin 193, *op cit*.
[153] *Id.*
[154] Saxon, et al. *op cit*.

literature and may place women at increased risk of complications from undiagnosed ectopic pregnancy, including a delay in diagnosis. Moreover, abortion is most commonly not required in such situations due to the high rate of spontaneous abortion in women with ectopic pregnancies.

79. Moreover, administering abortion-inducing drugs before the pregnancy can be visualized likely increases a woman's risk of failed chemical abortion and likely increases her chance of ongoing pregnancy. If the pregnant woman wishes to proceed with a chemical abortion, the brief delay to resolve the location of her pregnancy, typically by 6 weeks gestation, does not meaningfully increase the risk of abortion, but does increase its likelihood of success. Thus, physicians should follow ACOG's recommended standard of care for pregnant women with possible ectopic pregnancy and undesired pregnancy by performing an aspiration D&C.

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

Executed on December 11, 2023.



Catherine J. Wheeler, M.D.

EXHIBIT # A

CATHERINE J. WHEELER, MD

WORK HISTORY

St. Mark's Gynecology, HCA Mountainstar

Salt Lake City, UT
September 2012-July 2015

Gynecology Physician

- Recruited to develop a gynecology clinic
- Provided and oversaw gynecology care of women at all stages of life.

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University of Utah School of Medicine, Ob/Gyn Department

Salt Lake City, UT

August 2008-May 2012

Gynecology Physician, Associate Professor

- Recruited to develop the Women's Midlife Assessment Clinic
- Met with colleges and departments across the University of Utah campus to identify, recruit and coordinate services for Women in Midlife.
- Successfully developed the comprehensive multidisciplinary midlife assessment clinic
- Two poster presentations at North American Menopause Society convention, regarding the development of the clinic, and the clinic outcomes of the women served
- Ob/Gyn education and oversight of medical students and residents
- Developed women's midlife health education series for residents and fellows

Millcreek Women's Center

Salt Lake City, UT

September 1991-May 2008

Obstetrics and Gynecology Physician, Shareholder

- Developed and expanded, along with three physicians, an Ob/Gyn practice known for providing compassionate and exemplary care of women
- Gave public presentations regarding health topics related to women
- Participated on multiple insurance utilization review/ quality assurance committees
- Medical director, United Health Care of Utah, 1992
- Mentored medical students as Adjunct Faculty, University of Utah

PROFESSIONAL EDUCATION

University of Utah, Ob/Gyn Residency

Salt Lake City, UT
June 1987-June 1991

Colorado State University

Degree: B.S.

Fort Collins, CO
1977-1981
Major: Human Nutrition

Tulane University School of Medicine

New Orleans, LA
1984-1987

Degree: MD

Honors: Alpha Omega Alpha

Experience: Student Executive Committee President, Vice President, Secretary; Honor Board Chair and Vice-Chair; Owl Club (liaison between students and staff)

PROFESSIONAL VOLUNTEER EXPERIENCE

Save the Storks, Medical Advisory Board

Colorado, 2023-current

- Provide expert guidance regarding medical policies
- Assist in developing medical services and programs

Life Decisions, Speaker

Colorado, 2020-current

- Speak publicly throughout Colorado, and elsewhere, regarding the truth about abortion
- Write editorials regarding the truth about abortion
- Testify at Colorado State Legislature
- Provide interviews regarding pro-life and the truth about abortion
- Active member of Prolife Colorado (coalition of pro-life groups)

Path of Life, Client Advocate

Spokane, WA, 2017-2018

- Meet with clients regarding pregnancy and options
- Review, revise and develop medical policies and procedures, as requested; Path of Life was beginning an ultrasound service for clients

4th Street Clinic, Gynecology Physician

Salt Lake City, UT, 2007-2008

- **Volunteer physician, providing gynecology services, especially management of patients with abnormal pap smears**

OTHER PROFESSIONAL EXPERIENCE

Utah Medical Association, President-Elect, President, Past President

Salt Lake City, UT, 2004-2007

- Represented Utah Physicians at legislature, in media
- Legislative committee, assessed proposed legislation and determined UMA stance
- Testified at legislature
- Chair of committees and regular meetings
- Developed program for and chaired annual House of Delegates, and Spring Retreat
- Communication with and to Utah Physicians
- Public presentations on medical and health topics

Utah Governor's Task Force, Pandemic Preparedness, Member, 2006-2007

Colorado Springs Human Trafficking Task Force, Speaker

- **Presentations to physicians and medical students to educate about human trafficking**

Board Certification: American Board of Obstetrics and Gynecology, 1994-current

Licensure: Physician & Surgeon, Utah, current

Professional Organizations

American College of Obstetrics and Gynecology, Fellow

American Association of Prolife Ob/Gyns, Member

- Member of Research Committee. Research literature to write and/or edit Practice Bulletins and Committee Opinions

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COMMUNITY AND VOLUNTEER EXPERIENCE

Food Banks Divide, Colorado Woodland Park, Colorado Spokane, Washington Apache Junction, AZ	**Community Bands, Tenor Saxophone** • **Woodland Park Wind Symphony, Colorado** • **Swing Factory, Colorado** • **In-House Jazz Band, Colorado** • **Spokane Community Band, Washington**
Woodland Park School District Accountability Committee, Member	**Fostering Hope, Woodland Park, CO** • Provide support for a local fostering family, including providing meals, transportation
Summit Elementary School Accountability Committee, Member	.

Exhibit 4

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**

EXPERT REPORT OF SUSAN BANE, M.D., Ph.D.

I, Susan Bane, MD, PhD, pursuant to 28 U.S.C. section 1746 and Federal Rule of Civil Procedure 26(a)(2), 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, familiarity

with the medical literature, and expertise as an obstetrician/gynecologist who sees patients with unplanned pregnancies in eastern North Carolina.

2. I have been asked to serve as an expert witness in this case and to provide my opinion as to whether there is medical justification for two challenged provisions of North Carolina law: the Hospitalization Requirement for surgical abortions performed after 12 weeks gestation and the IUP Documentation Requirement that necessitates an ultrasound demonstrating an intrauterine pregnancy prior to a chemical abortion.

3. I have previously provided a declaration and been deposed in this case. I stand by my prior opinions and put forth the following additional opinions. These opinions are my own and do not represent any group with which I am affiliated.

I. Introduction and Professional Background

4. 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 (M.D.) and Doctorate (Ph.D.) 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.

5. 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."

6. During my time in private practice, I helped women deliver over one thousand 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 unborn 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 care, and primary care.

7. I was sidelined from delivering babies in 2010 due to a shoulder injury, at which time I became a faculty member at Barton College in Wilson, NC, where I worked from 2011 to 2023. I was a tenured associate professor of Allied Health and Sport Studies. I had both teaching and administrative responsibilities, including 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 LAHEC Partnership.

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 work 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 to give permission for a health care provider to end the life of their unborn child (abortion).

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 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 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 ending the life of their very own unborn 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.

12. A list of my publications can be found in my CV, attached as Exhibit A. In the past four years, I have not testified as an expert witness in any cases.

13. I am being compensated for my testimony at a rate of $500 per hour.

II. Summary of Expert Opinions

14. Both the Hospitalization Requirement for surgical abortions performed after 12 weeks gestation and the IUP Documentation Requirement that necessitates an ultrasound demonstrating an intrauterine pregnancy prior to a chemical abortion are essential for sound medical reasons. I disagree with the plaintiff's witnesses, Dr. Boraas and Dr. Farris, who state otherwise. The arguments that they both make

[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/.

against the hospitalization requirement and IUP documentation requirement are grounded on the assumption that *"abortion is safe."* This is a false assumption. There are serious and clearly identified limitations in how both maternal mortality and abortion data are collected and in how these data are utilized in research.

15. This expert report will (1) summarize these limitations and highlight incorrect conclusions drawn by research cited by Dr. Boraas and Dr. Farris, and (2) provide medical evidence for the need for both the Hospitalization and Documentation of IUP requirements.

16. I will use the term *induced abortion* in the remainder of this report to align with the Center for Disease Control (CDC) which oversees data surveillance and defines an 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*."[2]

17. There are two primary types of induced abortions performed in the outpatient setting that will be discussed in this report: 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

[2] https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.

the cervix followed by vacuum aspiration or removal of the fetus by dismemberment, depending on the gestational age of the embryo/fetus.

III. Expert Opinions and Reasons for Them

18. Induced abortion is a culturally divisive topic, and that division is no greater than in the profession of obstetrics and gynecology itself. It is crucial as I begin my expert report that I address the humanity of the fetus to provide context for the opinion I provide.

A. The Humanity of the Fetus

19. When I was a medical student in 1995 at the University of Illinois and again, when I began residency at East Carolina University in 1997, I was told that obstetrics and gynecology is the most unique specialty in medicine because we provide health care for two patients at the same time—a maternal and fetal patient.

20. 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:

> [H]uman 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).[3]

21. On the same page, the text summarizes the development periods, dividing human development into prenatal (before birth) and postnatal (after birth) periods.[4] The prenatal period has two main periods: embryonic (through the first eight weeks after conception) and fetal (after eight weeks until birth).[5] The postnatal period is divided into infancy, childhood, puberty, and adulthood.[6]

22. 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% performed an induced abortion in 2013–14.[7] Grossman *et al.* conducted a cross-sectional survey of a national sample of ACOG Fellows and Junior Fellows and found that in 2016–17, 72% reported having a patient in the prior year who needed or wanted an induced abortion, but only 23.8% reported having provided an induced abortion.[8] 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%).[9]

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[3] Moore, K. (2016). The Developing Human: Clinically Orientated Embryology. Saunders.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] 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.
[8] 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.
[9] *Id.*

23. The simultaneous care of both our maternal patient and this fetal patient described above is evident in the routine work of most obstetrician/gynecologists: evaluating the risks for the embryo/fetus of continuing or starting a new medication in pregnant women, offering screening for diabetes during pregnancy (good control lessens mom's risk for diabetes after pregnancy, but also improves health of baby), counseling a woman not to drink alcohol during pregnancy to prevent fetal alcohol syndrome, monitoring the baby/fetus during labor, ensuring a woman who is Group B strep positive receives antibiotics during labor, and performing emergency c-sections for fetal indications.

24. We even have a sub-specialty in our field called maternal-fetal medicine 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.

25. Providing health care to both our patients is consistent with an oath to heal –to work towards health and wholeness for both our patients—to "first, do no harm." Induced abortion is the only intervention in which our fetal patients are intentionally not provided health care. Neither Dr. Farris nor Dr. Boraas' declarations, depositions, rebuttals, or expert reports acknowledge that they care for two patients when they consider their clinical time spent performing induced abortions. Dr. Boraas was asked in her deposition, "as an obstetrician, when you

perform those induced abortions, do you consider the unborn child or the fetus to be your patient at that point?" She responded, "I don't."[10]

26. To justify this failure to acknowledge the fetus in their practices, Dr. Farris and Dr. Boraas, along with the minority of doctors who choose to perform induced abortions, must reconcile the cognitive dissonance that exists when two different fetuses are "treated" so diametrically differently—one is provided health care while the other is directly and intentionally killed through induced abortion.

B. Limitations in Data Collection Lead to Faulty Conclusions

27. Our current surveillance system does not allow us to draw the conclusions needed to make the claim that "abortion is safe." Yet Dr. Boraas and Dr. Farris repeatedly make this claim in their expert reports.[11]

i. Maternal Mortality and Abortion Safety

28. Maternal mortality rate is defined by the CDC as the number of maternal deaths/100,000 live births.[12] There are two essential requirements for an effective maternal mortality surveillance system: (1) standardization of reporting and (2) complete coverage of the target population being measured.[13] The current maternal mortality reporting system fails to meet these requirements. Historically, gathering accurate maternal mortality data at both the state and national level has

[10] Boraas Dep. 18:10–13.
[11] Boraas Report ¶¶ 9, 16, 23; Farris Report ¶¶ 30, 34.
[12] https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.
[13] Studnicki, J. et al. (2017). Improving Maternal Mortality: Comprehensive Reporting for All Pregnancy Outcomes. Open Journal of Preventive Medicine; 7:162-181.

been fraught with errors, leading to the inability to draw meaningful conclusions.[14] The National Center for Health Statistics (NCHS) released in 2018 the first national estimate of maternal mortality in more than a decade because data collection was so poor. [15]

29. The CDC oversees this collection process and continues to recognize that serious continued efforts are needed to improve data quality, and data will continue to need to be evaluated for possible errors. [16]

30. The data derived from death certificates are only as accurate as the information provided on the record and standardization of reporting is flawed. A pregnancy checkbox was added to death certificates in 2003 because of significant underreporting of maternal deaths.[17] Individual states have been slow to add the pregnancy checkbox. It was finally added to the North Carolina death certificate beginning in 2014.[18]

31. As an example of these basic deficiencies in data collection, the National Center for Health Statistics released in 2022 a reference guide to provide general guidance and instructions on how to complete a death certificate for women with maternal-associated deaths given miscoding that continues to occur.[19]

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[14] 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.
[15] https://www.cdc.gov/nchs/maternal-mortality/faq.htm.
[16] https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.
[17] 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] https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.
[19] https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg004.pdf.

32. Another major limitation in data collection that leads to error is that the maternal mortality rate (maternal deaths/100,000 live births) is not the ideal maternal mortality rate that should be measured. A more accurate representation of maternal deaths would be to measure the number of maternal deaths per 100,000 pregnancies. Utilizing 100,000 pregnancies versus 100,000 live births would capture all pregnant women and fulfill the essential requirement of proper surveillance that includes the complete coverage of the target population.[20]

33. The current measurement of maternal mortality using number of live births as the denominator only includes women who deliver a live baby. Approximately 60–70% of all pregnancies in the United States result in a live birth and this number drops to less than 50% in non-Hispanic black women.[21] Our current surveillance system excludes 30–50% percent of pregnancies in which the pregnancy ends by natural fetal loss (ie., miscarriage, ectopic pregnancy, molar pregnancy) or by induced abortion. By excluding all these women, the denominator is smaller and automatically leads to a higher maternal mortality rate. For example, in the current surveillance system, 50 deaths/100,000 live births is a maternal mortality rate of 0.05%. If the same number of women died (50), but the denominator included all pregnant women (200,000), the maternal mortality rate would be cut in half (0.025%) simply because all women were included.

[20] Studnicki, J. et al. (2017). Improving Maternal Mortality: Comprehensive Reporting for All Pregnancy Outcomes. Open Journal of Preventive Medicine; 7:162-181.
[21] https://www.cdc.gov/nchs/data/nvsr/nvsr72/nvsr72-01.pdf.

34. Priority must be given to improving this surveillance system to capture maternal deaths in all pregnant women, so we have a comprehensive understanding of why women die. Until then, we must proceed with caution making assumptions such as "abortion is safe."

ii. Safety of Induced Abortions

35. There is no mandatory requirement to report numbers of induced abortions or complications of abortions nationally or in individual states. This has led to an incongruence in the reported number of induced abortions since abortion was legalized in 1973. The CDC estimates 43 million induced abortions, while the Guttmacher Institute estimates 63 million induced abortions. [22] This 20 million count difference highlights the serious flaws in our monitoring system.

36. Faulty data lead to faulty conclusions. Dr. Farris and Dr. Boraas both state in their expert reports that induced abortion is extremely safe and has extremely low complication rates. We simply cannot make this broad assumption. Both support this assumption by stating the FDA provides evidence that there is long-standing safety regarding complications related to chemical abortions.[23] Neither mention that many clinicians are unaware of adverse reporting requirements, that there are many logistical barriers to accurately report adverse events, and that the FDA reporting requirement since 2016 only applies to reporting a maternal death, not other complications such as hospitalizations, hemorrhage, blood transfusions,

[22] https://www.cdc.gov/nchs/data/nvsr/nvsr72/nvsr72-01.pdf.
[23] Farris Report ¶ 18; Boraas Report ¶ 22.

emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications.[24]

37. Both cite a study by Upadhyay et al. (2018) as evidence that the complication rate from induced abortion is extremely low.[25] What they fail to discuss is that coding for the event that brought the patients to the emergency department (ie., hemorrhage) is often correctly done, but the event that caused it (induced abortion) may not be included. While the authors used a Nationwide Emergency Department Sample, they did not actually confirm that an abortion had occurred, leading to no linkage of that visit to a prior induced abortion if the woman did not disclose that information.[26] The extremely low percentage of abortion-related events revealed may or may not be due to a truly low complication rate.

38. Studnicki *et al.* (2021) conducted the first longitudinal cohort study of postabortion emergency room use following both chemical and surgical abortion.[27] Unlike Upadhyay's study, this study confirmed if an induced abortion had occurred.[28] They found that ER visits for both types of abortion visits are growing, with chemical abortions associated with more postabortion ER visits.[29] A trend in miscoding of these events was particularly troubling and will only contribute to the difficulties acquiring accurate data as already described.

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[24] Mifeprex 2016 label.
[25] Upadhyay, U. et al. (2018). Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample. BMC Medicine. 16:88.
[26] *Id.*
[27] Studnicki et al 2021.
[28] *Id.*
[29] *Id.*

39. My experience seeing women in the emergency department post-abortions and following up with them after their chemical abortions does not concur with Dr. Farris' statement that all methods of abortion provided at PPSAT are simple, straightforward medical treatments that typically take no more than 10 to 15 minutes and have an extremely low complication rates.[30] Patients have reported a chemical abortion causing significant psychological distress, being in severe pain, and experiencing very heavy bleeding—all lasting days versus 10–15 minutes. I recently had a patient who had a chemical abortion and used 32 Depends undergarments, reporting symptoms of hemorrhage, though she chose not to go to the hospital. Her experience was definitely not as Dr. Farris makes having an induced abortion seem to be.

40. Dr. Boraas and Dr. Farris both state that "abortion is approximately 12–14 times safer than continuing a pregnancy through to childbirth."[31] This conclusion is based on a study by Raymond and Grimes and is an example of how a faulty surveillance system leads to faulty conclusions.[32] The study utilized 1998–2005 data from several national data sets.[33] The pregnancy checkbox on death certificates was not introduced until 2003 and most states did not implement its use for years later.

[30]Farris Report ¶ 14.
[31] Boraas Report ¶ 23; Farris Report ¶ 34.
[32] Raymond, E. & Grimes, D. (2012). The Comparative Safety of Legal Induced Abortion and Childbirth in the United States. *Obstetrics & Gynecology* ; Vol 119, No. 2, Part 1:215-219. Maternal Mortality Rate: Disentangling Trends From Measurement Issues. Obstetrics Gynecology 128(3): 447-455.
[33] *Id.*

Thus, maternal deaths were often underestimated during these years according to the CDC.[34]

41. Raymond and Grimes also utilized the maternal mortality definition of number of maternal deaths per 100,000 live births, thus falling into the surveillance flaw described above in which the only pregnant women included would be those who had a live birth, leaving out at least 30% of pregnant women.[35]

42. These flaws lead to faulty conclusions that have very real practical implications for women in North Carolina and beyond, most importantly, we truly don't know how safe induced abortion is and thus misrepresent this to women who are deciding between giving birth or having an induced abortion.

43. The serious flaws in our monitoring system are unlikely to improve given a push by many abortion advocates to accept current surveillance data and even recommending that in a Post-*Roe* era, health care practitioners should intentionally miscode follow-up visits for complications after abortions, coding them as "treatment of missed abortion" or "incomplete spontaneous abortion."[36] Doing so is not only unethical, but it compounds the current challenges of compiling accurate data.

C. Increasing Safety for North Carolina Pregnant Women

44. North Carolina prioritizes safety for all North Carolina women who are pregnant and thus this law has two very important provisions that address maternal

[34] MacDorman, M.F., MacDorman, M.F., Declercq, E. Cabral, H, and Morton, C. (2016). Recent Increases in the U.S.
[35] Raymond & Grimes, *supra* n.32.
[36] Muqaddam, R. et al. (2023). Navigating Legal Risks When Providing Essential Reproductive Care Post-Roe. JAMA.

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

45. North Carolina law protects unborn life after 12 weeks gestation except in medical emergencies, life limiting anomalies, and rape or incest. Abortions after 12 weeks fitting into these exceptions must take place in a hospital.

46. Complex cases require complex care. Obstetricians and gynecologists complete four years of general obstetrical and gynecological training (residency) after medical school, but there is an opportunity to receive more specialized training in obstetrics and gynecology. There is a maternal-fetal medicine sub-specialty that focuses on complex and high-risk issues during pregnancy. A more recent sub-specialty area is complex family planning. This fellowship focuses on subspecialist training in research, teaching, and clinical practice in complex abortion and contraception, specifically training obstetricians/gynecologists to do second and third trimester abortions.[37]

47. 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, with the most highly trained specialist possible. All the exceptions for the North Carolina law in which induced abortions after 12 weeks are available involve complex patient situations, and it is my opinion

[37] https://societyfp.org/fellowship/.

that they should take place in a hospital setting given these complexities and short-term risks associated with induced abortions.

48. Induced abortion is associated with several documented short-term risks that can occur at the time of the procedure or shortly thereafter. 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.[38] Short-term 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.[39] 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.[40] 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.

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[38] National Abortion Federation. 2022 Clinical Policy Guidelines for Abortion Care. https://prochoice.org/wp-content/uploads/2022-CPGs.pdf. Accessed 12/17/2022.

[39] 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.

[40] 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.

49. The Hospitalization Requirement is medically justified for several reasons:

50. *Hospitals are more equipped than outpatient settings to handle major complications in our maternal patients*: Life-threatening hemorrhage, uterine perforation, damage to organs, and death may occur during a surgical abortion or immediately afterwards. Hospitals have more resources to manage these complications, including blood banks for transfusions during emergencies, laboratories that can provide immediate turnaround of ordered labs, nurse anesthetists and 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.

51. *Hospitals are more equipped than outpatient settings to handle a live birth in our fetal patients:* Live births can occur after induced abortions. The CDC estimates that between 2003 and 2014, at least 143 babies died after being born alive during abortions, and the CDC acknowledges it is very possible that this undercounts the actual number.[41] Additionally, the CDC report counts only babies who were born alive during abortions and then later passed away—it does not include babies who survived attempted abortions and are still alive.[42] Gestational age can be

[41]https://www.cdc.gov/nchs/health_policy/mortality-records-mentioning-termination-of-pregnancy.htm.
[42] *Id.*

underestimated, and babies can be more developed than assumed. These babies need immediate life-saving care that cannot and may not be provided in the outpatient setting. It is well recognized that babies born who need intensive care do better if they are born in a hospital with a neonatal intensive care unit (NICU) than if they are moved after birth.[43] Hospitals have more resources to care for these patients including blood banks for transfusions during emergencies, laboratories that can provide immediate turnaround of ordered labs, nurse anesthetists and anesthesiologists who can provide immediate intubation, code carts and code teams, operating rooms, and the NICU.

52. *Lack of anesthesia professionals in abortion clinics:* Women experience pain when they have surgical abortions, and many desire anesthesia. Hospitals have anesthesia professionals administering sedation. PPSAT has non-anesthesiologists managing sedation.[44] The American Society of Anesthesiologists "has genuine concern that individuals, however well intentioned, who are not anesthesia professionals may not recognize that sedation and general anesthesia are on a continuum and thus deliver levels of sedation that are, in fact, general anesthesia without having the training and experience to recognize this state and respond appropriately."[45] They recommend that only physicians who are qualified with appropriate education, training and licensure to administer moderate sedation

[43]https://www.stanfordchildrens.org/en/topic/default?id=the-neonatal-intensive-care-unit-nicu-90-P02389.
[44]Farris Dep. 87:6–9.
[45] https://www.asahq.org/standards-and-practice-parameters/statement-on-granting-privileges-for-administration-of-moderate-sedation-to-practitioners-who-are-not-anesthesia-professionals.

should supervise the administration of moderate sedation. They also state that individuals monitoring the patient should be distinct from the individual performing the diagnostic or therapeutic procedure. There is no evidence that this occurs routinely in abortion clinics in North Carolina.[46]

53. *Concern that clinicians are practicing out of their scope of practice:* Dr. Farris stated in her deposition that though she has no formal education or training in D&E procedures during the second trimester, she still performs them.[47] This is particularly concerning and brings up many questions about who is performing second-trimester abortions in clinics across our state. Second-trimester D&E surgeries are technically difficult. The complex family planning fellows in obstetrics and gynecology receive advanced training in D&E surgeries for two years after they have already completed four years of gynecological and obstetric training. That providers without any formal training are doing these procedures is concerning and not consistent with ACOG's Committee Opinion 612 on Abortion Training and Education related to non-obstetrical and gynecological surgeons providing induced abortions in the second trimester.[48]

54. *There are differences in the surgical management for miscarriages and surgical abortions:* Dr. Boraas states in her expert report that "while miscarriage management more typically happens in hospitals or ambulatory surgical centers, usually there is no medical or scientific reason for that—it is simply that abortion

[46] https://societyfp.org/wp-content/uploads/2022/01/PIIS0010782421003516.pdf.
[47] Farris Dep. 37:18–25.
[48]https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/11/abortion-training-and-education.

care has been stigmatized and siloed, whereas miscarriage management has not."[49] This statement is a broad generalization backed by no credible source. She fails to mention that the potential complications that could happen during or immediately after surgery are a key reason doctors prefer surgery for miscarriage in the hospital.

55. Similarly, Dr. Farris states in her expert report that "this Hospitalization Requirement is also illogical as a matter of patient health and safety because, even if the Act takes effect, licensed clinics like PPSAT's will still be allowed to perform **identical** procedures after twelve weeks to treat miscarriage."[50] Although on paper both surgical procedures are reported as the same, D&C or D&E, but as all surgeons recognize, the actual operations themselves can be vastly different. I have been the primary surgeon for over a thousand surgeries, including cesarean sections, hysterectomies, laparoscopic surgery, hysteroscopic surgery, and D&C and D&E procedures for a wide range of clinical indications, including miscarriages. Every surgical procedure is unique based on many different variables. This is particularly true when doing a D&C or D&E for a miscarriage or stillborn.

56. When a woman has been diagnosed with a nonviable pregnancy (no cardiac activity), her body is physiologically preparing to expel the embryo/fetus. Autolysis or destruction of the cells and tissues occurs. The cervix may already be softening and partially open. The patient may no longer feel her symptoms of pregnancy such as nausea, breast tenderness, and fatigue. Most women will naturally expel the pregnancy within two weeks and thus expectant management is an option

[49] Boraas Report ¶ 19.
[50] Farris Report ¶ 8.

given to women.[51] None of these physiological changes happen with a surgical induced abortion in which the woman's body is not attempting to expel the fetus and other pregnancy tissue. Rather, the fetus is alive and attached to the placenta which is attached to the uterus with the blood and other nutrients pumping from the mother's heart into the fetus's body. The cervix will likely be "closed and thick," a term used to describe a cervix that has not effaced (softened or thinned).

57. Surgery for a live versus dead embryo/fetus can lead to technical differences that can impact the difficulty of the procedure and thus a D&C and D&E for a miscarriage or induced abortion are not identical. The operative note may both have D&C or D&E as the surgical procedure performed, but the pre-op diagnosis of missed abortion (embryo/fetus dies with no symptoms) or stillbirth versus an induced abortion does not mean the surgeries are the same. That the field of obstetrics and gynecology has a sub-specialty designed to train doctors specifically in D&E surgery for surgical abortions speaks to the complex and technically difficult nature of performing surgical abortions.

58. *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 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

[51] https://www.acog.org/womens-health/experts-and-stories/the-latest/what-happens-after-a-miscarriage-an-ob-gyn-discusses-the-options.

women and ensure the forensic chain of evidence is followed.[52] 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 and psychological support is essential. They may also need genetic testing, autopsy, and/or funeral arrangements which are available in a hospital setting.

ii. Intrauterine Pregnancy Documentation Requirement

59. Plaintiffs' witnesses argue that documentation of an intrauterine pregnancy is not medically necessary prior to a chemical abortion.[53] This statement and their protocol are not only unreasonable, but also go against the standard of care for managing ectopic pregnancies.

60. 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[54]). After that, the risk of hemorrhaging increases and a surgical abortion is recommended. At 10 weeks gestation, 1 in 10 women will require surgery to complete their abortion.[55] At 13 weeks gestation, this complication increases to 1 in 2-3 women.[56] Chemical abortions have a 4x higher risk of complications than do surgical abortions in women who have been examined by a

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[52] https://www.acep.org/patient-care/policy-statements/management-of-the-patient-with-the-complaint-of-sexual-assault.
[53] Boraas Report ¶ 9; Farris Report ¶ 9.
[54] Farris Report ¶ 12.
[55] 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.
[56] *Id.*

physician and the drugs are given through nine weeks gestation.[57] 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.

61. 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.[58] This Committee Opinion states that only 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).[59] 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.[60]

62. 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.[61] Without ultrasound to document an IUP, gestational age cannot be confirmed, and women cannot be adequately counseled on their risks if their gestational age is unknown. An

[57] 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.
[58] ACOG Committee Opinion 700. (2017). Methods of Estimating the Due Date: ACOG.
[59] *Id.*
[60] *Id.*
[61] ACOG Practice Bulletin 200. (2018). Early Pregnancy Loss: ACOG.

induced abortion is a medical procedure, and informed consent is required by law for all medical procedures.

63. An ultrasound is required to adequately rule out an ectopic pregnancy, one of the main contraindications to chemical abortion. An ectopic pregnancy is defined as a pregnancy that occurs outside the uterine cavity. The most common site is the fallopian tube, which is why ectopic pregnancies are often called tubal pregnancies. Practice Bulletin 193 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 but could be as high as 18% in women presenting in the emergency department with first-trimester vaginal bleeding, abdominal pain, or both (9 in 50 pregnancies).[62] 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 massive internal bleeding.

64. The management of ectopic pregnancy remains the same pre- and post-*Roe*. An induced 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.

65. ACOG states in this same Practice Bulletin that "an untreated ectopic pregnancy is life-threatening; withholding or delaying treatment can lead to death."[63]

[62] ACOG Practice Bulletin 193. (2018) Tubal Ectopic Pregnancy: ACOG.
[63] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.

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.[64] 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."[65]

66. Since the medications used to induce an abortion do not treat ectopic pregnancy, women who desire an induced abortion and receive abortion drugs (mifepristone and misoprostol) without an ultrasound 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. The patient agreement form that PPSAT patients and the providers sign before taking mifepristone cautions patients to contact the clinic/office right away if they experience severe pain in the stomach area (abdominal pain) or stomach pain. [66]

67. The IUP Documentation Requirement requires that a physician document in the women's medical chart the existence of an intrauterine pregnancy prior to a chemical abortion. This can only occur by use of an ultrasound. 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

[64] *Id.*
[65] *Id.*
[66] PPSAT Mifepristone Patient Agreement Form.

care. As stated in ACOG's Practice Bulletin 193, "measurement of the serum hCG level aids in the diagnosis of women at risk for ectopic pregnancy. However, serum hCG values alone should not be used to diagnose an ectopic pregnancy and should be correlated with the patient's history, symptoms, and ultrasound findings."[67]

68. As I have examined the literature related to very early abortions, I agree with some authors that state diagnosing an ectopic pregnancy as early as possible is a benefit of these protocols. However, this is no justification for prescribing abortion drugs without a known gestational age, viable pregnancy, including number of embryos/fetuses, and confirming an intrauterine pregnancy by ultrasound given the risks I have already discussed. I fully support researching methods for early detection of ectopic pregnancies, but do not support the use of abortion drugs using a protocol that is contraindicated.

69. I also disagree with Dr. Farris who states in her expert report that "denying medication abortion to patients whose pregnancies cannot yet be seen on an ultrasound will force those patients either to delay wanted care or to obtain a procedural abortion even if they have important reasons for preferring a medication-only method."[68] This is simply not true because the patients are likely 4–5 weeks pregnant if they have an ultrasound that reveals a pregnancy of unknown location. Repeating an ultrasound in one week when the patient is then 5–6 weeks pregnant still gives the patient several weeks in which she is eligible for a chemical abortion.

[67] ACOG Practice Bulletin 191. (2018) Tubal Ectopic Pregnancy: ACOG.
[68] Farris Report ¶ 9.

IV. Conclusion

70. The state of North Carolina values each woman's life. It is rational then for the state to require that (1) abortions in complex cases after 12 weeks gestation be performed in a hospital and (2) a documented IUP by ultrasound prior to a chemical abortion to rule out an ectopic pregnancy. This expert opinion is fully my own and consistent with North Carolina's 2021 MMRC report that has as a goal to "make sure no woman dies as a result of pregnancy."[69]

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 11, 2023.

Susan Bane, MD, PhD

Susan Bane, M.D., Ph.D.

[69] https://wicws.dph.ncdhhs.gov/docs/2014-16-MMRCReport_web.pdf.

EXHIBIT # A

Susan Maxwell Bane, MD, PhD
4831 Wimbledon Court, Wilson, NC 27896
252-717-1891

SKILLS SUMMARY

- **Physician** Board-certified obstetrician-gynecologist. 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.
- **Medical Administrator** Leader who values members of the team, encourages them to perform optimally, and can lead the team by identifying and solving problems through collaborative and creative solutions.
- **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, published author, and successful negotiator.
- **Consultant.** Professional development coaching for individuals, teams, and organizations, teaching the value of character strengths and emotional intelligence to create stronger teams.

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

PinkGlasses Consulting

Health care consulting with a vision of providing exceptional health care in pregnancy center medical clinics.

Founder and CEO, 2021-present

Administration

- Serves as clinic medical director.
- Provides strategic direction and vision for clinical operations.
- Works with the 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.
- Oversees medical procedures within the clinics, including providing direct patient care.

  Clients:
  - Medical Director, Choices Women's Center 2021 - present
  - Medical Director, Albemarle Pregnancy Resource Center and Clinic, 2023 - present
  - Medical Director, WaterLife Pregnancy Center, 2023 - present

Clinical

- Provides direct patient care for women with unplanned pregnancies, including performing assessments, ultrasound, educating, supporting, and empowering women facing unplanned pregnancies with compassionate and professional medical care.
- Provides teleradiology services including reading, diagnostic interpretation, and reporting of ultrasounds.

Advocacy

- Advocates at the local, state, and national level for the profession of medicine through written and oral communication.
  - Women's Health
  - Conscience Protections
  - Hippocratic Medicine
  - Stress and Burnout
  - Compassionate health care
  - Health careers workforce
  - Diversity, Equity, and Inclusion
  - Trauma-informed care

Executive Coaching

- Provides individual emotional intelligence coaching for health care professions, particularly physicians.
- Provides training for organizations to strengthen communication through awareness of emotional intelligence skills and character strengths.

Peer Reviewed Presentations

Curlin, F., Bane, S., & Thorp. *Purpose of Abortion in Health Care*, Practice and Presence Conference, Duke University, October 2023.

Non-Peer Reviewed Publications
Monthly Opinion Column, Wilson Daily Times, 2021-present
Bane, S. (2023, November). On Ohio's Issue 1, OB-Gyn Debunks Deceptive Abortion Narrative. The Daily Signal. https://www.dailysignal.com/2023/11/20/on-ohios-issue-1-ob-gyn-debunks-deceptive-abortion-narrative/
Brown, G. & Bane, S. (2023, October 31). *Two Twin Stories of Growth Through Birth.* Rehumanize International. https://www.rehumanizeintl.org/post/two-twin-stories-of-growth-through-birth
Brown, G. & Bane (2023, July 3). *Unforgettable Hours of Love.* Rehumanize International. https://www.rehumanizeintl.org/post/unforgettable-hours-of-love
Bane, S. (2023, March 23). *Broken Medical Ethics Are Hurting Patient Care*. Politico/Real clear Health.https://www.realclearhealth.com/articles/2023/03/31/broken_medical_ethics_are_hurting_patient_care__111483.html
Bane, S. (2023, April 3). *Women Should Be Empowered by Doctors, Not Rushed to Medical Abortion Without Them.* https://thefederalist.com/2023/04/03/women-deserve-to-be-empowered-by-doctors-not-rushed-to-medical-abortion-without-them/

Non-Peer Reviewed Presentations
Bane, S. *What is Your Major? Exploring Careers in Health Care*, Barton College Guest Lecture, November 21, 2023.
Bane, S. *Diversity and Inclusion in the Workplace: Strategies to Create a Thriving Pregnancy Center,* Care Net National Conference, August 2023.
Bane, S. *Purpose, Passion, and Pregnancy Centers: Strategies to Move From Fatigue to Fulfillment,* Care Net National Conference, August 2023.
Bane, S. *A Witness for our Patients: Our Response Post-Roe/Dobbs*. Students for Life 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. *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.

Peer Review Editing
Peer Reviewer, Obstetrics & Gynecology, 2023-present.

Awards
Game Changer Award, NC Values Coalition, 2023

Professional Organizations
North Carolina Medical Society, 2023-present
American Association of Prolife Obstetricians and Gynecologists, 2020-present

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
Health and Wellness Coach, 2017
Emotional Intelligence Coach, 2016

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. & 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

Bane, S. Youth Mission Trip Inspires Adult, *NC Catholic,* 2013, pp. 6-7

Non-Peer Reviewed Presentations

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 Exceptional 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

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

Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

REBUTTAL EXPERT REPORT OF TIMOTHY R.B. JOHNSON, M.D.

Pursuant to Federal Rules of Civil Procedure 26(a)(2)(B) and 26(a)(2)(D)(ii), Timothy R.B. Johnson, M.D., makes the following disclosures:

BACKGROUND AND QUALIFICATIONS

1. I am a Michigan-licensed physician board-certified in Maternal Fetal Medicine and Obstetrics & Gynecology. For nearly five decades, I have treated patients with high-risk pregnancy and general obstetric and gynecologic conditions.

2. Until my retirement effective December 31, 2023, I held the position of Professor of Obstetrics and Gynecology at the University of Michigan Medical School. I served as the chair of the Department of Obstetrics and Gynecology at the University of Michigan from 1993 to 2017. I was also the Arthur F. Thurnau Professor of Women's and

Gender Studies and a Faculty Affiliate at the Institute for Research on Women and Gender at the University of Michigan.

3. Before coming to the University of Michigan in 1993, I was an associate professor in the Department of Gynecology and Obstetrics at the Johns Hopkins University School of Medicine. I served as the director of the Division of Maternal Fetal Medicine in that department from 1988 to 1993.

4. In these capacities I taught courses for medical students in obstetrics and gynecology for almost four decades, including in the management of abortion, as well as women's studies courses at the undergraduate college level on women's reproductive health, including on contemporary issues in women's health and men's health.

5. I am a Fellow of the American College of Obstetricians and Gynecologists ("ACOG"); a Fellow of the American Institute of Ultrasound in Medicine; an honorary Fellow of the West African College of Surgeons and the Ghana College of Physicians and Surgeons; and Fellow *ad eundem* of the Royal College of Obstetricians and Gynaecologists (London). I was elected a member of the National Academy of Medicine of the National Academy of Science in 2003. I have been awarded ACOG's highest honor, the Distinguished Service Award; the highest honor of the International Federation of Gynecology and Obstetrics ("FIGO"), the Distinguished Merit Award; and the Society of Family Planning's Alan Rosenfield Award for Lifetime Contributions to International Family Planning.

6. I have authored over 250 articles, chapters, and books on topics including prenatal care, fetal assessment, and global women's health issues, and have served on numerous editorial boards, study sections, professional committees, societies, and boards. I have served as President of the Association of Professors of Gynecology and Obstetrics and am currently Past Editor (previously Editor-in-Chief) of the International Journal of Gynecology and Obstetrics, the official publication of FIGO.

7. My *curriculum vitae*, including a list of all publications authored in the previous ten years, is attached as **Exhibit A.**

FACTS OR DATA CONSIDERED IN FORMING OPINIONS AND EXHIBITS TO BE USED TO SUMMARIZE OR SUPPORT OPINIONS

8. The opinions I state here are based on my education, clinical training, experience as a practicing physician providing obstetrical and gynecological care to thousands of patients, regular review of medical research in my field, my teaching experience, regular attendance and presentation at professional conferences (including conferences for abortion providers), other professional experiences (including various leadership positions I have held), my knowledge of standard medical practice, and my knowledge of the relevant literature. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this report.

9. I may use copies of the sources cited in this report and/or the sources cited in the opposing witnesses' reports as exhibits to support my opinions. I may also present demonstrative evidence at trial, and I reserve the right to do so.

EXPERT OPINIONS AND THE REASONS AND BASES FOR THEM

10. I understand that Plaintiffs Planned Parenthood South Atlantic ("PPSAT") and Dr. Beverly Gray are seeking to block two components of North Carolina Session Law 2023-14 ("S.B. 20") (codified as amended by Session Law 2023-65 ("H.B. 190") at N.C. Gen. Stat. art. 1I, ch. 90 (the "Act")), which bans abortion after the twelfth week of pregnancy in all but a few circumstances.

11. Specifically, I understand that the Act allows abortions in the case of rape or incest through 20 weeks of pregnancy, and abortions in the case of a "life-limiting anomaly" through 24 weeks of pregnancy. However, I also understand that the Act requires that an abortion provided after the twelfth week of pregnancy in cases of rape, incest, or "life-limiting anomaly" be provided in a hospital, not an outpatient clinic (the "Hospitalization Requirement"). I understand that this requirement does not apply to the same medical procedures if they are being used to manage spontaneous pregnancy loss[1] rather than for induced abortion.

12. I have not previously submitted a Rule 26(a)(2)(B) expert report in this case. Counsel for Plaintiffs asked me to review and respond to the expert reports that Drs. Susan Bane, Catherine Wheeler, and Monique Chireau Wubbenhorst submitted in this litigation. In this rebuttal report, I offer my opinions on certain assertions in those expert reports. The

[1] Although common in colloquial speech, "miscarriage" is not a medical term. The medical terms "spontaneous pregnancy loss" and "spontaneous abortion" describe what is commonly referred to as a miscarriage.

fact that I do not address a particular statement or assertion in the reports does not mean that I agree with the statement or assertion. I understand that, although I have been asked to respond to the opinions identified below, it does not necessarily mean that the Plaintiffs believe the opinions to which I have been asked to respond are relevant to the case.

13. It may be necessary for me to revise or supplement this report based on material subsequently presented, and I reserve the right to do so.

14. After reviewing their reports, I can conclude that Drs. Bane, Wheeler, and Wubbenhorst are wrong that there is any medical justification for a requirement that manual or electric vacuum aspiration procedures (a method using syringe suction to remove the contents of the uterus) and dilation and evacuation (D&E) procedures (a method using suction aspiration equipment, surgical instruments, or a combination of the two), be performed in a hospital if those procedures are being done for abortion, but not if they are being done to empty a patient's uterus after spontaneous pregnancy loss. In my opinion, there is no medical justification for this distinction. Instead, it reflects the views—clearly held by all three witnesses, and presumably also held by proponents of the Hospitalization Requirement generally—that abortion is distasteful, that contemporary abortion providers provide substandard medical care, and that women with undesired pregnancies are less deserving of compassionate and holistic care than women undergoing spontaneous pregnancy loss. This reflects abortion stigma, not evidence-based medical practice.

Abortion Stigma & Stigma-Leveraging Language Choices

15. Precision in word choice is important to me.[2] In addition to providing accuracy (or revealing its absence), word choice reveals much about the biases and beliefs of the speaker or writer. For these reasons, I want to begin this rebuttal by discussing the nature of abortion stigma, the language we use to talk about abortion, and the ways this language can reflect and reinforce abortion stigma.

16. People in many areas across this country have extremely limited access to safe abortion. This was true even before the Supreme Court overruled *Roe v. Wade* in *Dobbs v. Jackson Women's Health Organization*, but accessing safe abortion has become exponentially more difficult in many states since that decision—with abortion being severely restricted or entirely unavailable to people living in many states, including North Carolina and two of three states with which it shares borders.[3] This public health crisis is the direct result of laws banning or restricting abortion. The crisis is exacerbated by the abortion stigma that these laws codify and reinforce, because stigma reduces the pool of clinicians who are willing and able to provide abortions—not only in states where abortion is criminalized, but also in states where it remains legal.

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[2] Timothy R. B. Johnson et al., *Language Matters: Legislation, Medical Practice, and the Classification of Abortion Procedures*, 105 Obstetrics & Gynecology 201 (2005).

[3] South Carolina and Tennessee have banned abortion once cardiac activity is detected with very limited exceptions. S.C. Code Ann. § 44-41-610; Tenn. Code Ann. § 39-15-216.

17. Moreover, laws restricting and prohibiting abortion are leading to a net exodus of well-trained obstetricians and gynecologists from the states with such laws in place. These laws also negatively impact medical training in states that restrict or prohibit abortion, since residency programs in those states cannot provide training in the full range of obstetric and gynecological care. One recent study observed that 29% of family medicine programs in the United States are located in states that ban or severely restrict abortion.[4] It is essential that physicians develop the knowledge and skills necessary to provide comprehensive, evidence-based care to their patients. If prospective medical residents know that a state's abortion laws will limit their clinical training, they may look elsewhere for training. This negatively impacts medical care, since residency programs are a pipeline for future practitioners in the state. States with laws that ban or severely restrict abortion are already experiencing a decrease in the number of applicants for residency training programs located within their borders.[5]

18. A brief history of abortion practice is helpful to understand the current stigmatization and targeting of abortion providers. Prior to abortion's national legalization in 1973, illegal abortions were quite common in states where abortion was banned, and regularly performed by people without professional medical training, whom mainstream

[4] Sarah Wulf et al., *Implications of Overturning Roe v Wade on Abortion Training in US Family Medicine Residency Programs*, 21 Annals Fam. Med. 545 (2023).

[5] Arielle Dreher & Oriana Gonzalez, *Change in U.S. M.D. Seniors Applying to Medical Residency Programs, 2022 to 2023*, Axios (Apr. 18, 2023), https://www.axios.com/2023/04/18/abortion-ban-states-drop-student-residents.

physicians labeled "criminal abortionists." These individuals were considered medically untrained, lacking in ethics, and seeking personal financial gain through illegal activity. Unsafe, illegal abortions from such individuals often resulted in injury or death. Accordingly, during the pre-1973 period of criminalization, physicians distanced themselves from the "greedy back-alley butchers" they regarded as demeaning the medical profession.

19. After the United States Supreme Court recognized a federal right to abortion in 1973, in *Roe v. Wade*, many interested professional medical bodies were inconsistent or silent on how abortion should be practiced. This institutional passivity and ambivalence often led to a failure to incorporate abortion into mainstream medicine. Freestanding abortion clinics proliferated to meet patients' needs. These specialized clinics provide evidence-based, safe, competent, and compassionate care. And together with non-specialized outpatient clinics and physician's offices, they currently provide over 96% of all abortions performed in the United States, with hospitals providing just 3% of abortions overall.[6]

[6] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2020*, 54 Persps. Sexual & Reprod. Health 128, 134 & tbl.3 (2022) (3% of abortions provided in hospitals); Jeff Diamant & Besheer Mohamed, *What the Data Says About Abortion in the U.S.*, Pew Research Center (Jan. 11, 2023), https://www.pewresearch.org/short-reads/2023/01/11/what-the-data-says-about-abortion-in-the-u-s-2/ ("While clinics make up half of the facilities that provide abortions, they are the sites where the vast majority (96%) of abortions are administered, either through procedures or the distribution of pills, according to Guttmacher's 2020 data.").

20. Despite the high-quality care specialized clinics provide, their existence contributed to the historical stigmatization of abortion and the doctors who provide it. This stigma does not reflect the medical reality that specialized clinics provide safe, evidence-based, compassionate care. Moreover, isolating these freestanding clinics has made them easy targets for anti-abortion intimidation through protests and violence, as well as targeted regulation from hostile state legislatures. These abortion-clinic-specific regulations frequently rely on the trope that abortion providers are greedy, unsanitary, and reckless with patient safety, even though this stereotype is a historical artifact with no basis in modern medical practice.

21. The very word "abortionist"—used in place of "doctors," "physicians," or "medical providers"—evokes this baseless stereotype about abortion providers.[7] It conjures deeply embedded connotations of greedy, "dirty old men" preying on women with back-alley, non-sterile, unconsented procedures.[8] Historically, this stereotype also had

[7] Jenny O'Donnell et al., *Resistance and Vulnerability to Stigmatization in Abortion Work*, 73 Soc. Sci. & Med. 1357, 1358 (2011) (describing how Carol Joffe, in *Doctors of conscience: The struggle to provide abortion before and after Roe v. Wade* (1995), "specifically examines how the label 'abortionist' is sometimes derogatorily applied to those who perform abortions, invoking pre-legalization notions of morally deficient, profit-motivated, and/or technically incompetent 'back-alley' physicians").

[8] *Id.*; *cf. also* Emma L. Jones & Neil Pemberton, *Ten Rillington Place and the Changing Politics of Abortion in Modern Britain*, 57 Hist. J. 1085, 1088 (2014) ("[I]n representations of the abortion experience, male abortionists are presented as unsavoury and untrustworthy figures. The anxiety was that, in Allen's words, 'men abortionists read the abortion situation as sexualized or erotically exploitable.'"); Gillian Frank, *The Abortionist*, Am. Hist. Ass'n (Nov. 29, 2021), https://www.historians.org/research-and-publications/perspectives-on-history/december-2021/emthe-abortionist/em.

antisemitic dimensions, with "abortionists" often portrayed as greedy, "dirty old *Jewish* men."[9] "Abortionist" is therefore an extremely inflammatory, pejorative, and inappropriate term to use.

22. Using stigmatizing language around abortion care, and medical professionals who provide that care, is harmful.[10] Like the term "abortionist," the phrase "chemical abortion" evokes dangerous, back-alley activity—e.g., lye, bleach, and other caustic substances rather than FDA-approved medications. It is not a medical term (the commonly used medical term is "medication abortion") and it is not recognized by or commonly used in the medical community. Rather, this language plays upon negative, baseless historical stereotypes and tropes around abortion and abortion providers. Stigmatizing language nefariously mischaracterizes what is, in reality, safe, essential medical care.

23. I believe that using accurate, precise language in this area is critical. The expert reports that Drs. Susan Bane, Catherine Wheeler, and Monique Chireau

[9] Susan Weidman Schneider, *The Anti-Choice Movement: Bad News for Jews*, Lilith (June 12, 1990), https://lilith.org/articles/the-anti-choice-movement-bad-news-for-jews/ (describing how the "leader of the anti-choice group called PL.A.N. (Pro-Life Action Network), revealed to an interviewer . . . that, in his opinion . . . 'the majority of abortionists are Jewish,'" and citing postcards sent to abortion clinics in Massachusetts that read "Rich murdering Jewish doctors are dedicated to baby butchering"); *see also* Jessica Winter, *The Link Between the Capitol Riot and Anti-Abortion Extremism*, The New Yorker (Mar. 11, 2021), https://www.newyorker.com/news/daily-comment/the-link-between-the-capitol-riot-and-anti-abortion-extremism ("For a half century, a conspiracy-minded brand of anti-abortion extremism has been part and parcel of white-supremacist movements. . . . Anti-abortion leaders such as Randall Terry, of Operation Rescue, and Robert Cooley, of the Pro-Life Action Network, frequently alleged that most abortion providers were Jewish.").

[10] Johnson et al., *supra* note 2.

Wubbenhorst submitted in this litigation fail to do so and are replete with stigmatizing language that has no medical use or significance. The three expert reports also use imprecise and incorrect language, such as where Dr. Bane confuses "maternal mortality *rate*" and "maternal mortality *ratio*"[11] despite them being well-defined terms that refer to different measurements.[12] The fact that I do not address a particular term in the reports does not mean that I agree with its use.

24. Today, abortion providers are trained and licensed gynecologists, family-medicine doctors, or maternal fetal medicine specialists. In many states, advanced practice clinicians like certified nurse-midwives and physician assistants can also provide abortion with appropriate training. Most of the medical professionals providing abortion in 2023, like most obstetrician-gynecologists today, are women.[13] Their comprehensive, holistic practices often include family-planning services, and comprehensive family-planning care includes induced termination of pregnancy. These clinicians provide abortion out of a deep

[11] Expert Report of Susan Bane, M.D., Ph.D ("Bane") ¶¶ 28, 32–33.

[12] Maternal mortality "rate" refers to the number of pregnancy-related deaths per total reproductive age women: a denominator that is difficult if not impossible to identify. Maternal mortality "ratio" refers to the number of pregnancy-related deaths per 100,000 live births: a far more verifiable denominator, and therefore a far more reliable way of capturing maternal mortality data.

[13] *See* Daniel Grossman et al., *Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists*, 133 Obstetrics & Gynecology 477, 479–480 tbl.1 (2019); William F. Rayburn, *The Obstetrician-Gynecologist Workforce in the United States: Facts, Figures, and Implications,* Am. Cong. Obstetricians & Gynecologists, 3–4 (2017).

sense of responsibility, compassion, and justice.[14] Given the intense stigma they encounter, abortion providers are some of the bravest, most dedicated, and most patient-centered medical professionals working today.

25. Even though it is baseless, abortion stigma forces clinicians to weigh severe personal and professional consequences and economic concerns when deciding whether to provide abortion, either by working as full- or part-time staff at a specialized abortion clinic or by incorporating abortion into their gynecological practice at a hospital or other outpatient setting.[15] Physicians often rely on referrals from other physicians. In some communities, it is impossible to maintain a financially viable practice without such referrals. When a physician at a medical practice provides abortions, however, it frequently results in a loss of referrals from other medical providers who oppose abortion. As a result, many physicians—even those who would otherwise seek to provide abortions—are unable to do so because it would put their practices in jeopardy. Even physicians who are not opposed to abortion may be prevented by colleagues from providing abortions because the colleagues are unwilling and/or unable to risk the financial damage to the practice that a resultant loss of referrals would cause.

26. Moreover, even if a practice can subsist without referrals, doctors worry that they may lose their own patients who are opposed to abortion should those patients learn

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[14] *See, e.g.*, Lisa Harris, *Perspective: Recognizing Conscience In Abortion Provision*, 367 New Eng. J. Med. 981 (2012).

[15] Lori Freedman et al., *Obstacles to the Integration of Abortion Into Obstetrics and Gynecology Practice*, 42 Persps. Sexual & Reprod. Health 146 (2010).

that the doctor provides abortion services. Some medical practices also forbid employed or associated doctors from providing abortions *outside* the practice—either due to an institutional opposition to abortion, or due to a fear that simply employing a physician who provides abortion elsewhere will draw picketers or drive away existing patients who oppose abortion. This further reduces the number of providers in a given area.

27. In addition to these professional consequences, abortion providers worry about potential violence and threats against themselves and their families.[16] Providers are routinely stigmatized and ostracized in their communities—by neighbors, by members of their religious congregations, and by parents and teachers at their children's schools. Research has found that such isolation manifests in a number of ways, e.g., receiving harassing or threatening messages on social media, providers' children being bullied at school or excluded from social events, and frayed relationships with colleagues.[17] Some physicians cite the effect of picketing on their children and families as a reason they decided not to provide abortions.

28. All of these factors take a toll on abortion providers' personal, family, and professional lives and contribute to other doctors' unwillingness to provide abortions. Moreover, regardless of a potential provider's personal desire to provide abortions, their

[16] Diane J. Horvath-Cosper, *Being a Doctor Who Performs Abortions Means You Always Fear Your Is in Danger*, Washington Post (Oct. 29, 2015), https://www.washingtonpost.com/posteverything/wp/2015/10/29/being-a-doctor-who-performs-abortions-means-you-always-fear-your-life-is-in-danger/

[17] *Id.*; Freedman et al., *supra* note 15.

partners, parents, and friends are often persuasive voices against doing so because of the attendant risks and stigmatization.

29. I myself have been targeted by anti-abortion groups and listed on websites targeting obstetrician-gynecologists who provide abortion services to varying extents.[18] Being listed on this type of website carries particular concerns for providers in today's era of information proliferation—where one's personal information, like home address, can be easily located and posted online. When I served as a court's expert in a case related to abortion,[19] not only were all involved given United States Marshals Service protection, but my children received protection at school from the county sheriff's department.

30. The murder of Dr. Barnett Slepian is an example of the type of violence providers fear and face. Dr. Slepian was a general obstetrician-gynecologist who delivered babies. He also did routine gynecologic surgeries in his practice and provided reproductive health care, including abortion, only a few days a month at Buffalo Women's Services clinic in Buffalo, New York. He was killed by a long-range rifle—shot in his home while preparing a meal with his family present in 1998.[20] Dr. Slepian shared call and deliveries with other fully trained and qualified obstetrician-gynecologists who provided abortion as

[18] *Timothy Robert B. Johnson*, AbortionDocs.org, https://abortiondocs.org/abortionists/timothy-robert-b-johnson/.

[19] *Evans v. Kelley*, 977 F. Supp. 1283 (E.D. Mich. 1997).

[20] *Murder of New York Abortion Doctor Denounced as Terrorism*, CNN.com (Oct. 24, 1998), http://www.cnn.com/US/9810/24/doctor.killed.02/.

part of their practice.[21] These types of violence have a chilling effect on the willingness of doctors and other medical professionals to provide abortion.

31. Abortion stigma weighs particularly heavily on clinicians who practice in parts of the country where social and political environments are more hostile to abortion. Providers who do choose to provide abortions employ a variety of coping mechanisms to deal with the violence, harassment, and isolation they experience.[22] These coping mechanisms themselves illustrate how much more challenging it is for providers to practice in states where abortion stigma is expressed and codified through laws banning or severely restricting abortion.

32. For example, in one study where researchers conducted interviews of health care professionals in "a Western state," respondents acknowledged that their individual successes in deflecting abortion stigma were bolstered by a supportive political environment and the strength of their local abortion-providing community.[23] They explained that having a professional community that normalizes abortion seems to make the work more attractive and sustainable for those engaged in providing abortions. By contrast, many areas of the country without such a supportive political and professional

[21] Eyal Press, *My Father's Abortion War*, N.Y. Times Mag. (Jan. 22, 2006), https://www.nytimes.com/2006/01/22/magazine/my-fathers-abortion-war.html.

[22] Jenny O'Donnell et al., *supra* note 7.

[23] *Id.*

environment, and which already lack abortion providers, often do not have the sort of community necessary to support abortion providers and help defray stigma.[24]

33. Research has shown that even physicians who valued the abortion training they received during residency, whose political and moral ideologies strongly support access to safe abortion, and who planned to provide abortions as part of their practice face numerous obstacles in doing so. The constraints encountered by physicians who are considering whether to provide abortion differ by geographic location, structure of medical practice, and the political climate, but all of these constraints flow from the stigma and political controversy surrounding abortion.

34. Abortion stigma creates obstacles to care that patients do not encounter when seeking any other type of medical treatment. To attend their appointments, patients may be forced to cross picket lines in front of abortion clinics or hospitals that provide abortions. Patients may also fear that their abortion history or efforts to obtain an abortion will be publicized or made available to family members, friends, or other community members from whom they would prefer to keep this medical information confidential.

35. Abortion stigma also means that patients can be treated with less compassion when they are seeking abortion than when they are seeking management of spontaneous pregnancy loss. As I discuss in more detail below, one example of this is that hospital patients receiving procedures to manage spontaneous pregnancy loss are usually offered

[24] *Id.*

deeper levels of sedation than patients receiving procedures for induced abortion at the same gestational age, based on a conscious or subconscious view that women experiencing spontaneous (but not induced) pregnancy loss should be "shielded" from the experience.

Procedural Management of Induced & Spontaneous Abortion

36. There is no safety difference between procedural (also known as "surgical") induced abortion and procedural management of spontaneous pregnancy loss that would justify imposing a hospitalization requirement on induced abortion but not on management of spontaneous abortion. While Drs. Wubbenhorst, Wheeler, and Bane list potential complications that could arise from induced abortion using aspiration with manual vacuum aspirators (MVAs), dilation and curettage (D&C), or dilation and evacuation (D&E), all the same risks apply to the use of MVA, D&C, and D&E for management of spontaneous pregnancy loss. *See* Expert Report of Monique Chireau Wubbenhorst, M.D., M.P.H. ("Wubbenhorst") ¶¶ 74–88; Expert Report of Catherine J. Wheeler, M.D. ("Wheeler") ¶¶ 30–38; Bane ¶¶ 48–50.

37. More specifically, while there may be physiological differences in the cervix between some subset of patients presenting for management of spontaneous abortion and patients presenting for induced abortion, these differences do not make aspiration or D&E *riskier* for induced abortion than for management of spontaneous abortion. *See* Bane ¶¶ 55–57.

38. First, there is no difference between the clinical management of missed abortion (when the pregnancy has spontaneously terminated but has not been

spontaneously expelled from the patient's uterus) and induced abortion in the second trimester, as in both circumstances the patient's cervix is closed before medical intervention. In both circumstances, cervical ripening with medical agents or laminaria may therefore be used to prepare the cervix for dilation before using suction and possibly instruments to empty the uterus.

39. Second, the difference between incomplete abortion (when the pregnancy has spontaneously terminated and *has* been partially expelled from the patient's uterus) and induced abortion after 14 weeks is the status of the cervix: in an incomplete abortion after 14 weeks, the patient's cervix is already partially dilated, while in an induced abortion at that gestational age, the cervix is closed, and the patient may need cervical ripening as described above.

40. But this distinction in the degree of advance cervical preparation required does not mean that D&E for induced abortion is *riskier* than D&E for incomplete abortion: evidence-based methods for cervical ripening such as laminaria (osmotic devices placed in the cervix) and cervical-ripening medications are safely and appropriately used routinely in this setting. And the cervical preparation itself certainly need not occur in a hospital setting, as there is nothing about inserting laminaria or administering cervical-ripening medication that requires an operating room. Even when a patient is a candidate for receiving an abortion in an operating room rather than an outpatient clinic due to their individual medical circumstances, we could initiate the patient's cervical ripening in an outpatient setting rather than in a hospital operating room.

41. And while risks of morbidity and mortality from aspiration and D&E increase with advancing gestational age, there is no substantial difference between risks for spontaneous and induced abortion by gestational age. *Contra* Wubbenhorst ¶¶ 91–95.

42. Because Dr. Wheeler appears to suggest that it is routine to begin using instruments in addition to suction starting at 13 weeks' gestation, Wheeler ¶¶ 13–14, 29, I would note that generally instruments are used to supplement suction at 15 weeks' gestation and later, though different practitioners begin using instruments at different points in gestation based on their individual training and experience.

The Hospitalization Requirement Does Not Improve Safety

43. For most patients, including patients seeking abortion due to rape, incest, or fetal anomaly, D&E is just as safe in an outpatient clinic as in a hospital. Indeed, procedures in a hospital setting may carry *more* risk than the same procedures in an outpatient setting.

44. D&E is now commonly performed safely and with evidence-based protocols in the outpatient setting up to 24 weeks' gestation. Robust evidence demonstrates that "[m]ost abortions can be provided safely in office-based settings," and that for procedural abortion methods, "the minimum facility characteristics depend on the level of sedation that is used."[25] I therefore disagree with Dr. Wheeler's assertion that the hospital setting is "the safest location for patients to undergo a D&E," Wheeler ¶ 23, *see also id*. ¶¶ 49–50.

[25] Nat'l Acads. Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 1, 10 (2018), (available at http://nap.edu/24950); *see id.* at 65 ("The facility requirements that are appropriate for D&Es depend on the level of sedation and anesthesia that is used.").

The risks associated with D&E are rare and can be managed by evidence-based protocols and by referral and transfer from outpatient settings when needed. There is no reason to require *all* D&Es for induced abortion to occur in a hospital setting simply because complications are theoretically *possible*. We do not apply that standard to any other type of medical treatment. There is no reason to do so only for abortion.

45. Procedural abortion safety is primarily a function of the abortion provider's experience. For patients obtaining a D&E at a hospital, there is no guarantee that they will be treated by an experienced abortion provider. D&Es at hospitals therefore are *not* categorically "safer" than D&Es in outpatient clinics. Wheeler ¶¶ 23, 49–50. The vast majority of second-trimester abortion patients would be safer in an outpatient clinic with an experienced abortion provider than in a hospital operating room with a physician—even a highly trained and credentialed physician—who has not performed many D&Es.

46. It is simply not true that outpatient abortion clinics lack oversight. See Wubbenhorst ¶¶ 150–56. Clinics are overseen and regulated both by government agencies and by professional accrediting institutions. And health department deficiencies are routine for health care facilities: even the best hospitals are cited for deficiencies by health departments all of the time. Moreover, exposure to infections and infection-inducing procedures is more frequent in the hospital setting than in outpatient clinics.[26]

[26] *See, e.g.*, Centers for Disease Control and Prevention, *Healthcare-Associated Infections (HAIs)*, HAI Data, https://www.cdc.gov/hai/data/index.html (last accessed Jan. 5, 2024) (reporting that "[o]n any given day, about one in 31 hospital patients has at least one healthcare-associated infection").

47. Experienced clinicians are usually better equipped to have trauma-informed discussions with patients. For example, it may be challenging for a patient who is pregnant as the result of rape or incest to discuss care options that can include inserting instruments through the vagina. For patients in this situation, being able to discuss the full range of options with a provider trained in trauma-informed care is essential. Compassionate, trauma-informed care can be provided just as well, if not better, in a specialized reproductive health care center as compared to in a hospital. Bane ¶ 58. Clinics, like hospitals, can provide psychosocial support services to patients seeking abortion in complicated circumstances like rape, incest, or fetal anomaly. And trained abortion clinic staff are more likely than general hospital staff to treat each abortion patient with respect, compassion, and non-judgmentally, given that they have chosen to work in a setting specifically devoted to caring for abortion patients. Patients seeking abortion would rather not be in the situation of having an undesired pregnancy and needing to seek medical care. But they have come to the conclusion that they are certain that an abortion is the right decision for them. It is important to see the nuance in each patient's circumstances and to care for them individually with compassion. Abortion clinic staff are trained to provide this compassionate care that meets each patient where they are.

48. Additionally, the experience of receiving treatment in a hospital is likely to be worse for many patients than receiving the same treatment in an outpatient clinic. This results in part from challenges in getting to a hospital for care and the likelihood of being treated by hospital-based physicians and other care providers with less experience

providing abortions and care to pregnant people. Obtaining an abortion at a hospital can cost thousands of dollars more than obtaining an abortion in an outpatient clinic, such that people may be forced to delay their care while they collect the money needed to pay for their procedure and associated expenses (travel, lodging, childcare, lost wages due to time away from work in addition to hospital and physician charges and costs). This delay in turn exposes patients to the increased risk of complications that comes with increased gestational age.

49. Moreover, hospitals can be deeply impersonal places, particularly when they do not have established abortion care practices. Some patients receiving an abortion for a wanted pregnancy, such as those obtaining abortion due to life-limiting fetal anomaly, express discomfort about being treated in a facility where they may receive care in rooms with newborn babies in view around them. And given the legacy of Black patients' mistreatment by the medical system as well as personal experiences of systematic disregard and discrimination by medical professionals,[27] many Black patients and other patients of color experience understandable anxiety when receiving care in highly medicalized settings. These are all reasons why outpatient clinics are not only comparable, but actually *preferable* to hospitals for many patients seeking abortion.

[27] Martha Hostetter & Sarah Klein, *Understanding and Ameliorating Medical Mistrust Among Black Americans*, Commonwealth Fund (Jan. 14, 2021) https://www.commonwealthfund.org/publications/newsletter-article/2021/jan/medical-mistrust-among-black-americans.

50. The hospital setting is not the norm for aspiration and D&E after the twelfth week of pregnancy. Nor is it common practice for all second-trimester abortions to be performed in hospital settings. Outpatient clinics are the most common site for management of second-trimester abortions in most of those states where induced abortion remains legal and available.[28] Contrary to Dr. Wheeler's suggestion, it is not the "traditional norm" for second-trimester D&Cs and D&Es to be performed "in a surgical suite in a hospital." Wheeler ¶ 23. And as I explain below, evidence supports moving the management of spontaneous abortion *out* of the operating room and into an outpatient setting, despite the historical practice of managing pregnancy loss in operating rooms.

The Hospitalization Requirement Actually *Increases* Patient Risk

51. Abortion stigma means that people are treated with less compassion and fewer options when they are seeking induced abortion than when they are seeking spontaneous pregnancy loss management. Everyone experiencing any type of abortion—whether spontaneous or induced—should receive evidence-based, compassionate care from all of the health care professionals they come into contact with throughout their medical treatment. But because abortion is stigmatized, women with spontaneous pregnancy loss have long received different care—and have encountered fewer obstacles to care—than those obtaining induced abortion.

[28] Jones et al., *supra* note 6.

52. Notably, women experiencing spontaneous pregnancy loss are more likely than women seeking induced abortion to be offered general anesthesia, taken to operating rooms, and offered counseling and follow-up care for their reproductive loss.[29] But while this higher intensity of care is likely intended to be compassionate—grounded in a belief that patients experiencing spontaneous pregnancy loss should be "shielded" from the experience, including by rendering them unconscious for their procedure—it actually *increases* the patient's risk of complications. One study that examined early pregnancy failure care observed that "hemorrhage-related complications were 4 times more common" in study participants who received care in an operating room compared to study participants who received office-based care.[30] And many patients preferred to have their procedures in an office-based setting rather than in the operating room.[31] Deeper levels of sedation actually increase the risk of morbidity,[32] such that providing abortion in an operating room under general anesthesia is riskier than providing abortion in a clinic setting with conscious IV sedation.

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[29] *See* Lisa H. Harris et al., *Surgical Management of Early Pregnancy Failure: History, Politics, and Safe, Cost-Effective Care*, 196 Am. J. Obstetrics & Gynecology 445.e1 (2007).

[30] Vanessa K. Dalton et al., *Patient Preferences, Satisfaction, and Resource Use in Office Evacuation of Early Pregnancy Failure*, 108 Obstetrics & Gynecology 103, 108 (2006).

[31] *Id*. at 108 ("Overall, our institution's experience has been that about half of women choose to have their procedures completed in the office. In the study group, only 25% of study participants reported that being asleep for the procedure was highly important. Instead many participants opted for an office procedure that better meets other needs such as privacy and efficiency.").

[32] *See id.* at 104.

53. Deep sedation and general anesthesia are not necessary for adequate pain management for induced abortion and management of pregnancy loss. Rather, evidence-based pain management can include analgesia with oral medication, local anesthesia and conscious sedation, and even guided meditation and abortion doula care. Conscious IV sedation is more than adequate pain relief for most second-trimester abortion patients.

54. For these reasons, at the University of Michigan, we started managing pregnancy loss *more like* induced abortion. Previously, if a person came in with a spontaneous abortion, they would go to an operating room for curettage and receive a major anesthetic, even general anesthesia. That led to increased blood loss compared to people who received treatment using an MVA in the emergency room, under conscious sedation. We have now changed our practice so that physicians managing spontaneous abortion use MVAs with conscious sedation in the emergency room or outpatient clinic.[33] This change allowed us to expedite intervention to reduce bleeding and risks of infections. It also allows patients to return home after a shorter stay rather than waiting for hours for an operating room to become available.

55. Understanding the appropriate level and type of pain management to use for abortion is another reason why specialized outpatient clinics can be safer settings for this care than hospitals. Here, again, a provider's level of experience is important. When administering sedation for pain management during a procedure for abortion (either

[33] *See* Harris et al., *supra* note 29.

spontaneous or induced), it is important not to give the patient a form of sedation that will interfere with their uterus's ability to contract—because after the uterus is emptied, its contractions are what stops the flow of blood. Inhaled anesthetic, however, causes the uterus to relax, interfering with its ability to contract and stop bleeding.

56. In a hospital operating room setting, a patient may be given general anesthesia at all hours by whatever doctors are on staff at the time, who may not normally care for pregnant patients, and who may therefore give the patient excessive sedation, or a form of sedation that relaxes the uterus, thereby increasing the risk of complications from the abortion procedure.

57. Allowing abortions in specialized clinics does not, however, preclude patients from seeking treatment at a hospital if they desire a higher level of sedation than can be provided in-clinic. If, after being counseled about their options, a patient decides they want to receive deep sedation or general anesthesia, they can be referred for an in-hospital procedure. But there is no medical reason to require *all* abortion patients after the twelfth week of pregnancy to receive their abortion in a hospital.

* * *

58. In sum, the Hospitalization Requirement reflects abortion stigma rather than a legitimate health and safety measure. The Hospitalization Requirement also increases risk to patients. It will move medicine backwards.

TESTIMONY IN THE LAST FOUR YEARS

59. I have not testified as an expert at trial or by deposition in any case in the last four years.

COMPENSATION

60. My work on this expert report has been performed *pro bono*. I will be compensated at the rate of $300 per hour for any time spent testifying at trial or by deposition.

Dated: January 5, 2024

Timothy R.B. Johnson, M.D.

EXHIBIT A

CURRICULUM VITAE

PERSONAL DATA

Name: **Timothy Robert Bradley Johnson, M.D.**

EDUCATION

1965	L'Ecole Française, Cours Saint Louis, Stockholm, Sweden; B.E.P.C.
1967-1970	A.B. University of Michigan, Ann Arbor, Michigan; Romance Languages and Literature: French (with distinction and high honors) Honors thesis: Le temps racinien ("Time" in the theatrical work of Jean Racine)
1970-1971	A.M. University of Michigan Rackham School of Graduate Studies, Ann Arbor, Michigan; Romance Languages and Literature: French; Thesis: Le médicin comme personage dans le roman: Les Thibaults de Roger Martin du Gard (The physician as a character in the novel: The Thibaults by Roger Martin du Gard)
1971-1975	M.D. University of Virginia School of Medicine, Charlottesville, Virginia

POSTDOCTORAL TRAINING

1975-1979	House Officer I-IV, University of Michigan Hospitals, Department of Obstetrics and Gynecology
1979-1981	Fellow, Maternal-Fetal Medicine, The Johns Hopkins University School of Medicine

ACADEMIC APPOINTMENTS

1979-1981	Instructor, Department of Gynecology & Obstetrics, The Johns Hopkins University School of Medicine
1980-1981	Director, Outpatient Obstetric Clinics, The Johns Hopkins University School of Medicine
1981-1983	Chief of Obstetrics and Staff Perinatologist, USAF Medical Center, Keesler, Biloxi, Mississippi
1982-1983	Training Officer, Department of Obstetrics & Gynecology, USAF Medical Center, Keesler, Biloxi, Mississippi
1983-1985	Assistant Professor, Department of Obstetrics & Gynecology, Uniformed Services University of the Health Sciences (USUHS), Bethesda, Maryland

1983-1985	Uniformed Services University of the Health Sciences Medical Student Coordinator for Obstetrics and Gynecology, Malcolm Grow USAF Medical Center, Andrews AFB
1984-1985	Director, Maternal-Fetal Medicine Fellowship Program, Uniformed Services University of the Health Sciences, Bethesda Naval Hospital; Walter Reed Army Medical Center; Malcolm Grow USAF Medical Center
1985-1988	Assistant Professor, Department of Gynecology & Obstetrics, The Johns Hopkins Medical Institutions
1985-1993	Director, Fetal Assessment Center, The Johns Hopkins University School of Medicine
1986-1993	Director, Residency Training Program, Department of Gynecology & Obstetrics, The Johns Hopkins University School of Medicine
1988-1993	Associate Professor, Department of Gynecology & Obstetrics, The Johns Hopkins University School of Medicine
1988-1993	Director, Maternal Fetal Medicine Fellowship Program Department of Gynecology & Obstetrics, The Johns Hopkins University School of Medicine
1988-1993	Director, Division of Maternal Fetal Medicine, Department of Gynecology & Obstetrics, The Johns Hopkins University School of Medicine
1989-1993	Associate Professor, Department of Pediatrics, The Johns Hopkins University School of Medicine
1990-1993	Joint Appointment, Department of Maternal and Child Health, The Johns Hopkins University School of Hygiene and Public Health
1993 -1995	Adjunct Professor, Department of Maternal and Child Health, The Johns Hopkins University School of Hygiene and Public Health
1993-2018	Bates Professor of the Diseases of Women and Children, Department of Obstetrics and Gynecology, University of Michigan
1993-2017	Chair, Department of Obstetrics & Gynecology, University of Michigan Medical School
1993-	Professor, Department of Obstetrics and Gynecology, University of Michigan
1993-2020	Research Professor, Center for Human Growth and Development, University of Michigan
1995-	Professor, Women's Studies, College of Literature, Science and the Arts, University of Michigan
1997-2017	Director, National Center of Excellence in Women's Health

2003- Arthur F. Thurnau Professor, University of Michigan (Appointed in recognition of outstanding contributions to undergraduate education)

2009-2012 Faculty Associate, Center for Global Health, University of Michigan

2013- Faculty Associate, Global REACH, University of Michigan

2013- Academy for Educational Excellence and Scholarship, University of Michigan

2018- Faculty Affiliate, Institute for Research on Women and Gender (IRWG), University of Michigan

CONSULTING POSITIONS

1984-1989 Consulting Perinatologist, Naval Hospital, National Naval Medical Center

1986-1993 Medical Consultant, Nurse Midwife Service, The Johns Hopkins University School of Medicine

1986-1993 Francis Scott Key Medical Center, Baltimore, Maryland

1986-1995 Johns Hopkins Program for International Education in Gynecology and Obstetrics

1993-1995 Board of Trustees, Johns Hopkins Program for International Education in Gynecology and Obstetrics

1991-1993 Maryland General Hospital, Baltimore, Maryland

1993-2001 Maternal-Fetal Medicine, Catherine McAuley Health Center/St. Joseph Mercy Hospital, Ann Arbor, Michigan

1994-1998 Maternal-Fetal Medicine, Oakwood Hospital
Dearborn, Michigan

1995-1998 Board of Consultants, Lamaze Association
Ann Arbor, Michigan

SCIENTIFIC ACTIVITIES

Editorial Boards and Editorial Positions

1988-1993 Editorial Board: Current Opinion in Obstetrics & Gynecology
1991-1992 Editorial Board: Medical Aspects of Human Sexuality
1991-2000 Editorial Board: The Female Patient

1991-1993 Co-Editor with George Huggins, MD: "Primary Gyn-Ob Rounds at the Johns Hopkins Medical Institutions" in The Female Patient

1993-1998 Co-Editor: "Women's Primary Health Rounds at the University of Michigan" in The Female Patient

1994-1997 Editor: "Practice Maps: The Female Patient" in he Female Patient

1993 Task Force Member: PROLOG, Obstetrics, 3rd Edition, American College of Obstetricians & Gynecologists

1995- International Journal of Gynecology and Obstetrics (the official FIGO Journal)
1995-2006 Associate Editor
2002-2007 Section Co-Editor, (with S. Arulkumaran; Richard Adanu), Contemporary Issues in Women's Health
2007-2014 Editor (in-Chief)
2015-2021 Editor Emeritus
2021- Past Editor

1996-2000 Member at Large, Advisory Committee on Policy, American Journal of Obstetrics and Gynecology

1997-2000 Editorial Board, Obstetrics & Gynecology

1997-2005 Editorial Board, Postgraduate Obstetrics and Gynecology

2001 Guest Editor, "The Health of Africans", Archives of Ibadan Medicine, Volume 2, January 2001

2001-2007 Editorial Board, Journal of Midwifery & Women's Health

2007-2012 Editorial Board, Maternal Child Health Journal

2022 External Advisor, the Journal of Family Health University College (JFHUC)

Ad Hoc Reviewer

American Journal of Obstetrics & Gynecology
Obstetrics & Gynecology
American Journal of Perinatology
International Journal of Gynecology & Obstetrics
Journal of Psychosomatic Obstetrics & Gynecology
Medicine
Journal of Perinatology
Journal of Maternal-Fetal Medicine
Journal of Women's Health
Gynecologic Oncology
Annals of Internal Medicine
Epidemiology Reviews
Journal of Maternal-Fetal Investigation
New England Journal of Medicine
Fertility & Sterility
Journal of the American Medical Women's Association
Journal of Maternal Child Health
Journal of Obstetrics and Gynaecology
PNAS
International Journal of Women's Dermatology

Study Sections, other NIH activities

NIH/NICHD Special Emphasis Panel ZHD1 DSR-H 05. "Health Disparity in Preterm Birth: The role of infectious and inflammatory processes", July 2001.

NIH Research Enhancement Awards Program (REAP) Review Committee, June 2004.

NIH Research Enhancement Awards Program (REAP) Review Committee, June 2005.

NICHD Maternal Fetal Medicine Units Network (ZHD1 MCH-B 23 R), October 26, 2005

BIRCWH IV Training Program (ZRG1 HOP B 50 R), March 2007.

National Heart, Lung, and Blood Institute Special Emphasis Panel/Scientific Review Group 2009/10 CLTR (OA) meeting, "Antenatal corticosteroid therapy for reduction of respiratory morbidity in newborn infants born in the late pre-term period." June 29-30, 2009

National Institutes of Health, Office of the Director, Office of Disease Prevention, and the *Eunice Kennedy Shriver* National Institute of Child Health & Human Development, Panel Member for the Evidence-based Methodology Workshop on Polycystic Ovary Syndrome (PCOS), December 3-5, 2012.

Chair, NICHD Global Network Steering Committee (NIH), 2016-2017

NIH/NICHD Special Review Panel ZRG1 EMNR A 52. "BIRCWH – K12", Nov 2019

NIH: 2023/05 CIDH Clinical Informatics and Digital Health Study Section, 2/9/2023-2/10/2023

National Academy of Medicine

Committee on Addressing the Impact of Sexual Harassment in Academia on the Career Choices of Women in Science, Engineering and Medicine, National Academies of Science (NAS, NAE, NAM), 2016-2018

Proceedings reviewer: National Academies of Sciences, Engineering and Medicine, 2021. *Evaluating the Effectiveness of interventions to prevent and address sexual harassment: Proceedings of a workshop*. Washington DC: The National Academies Press.

GRANT SUPPORT

Recent

Medical Research Council (Britain): "International Multicenter Fetal Movement Trial", P.I.: Adrian Grant, M.D.; Site Coordinator: Timothy R.B. Johnson, M.D.; 06/1986-06/1988 (total direct cost: $3,000)

NIH Maternal-Fetal Medicine Network; P.I.: Frank R. Witter, M.D., Co-investigator: Timothy R.B. Johnson, M.D.; 1986-1992 (total direct cost: $845,000, 5% Effort)

Controlled Therapeutics Corporation, CR#AA1-003, "Clinical Investigation of the Safety and Efficacy of the ContRx Infusette-V PGE_2 Pessary for Cervical Ripening in the Induction of Labor"; P.I.: Frank R. Witter, M.D., Co-investigator: Timothy R.B. Johnson, M.D.; 1988-1989 (amount of grant: $91,773.00, 10% Effort)

"Physiologic Diagnostic Service Randomized Clinical Trial of a Home Uterine Contraction Monitor"; P.I.: Timothy R.B. Johnson, M.D.; 1989-1990 (total direct cost: $28,796, 5% Effort)

ACOG Syntex Issue of the Year Award, "Nutrition in Pregnancy"; P.I.: Timothy R.B. Johnson, M.D.; 1990-1991 (total direct cost: $10,000)

NICHD "Evaluation of the Guidelines for Maternal Transport"; P.I.: Donna M. Strobino, Ph.D., Co-investigator: Timothy R.B. Johnson, M.D.; 1989-1992 (total direct cost: $229,655, 10% Effort)

NIH-NICHD-NRSA Primary Care Fellowship in Ob/Gyn; P.I.: Timothy R.B. Johnson, M.D.; 1988-1993 (total direct cost: $484,328, 10% Effort)

NIH-R01, "Fetal Neuro-behavioral Development"; P.I.: Janet DiPietro, Ph.D., Co-investigator: Timothy R.B. Johnson, M.D.;1991-1996 (total direct cost: $136,467, 10% Effort)

Public Health Service/Office on Women's Health, National Centers of Excellence in Women's Health. Program Director: Timothy R.B. Johnson; 1997-2001 ($801,506) Continued 2001-2002 ($153,000) Continued 2002-2006 ($1,023,818)

National Heart Lung and Blood Institute, "Effect of self-regulatory education on women with asthma"; (#R18HL060884) Project Director: Noreen Clark, Ph.D., Co-I: Timothy R.B. Johnson; 2000-2007 ($3,424,135, 5% Effort).

NICHHD Obstetrics and Gynecology Health Services Research Training Program (1 T32 HD049340-01A1) Principal Investigator: Timothy R.B. Johnson, 2006-2011 ($1,400,836)

Bill and Melinda Gates Foundation, "Human Resources for Health: A learning grant for capacity strengthening in Ghana" (50786), 2008-2011 ($2,967,722)

NIH (R18HL094272), "Women of color and asthma control", Project Director: Noreen Clark, Ph.D., Co-I: Timothy R.B. Johnson, 2009-2014 ($3,781,501)

U.S. HHS PHS-National Institutes of Health, BIRCWH Career Development Program. (K12 HD01438-01) Principal Investigator and Program Director:

Timothy R.B. Johnson, 2000-2005 ($2,434,083); Continued 2005-2010 ($2,499,797); Continued 2010-2015 ($2,322,716)

NIH University of Michigan WRHR Career Development Program (K12HD065257)
Principal Investigator: Timothy R.B. Johnson, 2010-2015 ($2,375,575); Continued 2015-2017 ($1,681,222)

Current

CERTIFICATION AND LICENSURE

1976	National Board of Medical Examiners
1982	American Board of Obstetrics & Gynecology Recertification 2001
1983	Maternal Fetal Medicine Recertification 2001
1978	Maryland License (D-22889) - Inactive, 1994
1993-	Michigan License (4301060938)

MILITARY SERVICE

1981-1985	Major, Medical Corps, United States Air Force

HONORS AND AWARDS

1978	Bronze Beeper Award, Galen's Medical Society, University of Michigan Medical School
1982, 1983	Resident's Award for Teaching, Department of Obstetrics & Gynecology, USAF Medical Center, Keesler
1983	U.S. Air Force Commendation Medal
1983-1984	Department of Obstetrics & Gynecology USUHS, Award for Outstanding Performance in Medical Student Education and Training, Malcolm Grow USAF Medical Center
1983-1984	Outstanding Attending Physician, House Staff Council, Malcolm Grow USAF Medical Center
1985	"Honorary Nurse Midwife", USAF Nurse Midwifery Program, Andrews AFB, Washington, DC
1985	Merriweather Award: Best Scientific Paper in AFD/NAACOG on Obstetrics & gynecology, "Auscultated Fetal Heart Rate Accelerations II. An Alternative to the Non-Stress Test"
1989	Gemini Award, Center for the Study of Multiple Birth
1990	ACOG-Syntex Issue of the Year Award, "Nutrition and Pregnancy"

1990	Service Citation - Presidential Societies, University of Michigan
1991	J. Donald Woodruff Teaching Award, Department of Gynecology and Obstetrics, Johns Hopkins Hospital
1992	Best Scientific Paper on Obstetrics (from a teaching hospital), Armed Forces District ACOG. Wax JR et al: The Effect of Fetal Movement on the Amniotic Fluid Index. Am J Obstet Gynecol 1993;168:188-189
1994	APGO/Wyeth-Ayerst Academic Leadership Skills Program (organized by the Harvard Business School)
1996	Gold Star Management Award (Recognition of incorporating total quality management tools and techniques into practice) University of Michigan Health System
1997	Program of the Year Award, Women's Health Program, University of Michigan Hospitals and Health Centers
1997	Inclusion in "The 400 Best Doctors for Women", Good Housekeeping Magazine
1998-2013	Inclusion in "The Best Doctors in America", Woodward/White, Inc.
2001	Volunteer of the Year March of Dimes, Southeastern Michigan Chapter
2001	Honorary Member, Golden Key International Honour Society
2002-2010	Who's Who Among American Teachers
2002	Doctor of Science (Honorary), Central Michigan University
2003	Fellow, West African College of Surgeons (Honorary) Abuja, Nigeria
2003	Honorary Fellow, Ghana College of Physicians and Surgeons (conferred Nov 2007)
2004-2010	Who's Who in Medicine and Healthcare
2004-2005	America's Top Obstetricians and Gynecologists, Consumers' Research Council of America
2004	Helen W. and William G. Milliken Award of Freedom, Planned Parenthood Affiliates of Michigan
2004	"Defender of Choice", MARAL Pro-Choice Michigan
2005	Who's Who in Medical Sciences Education
2005	Who's Who in Humanities Higher Education
2005	"Detroit's Top Doctors", HOUR Detroit

2005	Distinguished Service Award, American College of Obstetricians and Gynecologists
2005	Sarah Goddard Power Award, Academic Women's Caucus, University of Michigan
2006	American Medical Women's Association Gender Equity Award, University of Michigan Medical School
2006-2023	Inclusion in: "America's Top Doctors", Castle Connolly Medical Ltd.
2007	Fellow *ad eundem*, Royal College of Obstetricians and Gynaecologists (London)
2010	Honorary Fellow, International College of Surgeons
2010	Man of the Year in Medicine and Healthcare, American Biographical Institute, Inc.
2010	*HOUR Detroit's* "Top Docs"
2011	Louis M. Hellman Midwifery Partnership Award Presented by the American College of Nurse Midwives, ACNM Foundation, and Midwifery Business Network
2012	Lifetime Achievement Award, Association of Professors of Gynecology and Obstetrics
2012	Doctor of Public Service *honoris causa*, University of North Texas Health Science Center, Fort Worth, Texas
2013	Harold R. Johnson Diversity Service Award, University of Michigan
2014	Society of Scholars, Johns Hopkins University
2015	Distinguished Merit Award, International Federation of Gynecology and Obstetrics (FIGO)
2016	University of Michigan's *Rudi Ansbacher Leadership Award for Support of Women in Healthcare*
2016	Distinguished Service Award, Rotary Club of Ann Arbor
2018	Katie (Katharine Dexter McCormick) Award, Planned Parenthood of Michigan
2018	Allan Rosenfield Award for Lifetime Contributions to International Family Planning, Society of Family Planning, North American Forum on Family Planning.
2022	University of Michigan President's Award for Distinguished Service in International Education

MEMBERSHIPS AND OFFICES IN PROFESSIONAL SOCIETIES

Alpha Omega Alpha, University of Virginia, Alumnus

Norman F. Miller Gynecologic Society
1979- Member
1986-1990 Council
1990-1991 President-Elect
1991-1993 President

The Johns Hopkins Medical and Surgical Association

American College of Obstetricians & Gynecologists
1979-1983 Junior Fellow
1983- Fellow
2005 Distinguished Service Award

J. Robert Willson Society

American Institute of Ultrasound in Medicine
1981-1986 Member
1986- 2004 Senior Member
2004- Fellow (elected)

Southern Perinatal Association
1982-1986

International Childbirth Education Association
1981-1993

National Perinatal Association
1982-1990

Society for Maternal Fetal Medicine (Society of Perinatal Obstetricians)
1983-1984 Associate Member
1984- Member
1995-1998 Board of Directors
1996-1998 Chair, Editorial and Publication Committee
1998-2003 Foundation Fellowship Committee
2015-2018 Global Health Committee
2018 Chair, Global Health Committee
2018- Queenan Scholar Mentor

Society for Health and Human Values
1980-1992

Association of Professors of Gynecology and Obstetrics
2007 President-Elect
2008 President
2012 Lifetime Achievement Award

Maryland Ob-Gyn Society
1979-1993

Maryland Perinatal Association
1986 Charter Member
1986-1993 Board of Directors

1986-1987 Program Chairman
1989 Program Chairman
1988-1990 President-Elect
1990-1992 President

National Eagle Scout Association
Life Member, Legacy Society

Baltimore City Medical Society, Medical and Chirurgical Faculty of the State of Maryland
1985-1993

American Association of Maternal and Neonatal Health
1989-1992 Vice President
1992-1994 President
1992-1995 Executive Board, Mother and Child International, Geneva

Society of Paediatric & Perinatal Epidemiology
1986-1992

International Society of Perinatal Obstetricians

International Society of Ultrasound in Obstetrics and Gynecology
1991 Founding Member

Association of Teachers of Maternal and Child Health
1991-2001

Howard A. Kelly Gynecologic & Obstetric Society
1991 Founding Member
1991-1993 Council

Society of Obstetricians and Gynecologists of Ghana
1986 Honorary Member

John E. Savage Obstetrical Society, Greater Baltimore Medical Center
1990 Honorary Member

Southwest Obstetrical and Gynecological Society
1991 Honorary Member

Central Association of Obstetricians and Gynecologists
1994-2000

Society for Gynecologic Investigation (now Society for Reproductive Investigation)
2000-

National Academy of Medicine (formerly Institute of Medicine), National Academy of Science
2003-

Ghana Physician and Surgeons Foundation (US)
2014-

TEACHING ACTIVITIES

National

1988-00 External Advisory Board, Postgraduate Training Program in Obstetrics & Gynecology, Ghana; Carnegie Corporation of NY

1989-93 Doctoral Student Adviser/Thesis Committee, The Johns Hopkins University School of Medicine:

Mimi Obendorfer	ScD	MCH*
Lisa L. Paine	DrPH	MCH (degree granted 1990)
Patricia DeHart	ScD	MCH (degree granted 1994)
Elisabeth Brach	DrPH	HPM**(degree granted 1995)
Judith Weiss	ScD	HPM (degree granted 1992)
Barbara Luke	ScD	MCH (degree granted 1991)
Elizabeth Jordon	PhD	Epid (degree granted 1991)
Sara Scholle	DrPH	HPM
Katherine Achuff	PhD	HPM
Nancy Fronczak	DrPH	International Health
Michael Fox	ScD	HPM (degree granted 1992)

*MCH = Maternal and Child Health
**HPM = Health Policy and Management

University of Michigan
1993-1999 Preceptor, Longitudinal Primary Care Clerkship

Undergraduate Honors Thesis Advisor (LS&A Honors Program)

Mona Kumar, 1996
Ami Shah, 1996
Aarin Benson, 1999
Samuel Bauer, 1999
Kyle Yanachura, 2000
Rachel Lappin, 2007
Adam Eichmeyer 2014
Carly Marten 2019
Anna Morgan 2019
Stephanie Johnson 2022
Isabelle Fisher 2022

Doctoral Student Advisor/Thesis Committee

S. Chipiro Mupepi	Ph.D.	Nursing (2001)
Shingairai Feresu	Ph.D.	Epidemiology (2001)
Juliet Rogers MPH	Ph.D.	Health Management and Policy (2002)
Daniela Deman	Ph.D.	Kinesiology (2005)
Lisa H. Harris MD	Ph.D.	American Culture (2006)
Cheryl A. Moyer MPH	Ph.D	Health Mgt & Policy, SPH, Chair (2012)
Amir Sabet	Ph.D	Design Science/Mechanical-Biomed. Engineering (2014)
Sue Anne Bell	Ph.D.	Nursing (2014)
Kelly Kean	Ph.D.	Nursing (2016)

INVITED/NAMED PRESENTATIONS OR LECTURES

Preston T. Brown Memorial Lecture, Southwestern Ob/Gyn Society, 1984

D. Frank Kaltreider Lecture
John Hopkins Bayview Medical Center, Baltimore, Maryland
"Prenatal Care as a Model for Women's Primary Health Care", 1994

19th Annual Graham G. Hawks Lecture
Department of Obstetrics and Gynecology
Cornell Medical Center/New York Hospital
"Fetal Assessment Update", June 1995

14th Annual Charles A. Hunter, Jr., M.D. Lecture
Department of Obstetrics and Gynecology
Indiana University
"Women's Primary Health: Lessons from Prenatal Care", June 1995

26th Annual Emil Novak Lecture, Obstetrical and Gynecologic
Society of Maryland
"There is a Future for Academic Obstetrics and Gynecology",
October, 1996

15th Annual W. Newton Long Lecture
Department of Gynecology and Obstetrics, Emory University School
of Medicine
"The Globalization of Obstetrics and Gynecology – Transnational issues
in Women's Health", April 1998.

Jean Claude Remy Lecture
Department of Obstetrics and Gynecology, SUNY Health Science Center
at Brooklyn, Kings County General Hospital
"Traditions and Change", June 1999

Thomas E. Elkins Memorial Lecture
29th Annual Emil Novak Symposium
OB/GYN Society of Maryland
"The Globalization of Women's Health-In tribute to Tom Elkins", October 1999

13th Leon Steiner McGoogan Lecture
Department of Obstetrics and Gynecology, University of Nebraska
"Global Issues in Women's Health", June 2000

21st Annual John Rudolph Memorial Lecture
Department of Obstetrics and Gynecology, University of Rochester
"Global Issues in Women's Health", June 2001

Keynote Address, 47th Annual Meeting of the American College of Nurse-
Midwives, Atlanta, Georgia
"Collaboration in Leadership", May 2002

Visiting Professor, Chief Residents' Day
Department of Obstetrics and Gynecology, Cornell University
"Transnational Issues in women's health: In the shadow of September 11"
June 2002
Nicholson J. Eastman Visiting Professor

Department of Gynecology and Obstetrics, Johns Hopkins University
"Capacity Building and Infrastructure Development in Global Women's Health", April 2003

Resident and Alumni Day Visiting Professor, Department of Obstetrics and Gynecology, Northwestern University Medical School
"Translational and Transcultural Issues in Women's Health", May 2003

Wayne Johnson Memorial Lecture
APGO/CREOG Annual Meeting
"Steadfastly forward", March 2005

Keynote Address, History of Women's Health: From Benjamin Franklin's Era to the Present, Department of Obstetrics and Gynecology, Pennsylvania Hospital
"Women's Health: 300 Years after Benjamin Franklin" April 2006

Guest Faculty, 11th Annual Robert C. Park Uniformed Services Residency in Obstetrics and Gynecology Resident Research Day, Uniformed Services University of the Health Sciences
"Global Issues in Women's Health" May 2006

Keynote Speaker, Annual Utah BIRCWH Day, University of Utah
"Promoting women's health research in a University setting: Obstacles or opportunities" June 2006

Fritz Fuchs Visiting Professor, Cornell University
"Clinical simulation and team training: Research base and clinical applications" September 2010

Carl M. Huber Memorial Lecture, Indiana Section, ACOG Scientific Session
"Maternal mortality as an exemplar of global issues in Women's Health"
April 2011

Alpha Omega Alpha Visiting Professor, Johns Hopkins University
"Global issues in Women's Health", May 2011

Fourth Annual Theodore M King, M.D., Ph.D. Lecture, Department of Gynecology and Obstetrics Johns Hopkins University
"Implementation Science: Evidence based practices to improve women's health"
March 2012

Seventh Annual Paul Harper Lecture, Division of Population and Family Health, Johns Hopkins Bloomberg School of Public Health
"Implementing maternal and child health globally", April 2012

Donald F. Richardson Memorial Lecture, ACOG Annual Clinical Meeting, San Diego, "Implementing Global Women's Health" May 2012

Inaugural Class Keynote Address, Gold Humanism Honor Society, University of Michigan, February 2017: "Ethics of engaged academic Global Health"

Therese Dondero Memorial Lecture, American College of Nurse Midwives, Chicago, May, 2017: "Collaboration, collaboration, collaboration"

John A. Krieger, M.D. Lectureship(s): "Engaged Academic Global (Women's)

Health"; "Sexual Harassment of Women: Climate, Culture, and Consequences in Academic Sciences, Engineering, and Medicine"; "Clinical Implications of Fetal Behavior: 2018", University of Hawaii, Department of Obstetrics and Gynecology, August 29-31, 2018

Charles Vincent MD Memorial Lecture: "Sexual Harassment of Women: Climate, Culture, and Consequences in Academic Sciences, Engineering and Medicine", Wayne State University School of Medicine, April 2019

Iffath Hoskins Lecture: "Global Women's Health: Issues, Opportunities and Responsibilities", ACOG District II annual mtg., Oct 18-20, 2019, NYC

Propelling Cedars-Sinai to the Next Level, the Langham Huntington Hotel, Pasadena: Sexual Harassment of Women: Climate, Culture and Consequences in Academic Sciences, Engineering and Medicine. A Consensus Study from the National Academies, Nov 3-4, 2019

John T. Repke Maternal Fetal Medicine Lecture, Penn State College of Medicine, Hershey: "Maternal-Fetal Medicine in low-income countries: the case of Ghana", April 2022

COMMITTEE AND ADMINISTRATIVE SERVICES

National and International

1988-2000	External Advisory Board, Postgraduate Training Program in Obstetrics & Gynecology, Ghana; Carnegie Corporation of New York
1989-1993	Medical Committee, Planned Parenthood of Maryland
1989-2002	Examiner, The American Board of Obstetrics and Gynecology and ABOG Division of Maternal-Fetal Medicine
1989-1993	Associate Professor Reappointment Review Committee, The Johns Hopkins University School of Medicine
1991	External Examiner, Faculty of Obstetrics and Gynecology, West African College of Surgeons, Ibadan, Nigeria
1992-1993	Joint Committee on House Staff and Postdoctoral Programs, The Johns Hopkins University School of Medicine
1992-1994	Representative, American College of Obstetricians & Gynecologists, Council of Academic Societies, American Association of Medical Colleges
1994-2000	Board of Directors, American College of Nurse-Midwives Foundation
1995-2000	Committee on International Affairs, American College of Obstetricians and Gynecologists Chair, 1996-2000
1996-2001	Increasing Women's Leadership in Academic Medicine Implementation Committee, Association of American Medical Colleges
2001-2003	American College of Obstetricians and Gynecologists Representative, ACGME Residency Review Committee for Obstetrics and Gynecology
2002	External Examiner, Faculty of Obstetrics and Gynecology, West African College of Surgeons, Accra, Ghana
2002- 2005	Advisory Board, Herbert H. and Grace A. Dow College of Health Professions, Central Michigan University

2003-2007 Advisory Committee on Research on Women's Health (ACRWH), NIH Office of Research on Women's Health (ORWH)
2003-2006 Board of Governors, Jacobs Institute of Women's Health (JIWH)
2008-2012 Chair, External Advisory Board, University of North Texas, Health Sciences Center, Fort Worth, Texas
2012- Board of Directors, Academy of Women's Health
2015-2016 FIGO (London) Working Group on Safe Abortion
2016- Board of Directors, American College of Nurse-Midwives Foundation
2016-2018 Committee on Addressing the Impact of Sexual Harassment in Academia on the Career Choices of Women in Science, Engineering and Medicine, National Academies of Science (NAS, NAE, NAM)
2016-2017 Chair, NICHD Global Network Steering Committee (NIH)
2018-2020 Nominating Committee, Association of Professors of Gynecology and Obstetrics (APGO)
2018- FIGO Safe Abortion Committee

Other (including Johns Hopkins University)

1979-1981 OB Inpatient Committee, The Johns Hopkins University School of Medicine
1980-1981 OB Clinic Committee, The Johns Hopkins University School of Medicine
1980-1981 Perinatal Mortality Committee, Baltimore City Medical Society
1982-1983 Pharmacy & Therapeutics Committee, USAF Medical Center, Keesler
1983-1993 Subcommittee on Maternal Welfare, Medical & Chirurgical Faculty of The State of Maryland
1985-1993 Joint Committee on Fetal Research, The Johns Hopkins University School of Medicine
1986-1989 Fetus and Newborn Committee, Maryland Chapter, American Academy of Pediatrics
1986-1988 Joint Committee on Ethics, The Johns Hopkins University School of Medicine
1988-1993 Joint Committee on Nurse Midwives, Maryland Board of Nursing
1988-1989 Search Committee, Chairman, Department of Maternal Child Health, School of Hygiene and Public Health, The Johns Hopkins University School of Medicine
1988-1993 Executive Committee, Department of Gynecology and Obstetrics, The Johns Hopkins University Hospital & School of Medicine
1988-1993 Board of Student Advisors, The Johns Hopkins University School of Medicine

University of Michigan

1975-1979 House Officer Committee, Department of Obstetrics & Gynecology, University of Michigan Hospitals
1987-1989 Co-Chair, J. Robert Willson Professorship Campaign, University of Michigan Medical Center (endowed 1989)
1989-1991 Co-Chair, John R.G. Gosling Lectureship Campaign, University of Michigan Medical Center (endowed 1991)
1990-1993 LS&A Visiting Committee, University of Michigan
1991-1994, 1999 Honors College Advisory Council, College of Literature Science and the Arts, University of Michigan

1993-2007	Institutional Advisory Committee, Robert Woods Johnson Clinical Scholars Program
1993-2017	Executive Director's Advisory Council, University of Michigan
1993-2017	Dean's Advisory Committee, University of Michigan
1993-2017	Clinical Council, University of Michigan
1993-1998	Michigan Initiative for Women's Health Executive Committee
1993-2017	Primary Care Executive Committee
1994-2010	Advisory Board to the North Campus Nursing Center, University of Michigan School of Nursing
1994-1996	Medical Service Plan Executive Committee
1994-1995	Chair, Pediatric Chair Search Committee
1994-1995	Chair, Medical School Review Committee
1994-1996	Patient Acquisition Task Force
1995-2001	Faculty Affairs Advisory Committee
1995-1998	Steering Committee for UMMC Primary Care Education Update
1995-1997	Executive Committee, Institute for Research on Women and Gender
1995-1997	Search Advisory Committee for Director of Family Planning and Reproductive Health, School of Public Health
1996	Search Advisory Committee for the Dean of the Medical School
1996-1997	Chair, Alternative Work Force Committee
1996-1998	Faculty Group Practice Board of Directors
1996-1998	Chair, Clinical Standards Subcommittee, Faculty Group Practice Board of Directors
1997-	Governing Member, Institute for Research on Women and Gender
1997-2009	Advisory Committee, Interdepartmental Concentration: Women's and Reproductive Health, School of Public Health
1997-2001	Sesquicentennial Committee, Medical School
1998-2001	Historical Center for the Health Sciences Steering/Advisory Committee
1998-1999	Chair, Clinical Redesign Committee, University of Michigan Health System
1998-2000	Children and Women's Center Facility Planning Steering Committee
1998-2001	University of Michigan Health System Strategic Planning Process (with The Lewin Group), Steering Committee
1999-2002	Advisor, Alpha Omega Alpha Chapter, University of Michigan
1999-2002	Reproductive Sciences Program Executive Committee
1998-2001	Operations Improvement Committee, University of Michigan Health System
2000-2001	Clinical Executive Committee, University of Michigan Health System
1999-2000	President's Commission on the Undergraduate Curriculum
2000-2004	Medical Staff Representative, University of Michigan Hospitals and Health Centers Executive Board
2001-2001	Search Committee, Director for Institute for Research on Women and Gender
2002-2012	Advisory Board of the Historical Center for the Health Sciences
2001-2004	Chair, Department of Medical Education Chair Search Committee
2001-2005	Chair, Executive Vice President for Medical Affairs Search Committee
2002-2017	University Advisory Board, Depression Center
2002-2007	Chair, Institutional Advisory Committee, Robert Woods Johnson Clinical Scholars Program
2004	Search Committee, Dean of the School of Public Health
2005-2009	Multidisciplinary Learning and Team-Teaching Steering Committee

(campus wide)
2006-2020 Training Advisory Committee, Minority Health and Health Disparities International Research Training (MHIRT) Program, Center for Human Growth and Development
2006-2008 President's Advisory Commission on Women's Issues (PACWI)
2009- 2011 Chair, Institutional Advisory Committee, Center for Global Health
2010-2011 Chair, Search Committee for the Chair of the Department of Ophthalmology and Visual Sciences
2012-2013 President's Africa Advisory Committee
2012-2015 Clinical and Educational Conflict of Interest (CECOI) Committee, Medical School
2012-2013 Search Committee, Executive Director, C S Mott Children's and Von Voigtlander Women's Hospitals, UMHS
2013-2015 Henry Russel Awards and Lecture selection committee, Rackham School of Graduate Studies
2013 Member, Search Committee, Chief Communication Officer, UMHS
2013- Advisory Committee, Academy for Educational Excellence and Scholarship, Medical School
2013 Presidential Search Advisory Committee, University of Michigan
2014-2015 National Advisory Board, UMHS Office for Health Equity and Inclusion (OHEI)
2016-2020 Board of Directors, University Musical Society
2016-2017 Search Advisory Committee, UM Museum of Art Director

External Reviewer- Department of Obstetrics and Gynecology (at request of Dean or higher authority)

2000 Emory University
2000 University of California, San Francisco
2003 UMDNJ-Robert Wood Johnson, New Brunswick
2004 University of North Carolina
2004 University of Texas Medical Branch, Galveston
2005 University of Iowa
2005 University of Virginia
2006 University of Cincinnati
2006 Harvard: Beth Israel Deaconess
2006 University of Wisconsin
2006 University of Toledo
2014 University of Pittsburg (OBGYN / Family Medicine)
2015 Washington University in Saint Louis
2017 University of Nevada
2018 University of Arizona, Tucson/Banner Health Care

Community Activities/Service

Ann Arbor Art Center
1995-2001 Board of Directors
1995-1998 Development Chair

March of Dimes – Southeastern Michigan Chapter
2000-2005 Board of Directors
2000-2019 Founder, MOD HealthWalk at Michigan Medicine

Friends of Nichols Arboretum/Mattaei Botanical Gardens

2001-2005 Board

Greenhills School, Ann Arbor, Mi
2001-2004 Board of Trustees
Admissions Committee
Trusteeship Committee
2003-2005 Chair, Science Curriculum and Space Advisory Task Force
2019- Judge Fellow

Rotary Club of Ann Arbor
2009-
2016 Distinguished Service Award, Rotary Club of Ann Arbor

Safehouse Inc Domestic Violence Center (Ann Arbor)
2013-2016 Board Member

University Musical Society, Board of Directors
2016-2021
2017-2018 Chair, Program Committee
2018-2019 Chair, Artistic Advisory Committee
2019-2021 Co-Chair, Artistic Advisory Committee

Southern Shores Field Service Council (Michigan Crossroads Council, Boy Scout of America) (National Eagle Scout Association Life Member)
2018-2020 Board President

Michigan Crossroads Council
Membership Development Committee, Washtenaw County
2020- Chair

NESA Michigan Crossroads Council
2020- President, MCC Board Representative

BIBLIOGRAPHY

Completed Publications in Scientific Journals

Peer Reviewed Publications

Rodriguez J, Sen KK, Seski JC, Menon M, Johnson TR Jr, Menon KMJ: Progesterone binding by human endometrial tissue during the proliferative and secretory phases of the menstrual cycle and by hyperplastic and carcinomatous endometrium. Am J Obstet Gynecol 133:660-665, 1979.

Johnson TR Jr, Peterson EP: Gonadotropin-induced pregnancy following "premature ovarian failure". Fertil Steril 31:351-352, 1979.

Johnson TR Jr, Comstock CH, Anderson DG: Benign gestational trophoblastic disease metastatic to pleura: Unusual cause of hemothorax. Obstet Gynecol 53:509-511, 1979.

Johnson TR Jr, Lorenz RP, Menon KMJ, Nolan GH: Successful outcome of a pregnancy requiring dialysis: Effects on serum progesterone and estrogens. J Reprod Med 22:217-218, 1979.

Johnson TR Jr, Work BA Jr: Dynamic graph for documentation of gestational age. Obstet Gynecol 54:115-117, 1979.

Holtz G, Johnson TRB Jr, Schrock ME: Paraneoplastic hypercalcemia in ovarian tumors. Obstet Gynecol 54:483-487, 1979.

Andersen HF, Lynch JP, Johnson TRB Jr: Adult respiratory distress syndrome in obstetrics and gynecology. Obstet Gynecol 55:291-295, 1980.

Johnson TRB Jr, Compton AA, Kirkish LS, Bozynski MEA, Barclay ML, McCann DS: Plasma estriol in the evaluation of third-trimester gestational age. Obstet Gynecol 55:621-624, 1980.

Johnson TRB Jr, Sanborn JR, Wagner KS, Compton AA: Gonadotropin surveillance following conservative surgery for ectopic pregnancy. Fertil Steril 33:207-208, 1980.

Budowick M, Johnson TRB Jr, Genadry R, Parmley TH, Woodruff JD: The histopathology of the developing tubal pregnancy. Fertil Steril 34:169-171, 1980.

Andersen HF, Johnson TRB Jr, Barclay ML, Flora JL Jr: Gestational age assessment. I. Analysis of individual clinical observations. Am J Obstet Gynecol 139:173-177, 1981.

Johnson TRB Jr, Compton AA, Rotmensch J, Work BA Jr, Johnson JWC: Significance of the sinusoidal fetal heart rate pattern. Am J Obstet Gynecol 139:446-453, 1981.

Andersen HF, Johnson TRB Jr, Flora JL Jr, Barclay ML: Gestational age assessment. II. Prediction from combined clinical observations. Am J Obstet Gynecol 140:770-774, 1981.

Johnson JWC, Daikoku NH, Niebyl JR, Johnson TRB Jr, Khouzami VA, Witter FR: Premature rupture of membranes and prolonged latency. Obstet Gynecol 57:547-556, 1981.

Daikoku NH, Kaltreider DF, Johnson TRB Jr, Johnson JWC, Simmons MA: Premature rupture of membranes and spontaneous preterm labor: neonatal infections and perinatal mortality risks. Obstet Gynecol 58:417-425, 1981.

Johnson TRB Jr, Corson VL, Payne PA, Stetten G: Late prenatal diagnosis of fetal trisomy 18 associated with severe intrauterine growth retardation. Johns Hopkins Med J 151:242-245, 1982.

Ginsburg DS, Hernandez E, Schwemlein GA, Daikoku NH, Johnson TRB Jr: An ominous undulating fetal heart rate pattern. Acta Obstet Gynecol Scand 61:39-42, 1982.

Johnson TRB Jr, Graham D, Sanders RC, Smith N, Simmons MA, Winn K: Ultrasound-directed paracentesis of massive fetal ascites. J Clin Ultrasound 10:140-142, 1982.

Graham D, Johnson TRB Jr, Sanders RC: Sonographic findings in abdominal pregnancy. J Ultrasound Med 1:71-74, 1982.

Graham D, Johnson TRB Jr, Winn K, Sanders RC: The role of sonography in prenatal diagnosis and management of encephalocele. J Ultrasound Med 1:111-115, 1982.

Marotz RJ, Johnson TRB Jr, Wheelock JB, Kaminski PF: Pregnancy and proximal femoral deficiency. J Reprod Med 28:798-800, 1983.

Corson VL, Sanders RC, Johnson TRB Jr, Winn KJ: Midtrimester fetal ultrasound: Diagnostic dilemmas. Prenatal Diag 3:47-51, 1983.

Davidson JM, Johnson TRB Jr, Ridgon DT, Thompson BH: Gastroschisis and omphalocele: Prenatal diagnosis and perinatal management. Prenatal Diag 4:355-363, 1984.

Wheelock JB, Johnson TRB Jr, Graham D, Saucer GJ, Teal CL, Sanders RC: Ultrasound-assisted cervical cerclage. J Clin Ultrasound 12:307-308, 1984.

Abbasi IA, Hess LW, Johnson TRB Jr, McFadden E, Chernow B: Leukocyte esterase activity in the rapid detection of urinary tract and lower genital tract infections in obstetric patients. Am J Perinatology 2:311-313, 1985.

Johnson TRB, Woodruff JD: Surgical emergencies of the uterine adnexa during pregnancy. Int J Gynaecol Obstet 24:331-335, 1986.

Smith GN, Frey KA, Johnson TRB: Assessing gestational age. Am Fam Phys 33:215-220, 1986.

Paine LL, Payton RG, Johnson TRB: Auscultated fetal heart rate accelerations: I. Accuracy and documentation. J Nurs Midwif 6:68-72, 1986.

Paine LL, Johnson TRB, Turner MH, Payton RG: Auscultated fetal heart rate accelerations: II. An alternative to the non-stress test. J Nurs Midwif 6:73-77, 1986.

Johnson TRB, Abbasi IA, Urso PJ: Fetal heart rate patterns associated with amniotic fluid embolism. Am J Perinatology 4:187-190, 1987.

Abbasi IA, Hemming VG, Eglinton GS, Johnson TRB: Group B streptococcus proliferation in human amniotic fluid in vitro. Am J Obstet Gynecol 156:95-99, 1987.

Repke JT, Kuhajda F, Hochberg MC, Winn K, Johnson TRB, Provost T: In utero diagnosis of complete heart block in the fetus of a patient with systemic lupus erythematosus; documentation of transplacental autoantibody transfer and fetal myocarditis. J Reprod Med 32:217-220, 1987.

Thomas RL, Hess LW, Johnson TRB: Prepartum diagnosis of limb-shortening defects with associated hydramnios. Am J Perinatol 4:293-299, 1987.

Hoskins IA, Johnson TRB, Winkel CA: Leucocyte esterase activity in human amniotic fluid for the rapid detection of chorioamnionitis. Am J Obstet Gynecol 157:730-732, 1987.

Hoskins IA, Hemming VG, Johnson TRB, Winkel CA: Effects of alterations of zinc: phosphorus ratios and meconium content on group B streptococcus growth in human amniotic fluid in vitro. Am J Obstet Gynecol 157:770-773, 1987.

Josten BE, Johnson TRB, Nelson JP: Umbilical cord blood pH and Apgar scores as an index of neonatal health. Am J Obstet Gynecol 157:843-848, 1987.

Paine LL, Johnson TRB, Alexander GR: Auscultated fetal heart rate accelerations. III. Use of vibroacoustic stimulation. Am J Obstet Gynecol 159:1163-1167, 1988.

Thomas RL, Hess LW, Johnson TRB: Antepartum sonographically directed computerized tomography in evaluation of a fetal intracranial tumor. J Med Imaging 2:214-221, 1988.

Berestka JS, Johnson TRB, Hrushesky WJM: Sinusodial fetal heart rate pattern during breathing is related to the respiratory sinus arrhythmia: A case report. Am J Obstet Gynecol 160:690-692, 1989.

Thomas RL, Johnson TRB, Besinger RE, Rafkin D, Treanor C, Strobino DM: Preterm and term fetal cardiac and movement responses to vibratory acoustic stimulation. Am J Obstet Gynecol 161:141-145, 1989.

Dans PE, Johnson TRB, King TM: Improving a university hospital obstetric clinic: Better but not best. Obstet Gynecol 74:262-266, 1989.

Besinger RE, Johnson TRB: Doppler recordings of fetal movement: Clinical correlation with real-time ultrasound. Obstet Gynecol 74:277-280, 1989.

Cherouny PH, Hoskins IA, Johnson TRB, Niebyl JR: Multiple pregnancy with late death of one fetus. Obstet Gynecol 74:318-320, 1989.

Rijhsinghani AG, Dubin NH, Zacur HA, Johnson TRB, Niebyl JR: Plasma prostaglandin metabolite and prolactin levels in patients undergoing breast stimulation contraction stress test. Am J Perinatol 7:43-45, 1990.

Peng TCC, Searle C, Shah K, Repke JT, Johnson TRB: Prevalence of human papillomavirus infections in term pregnancy. Am J Perinatol :189-192, 1990.

Johnson TRB, Jordan ET, Paine LL: Doppler recordings of fetal movement. II. Comparison with maternal perception. Obstet Gynecol 76:42-43, 1990.

Faden RR, Geller G, Powers M, Acuff K, Allen A, Areen J, Hutton N, Johnson T, Kass N, King P, Modlin J, Repke J, Saah A, Walters L, Wissow L: HIV infection, pregnant women and newborns: A policy proposal for information and testing. JAMA 264:2416-2420, 1990.

Paine LL, Strobino DM, Witter FR, Johnson TRB: Population differences affect nonstress test reactivity. J Perinatol 11:41-45, 1991.

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(revised 9-2023)

Exhibit 6

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

PLANNED PARENTHOOD SOUTH ATLANTIC, *et al.*,	)	
Plaintiffs,	)	
v.	)	
JOSHUA STEIN, *et al.*,	)	Case No. 1:23-cv-00480-CCE-LPA
Defendants,	)	
and	)	
PHILIP E. BERGER, *et al.*,	)	
Intervenor-Defendants.	)	

REBUTTAL EXPERT DISCLOSURE OF KATHERINE FARRIS, M.D., FAAFP

Pursuant to Federal Rules of Civil Procedure 26(a)(2)(C) and 26(a)(2)(D)(ii), Katherine Farris, M.D., FAAFP, makes the following disclosures:

1. I submit this rebuttal as a further disclosure of the expert opinions I would provide if asked to testify at trial regarding certain provisions of North Carolina Session Law 2023-14 ("S.B. 20"), as amended by 2023 House Bill 190 ("H.B. 190"), which is codified at Article 1I of Chapter 90 of the North Carolina General Statutes ("the Act").

2. I previously submitted an expert disclosure in this case, served on November 13, 2023. That disclosure described my qualifications as a board-certified family medicine physician and the Chief Medical Officer for Planned Parenthood South Atlantic ("PPSAT"), one of the two plaintiffs in this case. Since submitting that disclosure, I have

been awarded the degree of Fellow of the American Academy of Family Physicians; my updated *curriculum vitae* is attached as **Exhibit A**.

3. Like the opinions in my original disclosure, the opinions in this rebuttal disclosure are based on my education, clinical training, years of medical practice, personal knowledge, participation at professional conferences, and familiarity with relevant medical literature and statistical data recognized as reliable in the medical profession. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this disclosure. All of my opinions are expressed to a reasonable degree of medical certainty.

4. I have reviewed the expert reports submitted by Monique Chireau Wubbenhorst, M.D., M.P.H.; Susan Bane, M.D., Ph.D.; and Catherine J. Wheeler, M.D., and I am submitting this rebuttal disclosure to respond to certain of the statements and opinions expressed in their reports. Nothing in these reports alters the conclusions I reached or the opinions I expressed in my prior disclosure. The fact that I do not address every statement or issue raised in the intervenors' witnesses' reports does not suggest that I agree with them.

I. Abortion Is Health Care

5. Abortion is health care—safe, common, and essential health care. It should be treated like all other comparably safe health care, not singled out for medically unnecessary restrictions.

6. Leading medical authorities agree that abortion is one of the safest procedures in medical practice,[1] and it is safely and routinely provided in outpatient settings both here in North Carolina and nationally. I know that abortion is safe not only because high-quality research confirms it,[2] but also because of my own experience providing abortions in an outpatient clinic setting for over 20 years.

7. The intervenors' witnesses cast aspersions on the published data demonstrating that abortion complications are very low. Wubbenhorst ¶¶ 14–28; Bane ¶¶ 35–37 ("The extremely low percentage of abortion-related events revealed *may or may not* be due to a truly low complication rate." (emphasis added)). But PPSAT's own complication rates are comparable, which is to say that they are extraordinarily low—indeed, our rates are even lower than the rates documented in the literature. Expert Disclosure of Katherine Farris, M.D. ("Farris") ¶ 51.

8. We instruct patients to call us if they have any concerns or complaints, or if they seek care in an emergency department, and patients do call us in these rare circumstances. Usually, the patient calls us first to raise a concern before going to the hospital on our advice, but occasionally a patient calls us after having decided to go to the

[1] Nat'l Acads. Scis., Eng'g, & Med. (NASEM), *The Safety and Quality of Abortion Care in the United States* 1, 77 (2018), (available at http://nap.edu/24950) ("The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective.").

[2] *Id*.; Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); *see also* Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med. 1, 1 (2018).

hospital. Less frequently, the hospital will contact us with questions about the patient's care. When a patient visits a hospital after receiving an abortion from us, we follow up with the hospital and request the records from the visit for internal review. It is illogical to assume that the patients we do *not* hear from have all experienced serious complications requiring hospital treatment. Wubbenhorst ¶ 130.

9. While the risks of abortion do rise with gestational age, abortion remains extremely safe overall—and, as discussed below, the risks of abortion at later gestational ages are no higher than the risks of D&E for miscarriage management. Moreover, restrictions on where abortion can be performed, like the Hospitalization Requirement, delay patients by adding logistical complexity and expense, which in turn requires patients to have abortions at later gestational ages when the risk of the procedure has risen.

10. Dr. Wubbenhorst's claim that abortion is "not health care," *id.* ¶¶ 32–34, is an ideological opinion, not a medical one. And it ignores that pregnancy is a health condition with serious and sometimes permanent consequences. Even when desired, pregnancy can lead to significant morbidity and mortality. Thus abortion—offering the option of ending an undesired or medically harmful pregnancy—is a critical component of health care. Notably, for all the intervenors' witnesses say about potential complications from abortion, they completely ignore the potential complications from pregnancy and childbirth.

11. Despite its proven safety, abortion is stigmatized like no other form of medical care, as I described in detail in my opening disclosure. Farris ¶¶ 74–80. This stigma

is a significant reason why some health professionals do not provide abortion. Specifically, in my experience, clinicians are often discouraged from providing abortion by the lack of training available, by hospital or group practices that discourage or outright prohibit doctors from providing abortion, by the prevalence of provider harassment (sometimes violent) by protestors and anti-choice groups who directly target providers,[3] and by general societal stigma around abortion.

12. The study Dr. Wheeler cites[4] on why most ob-gyns do not provide abortion, Wheeler ¶¶ 16–20, actually did not ask why the surveyed providers do not perform abortions. The study authors did, however, ask the smaller percent who neither perform nor refer patients for abortion care *why* they do not refer. And even within that subset of physicians who neither perform nor refer, only 16% reported not referring due to a personal moral or ethical objection to abortion. *See also* Bane ¶ 22 (discussing research finding that, among the surveyed sample of fellows who did not provide abortion, only 34% cited "personal, religious, or moral beliefs against abortion" as the reason they did not—meaning 66% had other reasons).[5]

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[3] *2022 Violence & Disruption Statistics*, Nat'l Abortion Fed'n 1, 2, 6–7 (2022), https://prochoice.org/wp-content/uploads/2022-VD-Report-FINAL.pdf (documenting threats against abortion providers and patients including, in 2022, 218 threats of death or other physical harm and 92 cases of stalking—up from 182 threats and 28 cases of stalking in 2021).

[4] Sheila Desai et al., *Estimating Abortion Provision and Abortion Referrals Among United States Obstetrician-Gynecologists in Private Practice*, 97 Contraception 297 (2018).

[5] Daniel Grossman et al., *Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists*, 133 Obstetrics & Gynecology 477 (2019).

13. So rather than moral opposition to abortion itself, the studies that Dr. Wheeler cites speak to lack of access to training and the fact that most abortions occur in free-standing clinics, as well as the stigma that contributes to these other factors. Specifically, because most abortions are performed in outpatient clinics rather than in hospitals, medical residents often cannot obtain abortion training opportunities at the hospitals where their residency is based, and instead must obtain access to elective training at independent non-hospital-based clinics to get the experience they need to perform abortion procedures.

14. Dr. Bane describes ways that physicians regard their responsibility to both the pregnant patient and the fetus when they are caring for patients with desired pregnancies. Bane ¶¶ 19–26. In the context of desired pregnancy, this approach is consistent with the pregnant patient's treatment goals. ACOG's Committee on Ethics is clear, however, that when circumstances "arise during pregnancy in which the interests of the pregnant woman and those of the fetus diverge," the "most suitable ethical approach for medical decision making in obstetrics . . . . recognizes that the obstetrician–gynecologist's primary duty is to the pregnant woman."[6]

15. While abortion care can be complex and nuanced, ultimately it is my job to work with patients who have identified that it is in their own best interests (and often in the

[6] Comm. on Ethics, *ACOG Committee Opinion No. 664: Refusal of Medically Recommended Treatment During Pregnancy*, 127 Obstetrics & Gynecology e175, e177 (2016).

best interest of their family, as 60% of abortion patients already have children[7]) to end an undesired pregnancy or a pregnancy that threatens their health. When a pregnant person identifies that abortion is the appropriate healthcare decision for them, then I must prioritize the life and needs of the pregnant person as my patient. I approach my work with abortion patients from a place of deep compassion, non-judgment, and respect for their own autonomy and self-awareness of what is best for them. It is a profound honor and privilege to be able to support and treat patients during what is often a vulnerable time, especially in the traumatizing setting of severe abortion bans and restrictions, high levels of protester activity, and vocal stigmatization of this care.

II. There Is No Medical Justification For The Hospitalization Requirement's Disparate Treatment of Abortion and Miscarriage Care

16. Procedural abortions are safely performed in outpatient clinics, and performing them in a hospital does not decrease the already very low odds of complications arising.[8] Wubbenhorst ¶ 12. Moreover, procedural abortions are as safe as, if not safer than, procedural management of miscarriage at the same gestational age and using similar

[7] *See* Katherine Kortsmit et al., *Abortion Surveillance - United States, 2021*, 72 CDC Morbidity & Mortality Wkly. Rep. Surveillance Summaries 1, 6 (2023) (reporting that in 2021, among the reporting areas that reported the number of previous live births, 60.7% of abortions reported were among women who had one or more previous live births).

[8] David K. Turok et al, *Second Trimester Termination of Pregnancy: A Review by Site and Procedure Type*, 77 Contraception 155, 155 (2008); 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); Barbara S. Levy et al., *Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology*, 133 Obstetrics & Gynecology 255 (2019).

techniques. There is no medical reason to treat these two types of medical care differently by requiring a hospital setting for one but not the other.

A. The intervenors' witnesses mischaracterize D&E to suggest that it must be performed in a hospital to be safe.

17. As an initial matter, Dr. Wheeler seems to draw a line between aspiration and D&E at 13 weeks of pregnancy, but that is not consistent with my clinical practice. Wheeler ¶¶ 12–14. I and most of my colleagues at PPSAT do not typically use instruments in addition to suction until after 15 weeks of pregnancy.

18. Moreover, it is important to understand that early in the second trimester, aspiration and D&E are not a binary—rather, these procedures exist on a continuum, where the patient's individual medical characteristics and the abortion provider's individual training and practice determine whether instruments (and which instruments) are needed in a particular procedure, or whether suction alone will suffice.

19. Aspiration and D&E both use suction from a vacuum aspirator to empty the patient's uterus. The intervenors' witnesses take issue with my characterization of this suction as "gentle," *see* Bane ¶ 39, Wheeler ¶ 13. While Dr. Wheeler suggests that 400–500 mmHg is a great deal of suction, that is not true. I can (and regularly do when demonstrating suction to a trainee) attach the suction to the palm of my hand without causing pain, bruising, or harm of any kind. As a comparison, a typical breast pump has suction of 220–350 mmHg, and cupping therapy (an adjunctive therapy sometimes used to help with musculoskeletal pain, inflammation, and blood flow) can use pressures ranging

from 75–750 mmHg.[9] We are trained to, and do, use the suction cannula gently: Dr. Wheeler references using a curette, which is a sharp instrument rarely if ever used at PPSAT. And PPSAT routinely uses ultrasound guidance when performing D&Es after 14 weeks, just as Dr. Wheeler urges. Wheeler ¶ 28.

B. Most complications from D&E can be managed in an outpatient setting.

20. Even when complications do arise from procedural abortion, most of the time they can be safely treated at the clinic where the abortion was performed. And when a higher level of care is needed, abortion clinic staff are trained to stabilize the patient and facilitate their transfer. To make the transfer process as seamless as possible, PPSAT coordinates with OB-GYN groups at our local hospitals to figure out their preferred patient transfer process—for example, some hospitals prefer that we send patients to ER triage; others ask us to call the resident on call ahead of time. It is therefore not the case that abortion clinics "are not equipped to handle" serious complications, even if we do not *treat* certain serious complications at our health centers. Wubbenhorst ¶ 12; Bane ¶ 50; Wheeler ¶ 23.

21. We should not require all abortions past the twelfth week of pregnancy to be performed in a hospital setting because of the very low risk of complications requiring hospital treatment. Dr. Wheeler specifically lists a number of what she defines as "surgeries" (endometrial biopsy, suturing wounds, orthopedic manipulations, endoscopic

[9] Ku Weon Kim et al., *Pressure Levels in Cupping Therapy: A Systematic Review*, 37 J. Acupuncture Rsch. 28 (2020).

procedures), Wheeler ¶ 22; all of these procedures can and routinely do occur outside of a hospital operating room despite the fact that they can result in complications requiring hospitalization. It would be a terrible use of hospital resources to require all of those procedures to happen in a hospital. The features specific to an operating room (such as air-flow differentials, sterile corridors, and equipment for general anesthesia including intubation) are not needed to perform a procedural abortion safely because the procedure involves no incisions. *See* Farris ¶ 15. Using an operating room for abortion procedures would delay (or be delayed by) the scheduling of procedures that cannot be performed safely without a full sterile operating room setting and anesthesiologist support.

22. All patient-centered outpatient health care providers rely on hospital care for back-up; every clinic, regardless of the care they are providing, should have a system for transferring a patient to the hospital should they have a complication or adverse reaction. For example, primary care, internal medicine, pediatric, and allergy/immunology clinics that provide "allergy shots" must have a system to transfer patients who experience anaphylaxis after an injection.[10] The suggestion that abortion should be held to a different standard than all other medical care, without a safety reason for doing so, is the product of abortion stigma. *See* Wubbenhorst ¶ 135.

23. As I explained in my earlier disclosure, hospital providers' distaste for manual vacuum aspirators (MVAs) is another example of abortion stigma interfering with

[10] Phil Lieberman, *The Risk and Management of Anaphylaxis in the Setting of Immunotherapy*, 26 Am. J. Rhinology & Allergy 469, fig.1 (2012) (algorithm for when to call 911).

medical best practice. MVAs have been used in first-trimester abortion care for decades; at PPSAT, we use MVAs for abortion up to approximately 8 or 9 weeks of pregnancy, after which point we switch to electric vacuum aspirators (EVAs). Similarly, as Dr. Wubbenhorst acknowledges, MVAs can be used to manage miscarriage in the first trimester. *Id.* ¶ 79. Before 8 or 9 weeks, MVAs are preferable to EVAs because MVAs better facilitate examination of aspirated tissue at very early gestational stages and because EVAs are noisier, which can make patients feel nervous. But hospitals were historically hesitant to stock MVAs or to train physicians on how to use them for miscarriage management *because of* MVAs' association with abortion. While I disagree with Dr. Wubbenhorst's opinion that second-trimester D&Es—either for miscarriage management or for abortion—"should be" performed in a hospital, *id.* ¶ 80, the point of this MVA history is that abortion stigma leads to miscarriage management and abortion being provided differently even though they are clinically the same.

24. Hemorrhage is incredibly rare and occurs far less frequently as a complication of D&E than with full term delivery.[11] I disagree with Dr. Wheeler's

[11] *See* Comm. on Practice Bulletins—Obstetrics, *ACOG Practice Bulletin No. 183: Postpartum Hemorrhage*, 130 Obstetrics & Gynecology e168 (2017) (postpartum hemorrhage is the leading cause of severe maternal morbidity in the United States); William M. Callaghan et al., *Trends in Postpartum Hemorrhage: United States, 1994–2006*, 202 Am. J. Obstetrics & Gynecology 353.e1, 353.e2 (2010) (reporting that between 1994 and 2006, the percentage of delivery hospitalizations with a code for postpartum hemorrhage increased from 2.3% (85,954 deliveries) to 2.9% (124,708 deliveries)); Jennifer Kerns & Jody Steinauer, *Management of Postabortion Hemorrhage*, 87 Contraception 331, 331 (2013) (estimates for rate of hemorrhage after abortion in the second trimester range from 0.9 to 10 per 1,000 cases, or 0.09% to 1%).

suggestion that it is harder to treat hemorrhage arising from a second-trimester D&E than hemorrhage resulting from term childbirth. Wheeler ¶¶ 14, 31. While it was previously hypothesized that oxytocin might be a less effective uterotonic than other medications because the uterus has fewer oxytocin receptors in mid-trimester as compared with at term,[12] more recent clinical recommendations recognize that prophylactic oxytocin can be useful in decreasing bleeding in the second trimester.[13] For D&E procedures, PPSAT routinely adds prophylactic vasopressin to the paracervical block starting around 14 or 15 weeks of pregnancy, as this has been shown to reduce the risk of hemorrhage with D&E.[14] But more importantly, oxytocin is not considered a first-line therapy for hemorrhage—in the rare event of heavy bleeding following abortion, we prioritize other, more effective medications such as misoprostol, methergine, and TXA, which are not dependent on oxytocin receptors. Of course, for the vast majority of D&E patients, there is no heavy bleeding requiring additional treatment.

25. Patients who would benefit from a hospital setting are referred there for their abortion. Clinicians should, and do, assess in advance the safest setting for a given procedure in light of a particular patient's medical circumstances. *See* Wheeler ¶ 24. We screen patients and refer those at higher risk of complications to the hospital for their

[12] Kerns & Steinauer, *supra* note 11 at 333.

[13] Jennifer L. Kerns et al., *Society of Family Planning Clinical Recommendation: Management of Hemorrhage at the Time of Abortion*, 129 Contraception 1, 6, 7, 9 (2023) (prophylactic oxytocin is associated with lower blood loss in second-trimester abortions).

[14] Kenneth F. Schulz et al., *Vasopressin Reduced Blood Loss from Second-Trimester Dilation and Evacuation Abortion*, 326 Lancet 353 (1985).

abortion. As with many other outpatient procedures, the fact that there is a small risk of complications does not mean we should *always* perform the procedure in a hospital.

C. Abortion clinics ensure that patients receive adequate pain management.

26. Abortion clinics provide adequate pain management for the vast majority of procedural abortion patients, and patients who request a higher level of sedation are referred for hospital procedures. At PPSAT, we offer moderate sedation with IV medications for all abortions over 15 weeks gestation, as measured from the first day of the patient's last menstrual period (LMP). All PPSAT clinicians who oversee moderate sedation are specifically privileged to do so after appropriate training. Having trained non-anesthesiologists administer this IV sedation is consistent with the standard of care, as reflected in the North Carolina Medical Board's position statement on office procedures and sedation: they do not require or recommend anesthesiologists for minimal/moderate sedation (level I or II procedures).[15] *See* Bane ¶ 52. Minimal sedation is routinely achieved through oral or inhaled treatments such as oral lorazepam or inhaled nitrous oxide; moderate sedation involves delivery of medication through an intravenous line, with the patient remaining conscious and responsive throughout the procedure. Unlike with deep

[15] N.C. Med. Bd., *5.1.1: Office-Based Procedures*, Position Statements (Sept. 2021), https://www.ncmedboard.org/resources-information/professional-resources/laws- rules-position-statements/position-statements/office-based_procedures.

sedation or general anesthesia, no intervention is required to maintain a patient's airway during moderate sedation.[16]

27. Dr. Wheeler implies (without citing any data on pain relief for second trimester procedures[17]) that general anesthesia is required to provide adequate pain relief for procedural abortion. Wheeler ¶¶ 39–41. This is completely inconsistent with the standard of care. General anesthesia requires intubation and significantly *increases* the patient's risk of adverse reactions (as does deep sedation relative to moderate sedation). Anesthesia itself carries risks for patients, and additionally, general anesthesia with inhaled volatile anesthetics has been associated with an increased risk of hemorrhage during D&E for either abortion or miscarriage.[18] Therefore, while general anesthesia may be appropriate for some specific patients, it is not advisable pain relief for most procedural abortion patients after the twelfth week of pregnancy, and certainly is not a reason to require all patients to obtain their procedural abortion in a hospital setting.

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[16] Comm. on Quality Mgmt. & Departmental Admin., *Statement on Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia*, Am. Soc'y Anesthesiologists (last amended Oct. 23, 2019) https://www.asahq.org/standards-and-practice-parameters/statement-on-continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedation-analgesia.

[17] Regina M. Renner et al., *Pain Control in First-Trimester Surgical Abortion: A Systematic Review of Randomized Controlled Trials*, 81 Contraception 372 (2010).

[18] Hyun Ah Lee et al., *Impact of Anesthetic Agents on the Amount of Bleeding During Dilation and Evacuation: A Systematic Review and Meta-Analysis*, 16 PlosOne e0261494 (2021).

28. Moreover, in the study cited by Dr. Wubbenhorst, ¶ 83, n.74,[19] which surveyed patients obtaining abortion by D&E after 16 weeks' gestation at an outpatient abortion clinic, the bulk of the pain reported arose during the passive cervical dilation process (when medications or osmotic dilators were in place in the patient's cervix), not during the D&E procedure itself (when patients had intravenous sedation). Because any difference in sedation level between a clinic and hospital would occur during the D&E procedure, not while passive cervical dilation is taking place, we would expect patients' experience of pain during the dilation process to be the same in both settings.

29. The point is that patients who desire deeper sedation, or those for whom the provider feels deeper sedation is medically indicated, can still be referred for an abortion in a hospital setting, and patients should *also* have the option of getting care in a dedicated, high-quality, less-expensive clinical site if they choose—as the vast majority of abortion patients currently do.

D. Hospitals are not more equipped than clinics to care for patients seeking abortion due to rape, incest, or life-limiting anomaly.

30. Hospitals are not better situated than clinics to treat patients in the specific contexts of rape, incest, or life-limiting anomaly. These cases are not necessarily more medically complex than other abortions at the same gestational age. Bane ¶ 46. Patients with life-limiting anomalies are referred to PPSAT by hospital physicians, so those patients

[19] Ilana G. Dzuba et al., *Pain, Side Effects, and Abortion Experience Among People Seeking Abortion Care in the Second Trimester*, 3 Women's Health Reps. 533 (2022).

have already been counseled on the availability of perinatal hospice and patient support services, and PPSAT sends tissue to a pathology lab as needed, just as a hospital would. *See id.* ¶ 58.

31. Dr. Bane suggests that hospitals are better equipped to "ensure the forensic chain of evidence is followed" when survivors of rape or incest wish to preserve pregnancy tissue for law enforcement. *Id.* ¶ 58. But Dr. Bane ignores (or is unaware) that PPSAT, too, has training and protocols in place for when a patient wishes to preserve pregnancy tissue for law enforcement. Indeed, I have been complimented by crime scene investigators on the rigor of our protocols.

32. Specifically, we ask every abortion patient who is a survivor of rape whether they want to use tissue for law enforcement; most do not. But for those who do, or where release of tissue is compelled by a court order, warrant, or grand jury subpoena, we follow the chain of custody guidelines provided by law enforcement for processing, packaging, and transmitting pregnancy tissue for genetic/DNA testing. The patient completes a form granting consent to release the tissue. The abortion provider notes in the patient's medical record that the pregnancy tissue has been kept under their control from the time of the procedure through processing and until securely placed in a specimen container and sealed with a tamper-evident label. If a chain of custody/evidence form is required by the relevant law enforcement official, the provider or their designee will complete that form and scan it into the patient's medical record. If this form is not required by law enforcement, the provider or their designee will document in the medical record the name of the law

enforcement representative to whom the pregnancy tissue has been released, as well as the date released.

33. While abortions in the case of rape or incest are not more technically complicated than other abortions, they can be more socially or psychologically complex, and as I explained in my first disclosure, PPSAT physicians and staff are specially trained to care for these patients in a compassionate, trauma-informed way. Farris ¶¶ 93–96.

34. Dr. Wubbenhorst is wrong that abortion clinics are ill-equipped to screen for and support patients experiencing intimate partner violence, including reproductive coercion. *See* Wubbenhorst ¶¶ 165–68. PPSAT screens for abortion coercion and assesses decisional certainty as part of our informed consent and counseling process. We ask every patient a series of questions to assess their confidence and whether they have been pressured either to obtain an abortion or to remain pregnant. We ask them these questions without anyone else present in the room, even if a partner or other support person is present for all other parts of the visit. The purpose of these discussions is, among other things, to ensure the patient has considered their options; is confident in their decision to have an abortion; and is making an informed and voluntary decision. During this process, staff are trained to pay close attention to the patient's body language cues in addition to the patient's verbal responses. On the rare occasion a patient exhibits signs of ambivalence or suggests they are not firm in their decision, regardless of whether coercion is a factor, the staff member takes time to explore those feelings with the patient and discuss all their options, including continuing the pregnancy.

35. Dr. Bane's farfetched concern about abortion clinics' ability to treat a "live birth," Bane ¶ 51, is irrelevant to the abortions that PPSAT would provide under the rape, incest, and life-limiting anomaly exceptions—i.e., aspiration and D&E up to 20 weeks of pregnancy, when there is no reasonable possibility of a live birth.

E. Outpatient abortion providers provide excellent patient care.

36. The intervenors' witnesses suggest—both directly and through implication—that abortion providers at outpatient clinics lack necessary training and skill. This is a persistent stereotype about abortion providers that is grounded in abortion stigma, not fact.

37. For example, Dr. Bane suggests that the most highly trained abortion providers work in hospitals. *Id.* ¶¶ 46–47. While some experienced abortion providers do work in hospitals, many work in outpatient clinics (including PPSAT clinics)—either as full-time staff or in addition to their work at a hospital. Abortion providers who practice in outpatient clinics have more opportunity than hospital physicians to develop the experience necessary to provide the highest-quality care, simply because most abortions are provided in clinics, not hospitals.[20] And the converse is true, as well: patients seeking abortion in a hospital will not necessarily be treated by an experienced abortion provider, or by a physician with the Complex Family Planning or Maternal-Fetal Medicine specialist training that Dr. Bane describes. Bane ¶ 47.

[20] Turok et al., *supra* note 8.

38. Lastly, while Dr. Bane speculates baselessly about abortion providers exceeding their scope of practice, Bane ¶ 53, all PPSAT abortion providers who perform D&E—including myself—have procedure- and gestational-duration-specific privileges based on our training and demonstrated competence. It is standard practice in medicine for a clinician to continue to expand their skills after formal residency/fellowship training through peer training and proctoring.[21] Otherwise, no doctor would be able to perform any procedure that was developed after they graduated from residency or fellowship, including new standard-of-care surgical techniques. Lifelong learning is a trademark of medicine, and this includes learning new procedural skills. Here as elsewhere, abortion providers should not be held to a different standard than all other physicians.

39. In another illustration of abortion stigma, Dr. Wubbenhorst argues at length, but with only speculative anecdotal support, that PPSAT and abortion providers generally are unwilling to provide follow-up care for our abortion patients who experience complications. Wubbenhorst ¶¶ 130–148. As I have explained, Farris ¶¶ 46–51, and as PPSAT's complication data shows, Suppl. Br. in Supp. of Pls.' Am. Mot. for Prelim. Inj., Ex. 12, DE 74-12; *id.*, Ex. 13, DE 74-13; *id.*, Ex. 14, DE 74-14, we manage the vast majority of abortion complications in our clinics. Dr. Wubbenhorst is therefore wrong to suggest that even though abortion complications are rare, *all* abortion complications are

[21] Thomas E. Norris et al., *Teaching Procedural Skills*, 12 J. Gen. Internal Med. S64 (1997) ("Several studies . . . have demonstrated that primary care physicians are able to master complex procedures such as colposcopy, cesarean section, and ultrasound, with results that are indistinguishable from those of more narrowly trained specialists.").

severe and require hospital treatment. Wubbenhorst ¶ 117. Only rare complications require referral for a higher level of care. All PPSAT health centers are equipped with emergency carts that include resuscitative medications, resuscitative devices, IV kits and fluid bags for volume resuscitation, oxygen with nasal cannula or mask, and automated external defibrillator (AED) devices. PPSAT staff are trained to stabilize patients using these supplies and to transfer them to the hospital.

40. This is how all medicine is practiced. Primary care providers and specialists alike will routinely treat patients even though some of the complications that could *possibly* arise, even if extremely unlikely, could not be treated on-site and would require transfer to another facility. No one would suggest that all IUD placements should happen in hospital operating rooms simply because there is a remote possibility of uterine perforation during that procedure. We should not apply a different standard to abortion.

F. Abortion clinics are subject to comprehensive oversight.

41. Dr. Wubbenhorst opines that abortion clinics are insufficiently regulated and that hospitals are therefore safer generally. Wubbenhorst ¶¶ 150–57. To the contrary, abortion clinics are *highly* regulated and intensely scrutinized. All PPSAT health centers receive state oversight on their compliance with facility licensing regulations, including infection prevention standards and recordkeeping standards. State regulations dictate the contents of the emergency carts in all of our health centers. The North Carolina Department of Health and Human Services inspects our health centers' compliance with all applicable regulations as part of our routine facility license renewal process. While initial licensing

visits are announced, all follow-up visits are unannounced. And as evident from the Department of Health and Human Services archive Dr. Wubbenhorst cites,[22] all deficiencies identified at PPSAT health centers through those visits were minor, and all were corrected to DHHS's satisfaction. Indeed, our clinic licenses would not have been renewed otherwise. So while Dr. Wubbenhorst opines that North Carolina abortion clinics "cannot meet minimal state-mandated standards of safety and hygiene," Wubbenhorst ¶ 153, the *exact opposite* is true: North Carolina's abortion clinics remain open to the public *because* they have met state-mandated safety and hygiene requirements. Identification of deficiencies—and of their correction—is evidence of appropriate PPSAT quality control systems and rigorous state oversight, not of insufficient regulation.

G. Abortions are just as safe in clinics as in hospitals.

42. Research demonstrates that second-trimester D&Es are just as safe in clinics as in hospitals, if not safer.[23] Dr. Wubbenhorst and Dr. Wheeler argue that the study conducted by Turok et al., comparing the safety of second-trimester D&Es in hospitals to those in clinics, "overestimated" this point because the patient population at the hospital was generally more high-risk than the patients at the outpatient clinics. Wubbenhorst ¶¶ 139–44, Wheeler ¶¶ 43–48. But this just reflects that high-risk patients are already referred to hospitals for their abortions, without a detrimental effect on the safety of second-trimester D&Es for medically uncomplicated patients in outpatient settings. The clinical

[22] *Reports of Surveys for Abortion Clinics*, N.C. Div. Health Serv. Regul., (Mar. 2016), https://info.ncdhhs.gov/dhsr/ahc/sods/results.asp.

[23] Turok et al., *supra* note 8; Roberts et al., *supra* note 8.

setting of the abortion should be determined based on the patient's clinical circumstances, not solely whether the patient is past the twelfth week of pregnancy.

43. Dr. Wubbenhorst similarly discounts the relevance of the consensus guidelines on facility requirements for abortion published by Levy et al.[24] and the study by Roberts et al.[25] comparing the safety of abortions in ambulatory surgical centers versus clinics. But both papers support the broader point that abortion is as safe as other outpatient procedures, and that the facility in which the abortion is provided does not change abortion's safety.

44. As an alternative to arguing that hospitals are safer than outpatient clinics, the intervenors' witnesses acknowledge that abortion safety is primarily a function of the abortion provider's experience, and suggest that experienced abortion providers should just get hospital privileges to continue providing abortion under the Hospitalization Requirement. Wheeler ¶ 48. First, this suggestion ignores the significant burden that the Requirement imposes on patients by requiring them to obtain abortions in hospitals rather than clinics without medical justification. But second, requiring our North Carolina abortion providers to obtain admitting privileges at hospitals would be prohibitively difficult. Hospital privileges are a costly and onerous business agreement based on the amount of business that a health care provider does with a hospital. Because abortion is so safe and hospital transfers are so rare, it would be incredibly difficult and time-consuming,

[24] Levy et al., *supra* note 8.
[25] Roberts et al., *supra* note 8.

and in some cases may be impossible, for me and other PPSAT providers to obtain hospital privileges. Based on my experience obtaining courtesy privileges at one hospital, I know that it is time-intensive to get those privileges and that maintaining them also takes time and adds cost. Many of our providers work in multiple locations across the state, so they would need to obtain privileges at many hospitals in order to continue providing care to our patients in a hospital setting. Furthermore, there are many reasons doctors prefer to provide abortion in a clinic setting, including that abortions are less expensive and onerous for patients in that setting, and staff are specifically trained in compassionate, non-judgmental care.

H. Procedural abortions are just as safe as procedural management of miscarriage.

45. As an initial matter, I note that the intervenors' witnesses focus primarily on the alleged risks and complexity of the D&E procedure to justify the Hospitalization Requirement for all abortions after the twelfth week of pregnancy. *E.g.* Wheeler ¶¶ 18–32; Wubbenhorst ¶¶ 44–48, 111–12; Bane ¶¶ 53, 57. They overstate these concerns, as I explain above. But even taking them at face value, the risk and complexity of a D&E is the same when used to manage *spontaneous* pregnancy loss as when used for abortion. Indeed, as I explained in my first disclosure, Farris ¶ 28 & n.10, the risk of complications from D&Es to manage spontaneous pregnancy loss in the second trimester can be *higher* than

the risk of complications from D&Es for abortion at the same gestational age.[26] But the Hospitalization Requirement applies only to abortion.

46. Additionally, the intervenors' witnesses' focus on D&E ignores that PPSAT generally provides abortion using aspiration—not D&E—into the fourteenth or fifteenth week of pregnancy. The Hospitalization Requirement therefore forces patients to obtain first-trimester aspiration procedures as well as D&Es in the hospital setting. None of the intervenors' witnesses meaningfully attempts to justify this facility requirement for first-trimester aspiration procedures. *E.g.* Wheeler ¶¶ 23 ("[T]he safest location for patients to undergo *a D&E* is in the hospital setting." (emphasis added)), 50 ("[I]t is in the patient's best medical interest to perform *second trimester D&E procedures* in a hospital setting . . . ." (emphasis added)).

47. Focusing on D&Es, Dr. Bane describes physiological differences between patients with spontaneous fetal death and patients with ongoing pregnancies, but she does not give any reason why these differences would make *the D&E procedure* more dangerous when performed for abortion than when performed to manage miscarriage. Bane ¶¶ 54–57.

48. Rather than providing evidence that procedural abortion is riskier than procedural miscarriage management at the same gestational age, Dr. Wubbenhorst criticizes my reliance on an ANSIRH issue brief, Wubbenhorst ¶ 85. But the cited study on miscarriage complications does, in fact, "use[] a large national sample to compare the

[26] Kerns et al., *supra* note 13 at 1, 3.

safety of miscarriage treatment in different facilities,"[27] and in turn supports ANSIRH's (and my) conclusion that the rates of miscarriage-treatment-related complications are higher than documented rates of abortion-related complications. Specifically, the study examined whether miscarriage treatment-related morbidities and adverse events varied across hospitals, ASCs, and office-based settings: the researchers found no statistically significant differences in events after second-trimester procedures across hospitals (9.6%), ASCs (7.1%), and office-based settings (5.8%), and observed that "[t]he rates of miscarriage treatment–related events are notably higher than published rates of abortion-related events.[28]

49. Meanwhile, Dr. Wubbenhorst's reliance on complication rates for miscarriage management *using medications in the first trimester* is irrelevant to the Hospitalization Requirement, which applies only to abortions after the twelfth week of pregnancy. Wubbenhorst ¶¶ 89–90. Dr. Wubbenhorst also misstates the mortality ratios for miscarriage at various gestational ages by an order of magnitude, *see id.* ¶¶ 91–92 (presumably due to a mistake in converting a ratio of deaths per 1,000,000 miscarriages to a ratio of deaths per 100,000 miscarriages for ease of comparison with abortion). The 1985 study she cites by Berman et al.[29] lists the following mortality ratios:

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[27] Sarah C. M. Roberts et al., *Miscarriage Treatment-Related Morbidities and Adverse Events in Hospitals, Ambulatory Surgery Centers, and Office-Based Settings*, 16 J. Patient Safety e317 (2020).

[28] *Id.* at e320, e322.

[29] Stuart M. Berman et al., *Deaths From Spontaneous Abortion in the United States*, 253 J. Am. Med. Ass'n 3119, 3122 tbl.5 (1985).

Table 5.—Estimated Relative Risk of Death After Non-Intrauterine (Contraceptive) Device-Associated Spontaneous Abortion, by Gestational Age, United States, 1972 Through 1980

Gestational Age, Week From Last Menstrual Period	Percent Spontaneous Abortion by Week of Gestation*	No. of Spontaneous Abortions by Week of Gestation*	No. of Spontaneous Abortion Deaths Non-Intrauterine (Contraceptive) Device-Associated	Ratio†	Relative Risk‡
0-7	49	4,410,000	6	1.4	1.0
8-11	23	2,070,000	14	6.8	5
12-15	16	1,440,000	27	50.0	36
16-19	6	540,000	27	50.0	36
20-24	6	540,000	12	22.2	16
Total	100	9,000,000	86 (15 unknown)	...	...

*Assuming 9,000,000 spontaneous abortions for 1972 through 1980 and distribution of spontaneous abortions as per Harlaps et al.[6]
†Deaths per million spontaneous abortions.
‡Based on an index ratio of 1.4 for gestational age (0 through 7) weeks.

In any event, these mortality ratios for miscarriage are higher than the mortality ratios for abortion reported by Bartlett et al. up to 20 weeks (and PPSAT does not provide abortion past 20 weeks).[30]

50. Dr. Wheeler appears to agree that aspiration and D&E for abortion are clinically similar and similar in risk to those same procedures for miscarriage management. For example, Dr. Wheeler concedes that these procedures are technically "similar for management of miscarriage (spontaneous abortion), and induced abortion," and that "[i]t is the intentional taking of life"—not any medical or clinical difference—"that makes these completely different procedures." Wheeler ¶ 15. Later, while conceding that "technically the [aspiration or D&E] procedure is similar" when used for these two purposes, and that she is not aware of data comparing the safety of these procedures for abortion and for miscarriage care, Dr. Wheeler speculates that "underlying clinical conditions *may* alter the risks and difficulty of the procedure." *Id.* ¶ 50 (emphasis added). Based on her citation to

[30] Linda A. Bartlett et al., *Risk Factors for Legal Induced Abortion–Related Mortality in the United States*, 103 Obstetrics & Gynecology 729, 733 tbl.2 (2004).

the Turok study, I take her to mean that these procedures might be riskier when performed for medically complicated pregnancies—but a pregnant patient's underlying medical conditions increase the risk of abortion and miscarriage management procedures alike.

51. I cannot imagine what underlying clinical conditions would differentiate the safety of abortion from miscarriage, other than that the risk of disseminated intravascular coagulation (DIC) is heightened with spontaneous fetal demise later in the second trimester: in other words, D&E for miscarriage management can be riskier than D&E for abortion at the same gestational age.[31]

52. Dr. Wubbenhorst, too, appears to acknowledge this heightened risk of DIC from D&E for spontaneous fetal death as compared to D&E for abortion by agreeing that longer duration of fetal demise increases the risk of DIC. Wubbenhorst ¶¶ 86–88. While she states that "[w]ithout knowing the length of time a fetus had been dead, there is uncertainty about the conclusion that rates of DIC were higher in women undergoing D&E for miscarriage vs. abortion," her uncertainty is overstated: length of fetal demise may stratify DIC risk among miscarriage patients obtaining D&Es, but it would not make DIC more likely or prevalent with D&E for abortion. Among all patients, however, DIC is quite rare, and could present hours or days after the D&E procedure is complete—so performing the D&E in a hospital rather than a clinic may not facilitate earlier diagnosis or treatment. *See id.* ¶ 40.

[31] Kerns et al., *supra* note 13 at 1, 3; Jennifer L. Kerns et al., *Disseminated Intravascular Coagulation and Hemorrhage After Dilation and Evacuation Abortion for Fetal Death*, 134 Obstetrics & Gynecology 708 (2019).

III. The IUP Documentation Requirement Bans A Safe, Evidence-Based Treatment Option That Patients Should Be Allowed To Choose

53. The IUP Documentation Requirement will not lead to ectopic pregnancies being detected or treated sooner. Instead, it limits patients' medical options and delays access to time-sensitive care.

54. The Requirement mandates no additional ectopic pregnancy screening, testing, or follow-up. For example, Dr. Wubbenhorst speculates that patients with undetected ectopic pregnancies will fail to return for follow-up after receiving a medication abortion using the protocol for pregnancies of unknown location, Wubbenhorst ¶ 229, but nothing in the IUP Documentation Requirement requires patients to return for follow-up or to seek care elsewhere, either. It simply requires us to deny them the option of medication abortion. The Requirement therefore will not protect people from complications of undetected ectopic pregnancy by promoting faster or more effective diagnosis of ectopic pregnancy, whereas our protocol will serve to diagnose ectopic pregnancy *without* delaying the patient's access to their strongly desired abortion care. *See id.* ¶¶ 12–13.

A. PPSAT follows the evidence-based standard of care in treating patients with pregnancies of unknown location.

55. PPSAT's protocol is already consistent with what the intervenors' witnesses assert is the standard of care for screening for ectopic pregnancy and treating patients with undesired pregnancies of unknown location.

56. As the Mifeprex label makes clear, Def.-Intervenors' Resp. in Opp. to Pls.' Am. Mot. for Prelim. Inj., Ex. 2, DE 65-2, mifepristone is contraindicated for "confirmed or suspected" ectopic pregnancy because it does not treat ectopic pregnancy. Mifepristone is not contraindicated for pregnancies of unknown location, so Dr. Wubbenhorst is wrong to assert that providing medication abortion to patients at *low risk of ectopic pregnancy*, but with pregnancies of unknown location, "are ignoring clear warnings associated with the use of this drug." Wubbenhorst ¶ 230.

57. What Dr. Wubbenhorst describes as reasons to "suspect" or "confirm" ectopic pregnancy, *id.* ¶¶ 203–215, is completely consistent with how PPSAT screens for risk of ectopic pregnancy in patients seeking abortion. As required by North Carolina law, all patients seeking abortion at PPSAT first obtain an ultrasound. If there is no evidence of intrauterine pregnancy on a transvaginal ultrasound, the patient is screened for risk of ectopic pregnancy. Visualization of an extraovarian adnexal mass on the ultrasound would be a reason to categorize this patient as having a "suspected" ectopic pregnancy, as would symptoms like abdominal pain and/or vaginal bleeding and other medical-history based risk factors for ectopic pregnancy. *Cf. id.* ¶ 203. If we saw a gestational sac with a yolk sac or embryo outside the uterus, we would categorize the patient as having a "confirmed" ectopic pregnancy. *Cf. id.* ¶ 204. Patients in these categories would not be eligible for medication abortion.

58. Patients without these factors, however, would be categorized as having a "pregnancy of unknown location," or PUL, *not* a "confirmed or suspected" ectopic

pregnancy. They would be given an hCG blood test to assess their pregnancy hormone level, and offered the choice between (1) postponing care and doing a repeat ultrasound and an additional hCG blood test to monitor the change in their hormone levels over the course of a few days (what we call "watch and wait"); (2) having an aspiration procedure for the dual purpose of terminating their pregnancy and assessing for ectopic pregnancy (by examining the aspirated tissue to see whether products of conception are present, confirming that pregnancy was intrauterine); or (3) initiating a medication abortion while *also* doing additional hCG blood tests and receiving close follow-up and symptom monitoring from PPSAT clinicians, including repeat ultrasound when the patient is able to return to the clinic.

59. This protocol is consistent with what the intervenors' witnesses describe as best practices for screening for ectopic pregnancy and treating patients without a visible intrauterine pregnancy on transvaginal ultrasound. *Id.* ¶¶ 203–205, 213–221; Wheeler ¶¶ 59–66; Bane ¶¶ 67–69. Since we are following the standard of care for evaluating the risk of ectopic pregnancy to determine whether patients are eligible for medication abortion, close follow-up *concurrent* with medication abortion is a safe and appropriate course of treatment to offer to patients.

60. Importantly, patients who opt to initiate a medication abortion while continuing to test for ectopic pregnancy through serial hCG testing are closely monitored by PPSAT clinicians. We call the patient the day after they take the first abortion medication (mifepristone) to check on the patient's symptoms, and if the patient describes

symptoms potentially indicating ectopic pregnancy, we send the patient to the nearest hospital for ectopic pregnancy evaluation. No patient in this category would be left to determine on their own, without clinical guidance, "what are normal symptoms of medical abortion and what symptoms require urgent attention for possible ectopic pregnancy." *See* Wheeler ¶ 54; Wubbenhorst ¶¶ 13, 228; Bane ¶ 66.

61. Additionally, our general practice is to provide a follow-up transvaginal ultrasound to all patients who return to the PPSAT health center 48-72 hours after taking the second abortion medication for their second round of hCG labs. In some circumstances—if a patient's initial hCG levels are reassuring, if they do not have concerning symptoms, and if it would be particularly burdensome for them to have their second blood test performed at the PPSAT health center—we refer that patient for their second blood test at a lab closer to their home.

62. Dr. Wubbenhorst's opinions on the standard of care for treatment of patients with pregnancy of unknown location includes guidance specific to patients with "a desired pregnancy." Wubbenhorst ¶ 222, *see also* Wheeler ¶ 66. The guidelines she cites by Barnhart et al. state that the goal of treatment for patients with *desired* pregnancies of unknown location is to determine whether the patient has had a miscarriage or whether the pregnancy is ongoing, rather than determining whether the pregnancy is intrauterine or ectopic.[32] And these guidelines also recognize that "[f]or patients . . . in whom the

[32] Kurt T. Barnhart & Kassie Bollig, *Approach to the Patient with Pregnancy of Unknown Location*, UpToDate 1, 6 (2023).

pregnancy is undesired . . . management can be expedited, and subsequent testing may not be needed."

63. Similarly, the hCG levels that Dr. Wheeler cites, *see* Wheeler ¶ 66, are what you expect to see when following hormone level changes to diagnose ectopic pregnancy *where there has been no intervention*. By contrast, when we have intervened with medications to terminate the pregnancy, the expected trend of hCG levels would be different—namely, we would be looking for a clear pattern of decreasing hCG levels to confirm the pregnancy was disrupted. If we do not see that expected decrease, we either repeat the ultrasound (where the hormone level rise is suggestive of a normal growing intrauterine pregnancy) or refer the patient to a hospital for further ectopic evaluation (if there is an abnormal hormone level rise or drop suggestive of ectopic).

64. Because treatment of ectopic pregnancy requires specialized medications and equipment, including sometimes laparoscopic surgery, we do not treat patients for ectopic pregnancy in PPSAT's clinics and instead refer patients to a hospital for this care. It is routine in medicine to manage a large scope of practice in one's office but have a rare subset of care that requires referral to a more specialized provider or a higher level facility. The fact that some medical issues require referral does not mean that no care should be provided. If this were the case, then no one would be permitted to be a generalist in medicine (family physician, internist, pediatrician, or OB/GYN generalist for example) and only specialists would exist, which is demonstrably not the case nor in the best interest of patients.

65. Moreover, while we do not provide treatment for ectopic pregnancy at PPSAT's health centers, PPSAT staff are trained to screen for ectopic pregnancy, to counsel patients on the risks and symptoms, and to know when referral is required, so it is a mischaracterization to suggest that PPSAT providers "do not treat women with ectopic pregnancies." *Id.* ¶ 70.

66. Dr. Wubbenhorst invokes a 2020 paper from the *New England Journal of Medicine* that discusses a patient who took abortion medications without medical supervision and ultimately experienced a ruptured ectopic pregnancy. Wubbenhorst ¶¶ 255–256. Because this patient self-managed her medication abortion rather than receiving a medication abortion under PPSAT's protocol for pregnancies of unknown location, this case study does absolutely nothing to undermine the safety of our protocol. Indeed, it does precisely the opposite, as the central thesis of the article is that abortion restrictions that obstruct access to timely abortion care result in more patients self-managing their abortions outside the medical system, potentially incurring greater risks of complications.[33] This is an argument *against* the prohibitive IUP Documentation Requirement, not for it.

B. The IUP Documentation Requirement would interfere with patient-centered medical care.

67. As the Barnhart guidelines reflect,[34] the goals of treatment for pregnancies of unknown location are different with desired as compared to undesired pregnancies. If

[33] Lisa H. Harris & Daniel Grossman, *Complications of Unsafe and Self-Managed Abortion*, 382 New Eng. J. Med. 1029 (2020).

[34] Kurt T. Barnhart & Kassie Bollig, *Approach to the Patient with Pregnancy of Unknown Location*, UpToDate 1, 6 (2023).

the pregnancy is desired, then it is aligned with the patient's treatment goals to wait and absolutely confirm ectopic or failed pregnancy prior to initiating any interventional care. By contrast, when the pregnancy is undesired, the patient's treatment goal is to resolve the pregnancy as quickly as possible (especially in the setting of gestational limit bans and bans that require medically unnecessary repeated clinic visits, as we have here in North Carolina). Offering the patient all options is the most patient-centered approach—including waiting to determine the location of the pregnancy; diagnostic aspiration; *and* medication abortion using the protocol for pregnancy of unknown location. Patients should be permitted to make the decision that is best for them in consultation with their physician after being informed of the risks, benefits, and alternatives available to them.

68. Dr. Wheeler's statement that "[t]here is no clinical urgency nor clinical benefit" to expediting treatment of an undesired pregnancy of unknown location, Wheeler ¶ 64, is not only inconsistent with the Barnhart et al. practice guidelines discussed above; it also fails to account for the obstacles patients must overcome to obtain this care and their strong desire not to remain pregnant against their will any longer than necessary. *See also* Bane ¶¶ 67–69. In North Carolina, patients are already required to come in for two separate and redundant visits 72 hours apart, and each trip to the health center means another encounter with protestors—another product of abortion stigma. Denying patients access to abortion at the time of their visit and instead requiring more visits and tests prior to initiating abortion increases the financial burden on each patient. If abortion patients had free access to timely, affordable abortion, perhaps requiring them to wait would be less

onerous. But in North Carolina today, where abortion is banned after the twelfth week of pregnancy and highly restricted up to that point, patients are terrified of missing the narrow window of access and desperate to get care as soon as they possibly can.

69. The IUP Documentation Requirement would prevent us from continuing our current practice of providing evidence-based care that is responsive to our patients' urgency. By initiating medication abortion while concurrently conducting further testing for ectopic pregnancy through serial hCG tests and close monitoring, we have been able to confirm that the medications successfully ended the pregnancy in the same amount of time it would have taken to confirm an intrauterine pregnancy. Through concurrent serial hCG testing we can identify patients who need further evaluation for ectopic pregnancy, and patients who have a successful medication abortion can achieve their treatment goal sooner.[35] Contrary to what the intervenors' witnesses assert, *see* Wheeler ¶¶ 73–78, the safety and efficacy of this medication abortion protocol is supported both by published research and by my own experience overseeing its use in PPSAT's clinical practice. And because this medication abortion protocol can allow us to exclude ectopic pregnancy *sooner* than if patients were denied medication abortion until their pregnancies were visible

[35] *See, e.g.*, Alisa B. Goldberg et al., *Mifepristone and Misoprostol for Undesired Pregnancy of Unknown Location*, 139 Obstetrics & Gynecology 771 (2022); Karen Borchert et al., *Medication Abortion and Uterine Aspiration for Undesired Pregnancy of Unknown Location: A Retrospective Cohort Study*, 122 Contraception 109980 (2023); I. Bizjak et al., *Efficacy and Safety of Very Early Medical Termination of Pregnancy: A Cohort Study*, 124 BJOG: Int'l J. Obstetrics & Gynaecology 1993 (2017); Philip Goldstone et al., *Effectiveness of Early Medical Abortion Using Low-Dose Mifepristone and Buccal Misoprostol in Women With No Defined Intrauterine Gestational Sac*, 87 Contraception 855 (2013).

by ultrasound[36]—which is what the IUP Documentation Requirement mandates—it does *not* "place women at increased risk of complications from undiagnosed ectopic pregnancy, including a delay in diagnosis," as Dr. Wheeler speculates it "may" do. *Id.* ¶ 78.

70. Patients with pregnancies of unknown location are counseled on the possibility that they may be spontaneously miscarrying, such that their pregnancy would end even without medication abortion. Similarly, we educate patients who have been determined to be low-risk for ectopic pregnancy that it is still possible that they *may* have an ectopic pregnancy, and that if they do, the abortion medications may not end their pregnancy and we will need to refer them for further treatment. Many patients choose this option over the alternatives of "watch and wait" or aspiration. Providing a medication abortion to those patients is not an "unnecessary medical intervention[]," Wubbenhorst ¶¶ 224, 239, 241, 245, 258; it is voluntarily elected, evidence-based medical care.

C. Medication abortion is safe.

71. To justify banning this option for patients, the intervenors' witnesses indirectly argue that medication abortion is dangerous, *see id.* ¶ 13, Wheeler ¶ 55, but that is squarely contradicted by decades of medical evidence.[37] Dr. Wubbenhorst takes issue

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[36] Goldberg et al., *supra* note 35.

[37] *See* Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA Report, "Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018,"* Univ. Cal. S.F. (2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf; NASEM, *supra* note 1 at 7, 16 (explaining that in 2016, "based on extensive clinical research demonstrating the safety of the revised regimen," the FDA updated the approved protocol for medication abortion); *see also id.* at 55 ("Complications after

with my description of the FDA's 2019 report on post-marketing adverse events from mifepristone; the FDA reported 24 deaths following use of mifepristone for abortion (not 26, as Dr. Wubbenhorst's screenshot suggests) out of the approximately 3.7 million patients who took mifepristone for abortion between its FDA approval on September 28, 2000 and December 31, 2018.[38] Wubbenhorst ¶¶ 176–87. But even the screenshot of the FDA report included in Dr. Wubbenhorst's report likewise acknowledges that "fatal cases are included *regardless of causal attribution* to mifepristone," *id*. ¶ 176 (emphasis added), contradicting Dr. Wubbenhorst's insinuation that all 24 deaths were causally related to the abortion, *see id*. ¶ 177.

72. The most recent version of the FDA's report on post-marketing adverse events, which captures adverse events through December 31, 2022, lists 36 deaths following mifepristone use—out of approximately 5.9 million patients over the course of 22 years—and cautions that "[t]hese events cannot with certainty be causally attributed to mifepristone."[39]

73. Similarly, Dr. Bane and Dr. Wubbenhorst argue that mifepristone is more dangerous than Tylenol and Viagra, including because it "carries a black box warning." Wubbenhorst ¶¶ 180–87. In 2011, the FDA instructed manufacturers to include a "black

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medication abortion . . . are rare—occurring in no more than a fraction of a percent of patients.").

[38] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018*, https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM603000.pdf.

[39] FDA, *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2022*, https://www.fda.gov/media/164331/download.

box warning" on all *prescription* drugs containing acetaminophen, highlighting the possibility of severe liver injury.[40] The FDA explained that "OTC products containing acetaminophen (e.g., Tylenol) are not affected by this action," and that "[i]nformation about the potential for liver injury is already required on the label for OTC products containing acetaminophen."[41] But the more important point is that the FDA itself agrees that medication abortion is safe and effective, as reflected by its January 2023 modifications to its mifepristone dispensing requirements in recognition of the ever-growing body of evidence demonstrating the safety and effectiveness of medication abortion.[42]

D. Prohibiting medication abortion in the earliest weeks of pregnancy does not protect patients.

74. The intervenors' witnesses attempt to repackage their ideological opposition to medication abortion as a concern about patients being charged for unnecessary medical procedures, but this is simply a further example of the anti-abortion stereotype that abortion providers are greedy and lack regard for patient safety. *See* Wubbenhorst ¶¶ 12, 235. For

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[40] FDA, *FDA Drug Safety Communication: Prescription Acetaminophen Products to Be Limited to 325 mg per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure*, (Jan. 13, 2011), https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-prescription-acetaminophen-products-be-limited-325-mg-dosage-unit#:~:text=In%20addition%2C%20a%20Boxed%20Warning,prescription%20drug%20products%20that%20contain.

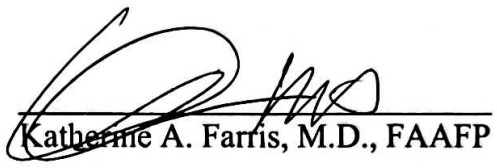
[41] *Id*.

[42] FDA, *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

example, Dr. Wubbenhorst's suggestion that providing medication abortion to patients who may be in the process of miscarrying involves charging a "fee for no reason," Wubbenhorst ¶ 227, fails to acknowledge that the patient has voluntarily chosen this course of treatment, despite the possibility of miscarriage. (It further ignores that the medication abortion regimen is also a known and appropriate regimen for managing miscarriage.)

75. Finally, the intervenors' witnesses argue that it promotes patient safety to ban medication abortion for pregnancies of unknown location because aspiration abortion has a higher efficacy rate for ending pregnancies of unknown location. *See* Wheeler ¶ 64; Wubbenhorst ¶ 251. But efficacy is not a *safety* interest. And some patients strongly prefer medication abortion over aspiration abortion, even knowing that there is a small chance the medication abortion will fail to end their pregnancy and they will require a follow-up dose of medication or an aspiration procedure to do so. They should not be denied this option.

Dated: January 08, 2024



Katherine A. Farris, M.D., FAAFP

EXHIBIT A

Katherine A. Farris, MD, FAAFP
3010 Maplewood Avenue Winston-Salem, NC 27603

Employment

Planned Parenthood South Atlantic Winston-Salem/Raleigh, NC

Chief Medical Officer: April 2020 – present

Duties of Affiliate Medical Director with increased focus on strategic planning, oversight of new service lines including Primary Care and telehealth, and increased advocacy work in support of PPSAT mission.

Affiliate Medical Director: December 2014 – April 2020

Clinical, policy, and administrative oversight of all licensed staff and clinical services for 14 health centers located throughout NC, SC, VA, and WV, including developing and implementing medical protocols, ensuring regulatory compliance, and overseeing quality of care provided.

Laboratory Director: December 2014 – present

Oversight of non-waived laboratories WS, NC; AVL, NC; WILM, NC; CLT, NC; waived laboratory VIE, WV

Infection Control Professional: 2014-present

Serves as consultant and expert on any infection prevention concerns as per medical training.

Interim Abortion Facility Administrator: December 2019 – March 2020

Acting Vice President of Patient Services: March – June 2016; May – August 2017

Oversight of administrative and operational departmental functions including regulatory compliance and financial solvency for 14 health centers located throughout NC, SC, VA, and WV including direct and indirect supervision of management and non-licensed staff within the health centers.

Interim Affiliate Medical Director: July 2013 – December 2014

Reproductive Health Care: September 2009-present

Provision of comprehensive family planning services to women of all ages as well as STI counseling, testing and treatment to men and women.

PPFA Succession Planning Task Force, Member: April 2017 – March 2021

Task force was charged with addressing some of the systemic challenges of abortion provider training and recruitment at Planned Parenthood affiliates.

Medical Directors Council (MeDC), Mentor: 2015 – present

Serve as mentor to new Medical Directors/Chief Medical Officers at other PPFA Affiliates.

BetterHealth IT Board of Directors,

Member: September 2020 – present

Chair, Compliance Task Force: January 2023 – present

Board member for the organization responsible for providing revenue cycle services and supporting and rolling out Epic electronic medical records system across PPFA affiliates.

(Prior to merger and name change January 2015, organization was named Planned Parenthood Health Systems, Inc.)

Heywood Medical Group/Henry Heywood Hospital Westminster/Gardner, MA

Family Practice/Obstetrics: August 2003 – May 2007

Meetinghouse Family Practice; 16 Wyman Rd.; Westminster, MA 01473

Provision of full-spectrum family medicine including comprehensive family planning and reproductive health care.

Planned Parenthood League of Massachusetts Boston/Worcester, MA

Reproductive Health Care: August 2003 – May 2007

Provision of comprehensive family planning services to women of all ages.

Education

Valley Medical Center Family Practice Residency Renton, WA

Chief Resident: 2002-2003

Residency: 2001-2003

Internship: 2000-2001

Northwestern University Medical School Chicago, IL
Degree: MD, 1995-2000

Northwestern University College of Arts and Sciences Evanston, IL
Degree: BA, 1991-1995
Major: Molecular and Cellular Biology Minor: Religion Studies

Certifications/Special Training

Physician for Reproductive Health, Leadership Training Academy Fellow 2018-2019
Basic Life Support/AED, Provider: renewed 11/2023
Title X Family Planning Program Training, Provider: 2015
CLIA Laboratory Director Training, Training for non-waived laboratory director: 2013
Single-rod Hormonal Implant Insertion Training, Provider: 2011, Certificate #30001820273

Professional Organizations / Positions

American Academy of Family Physicians (AAFP): 1995-present
North Carolina Academy of Family Physicians: 2007-present
National Abortion Federation (NAF): 2003-2005, 2018-present
Physicians for Reproductive Health: 2018-present
American College of Obstetricians and Gynecologists: 2020-present
Massachusetts Academy of Family Physicians: 2003-2007
Washington Academy of Family Physicians (WAFP): 2000-2003
American Medical Women's Association (AMWA): 1995-2000
Northwestern University Chapter President: 1997-1998
Vice-President: 1996-1997

Licenses

NC Physician License, active: 143375-2009
WV Physician License, active: 26126
VA Physician License, active: 0101265486
SC Physician License, active: MMD.84073 MD
American Board of Family Physicians, Board Diplomate, Fellow

Honors/Awards

Fellow of the American Academy of Family Physicians – Awarded December 2023
The Degree of Fellow recognizes AAFP members who have distinguished themselves among their colleagues, as well as in their communities, by their service to family medicine, by their advancement of health care to the American people, and by their professional development through medical education and research. Fellows of the AAFP are recognized as champions of family medicine. They are the physicians who make family medicine the premier specialty in service to their community and profession. From a personal perspective, being a Fellow signifies not only 'tenure' but additional work in your community, within organized medicine, within teaching, and a greater commitment to continuing professional development and/or research.

Sylvia Clark Award for Creativity in Clinical Services – Recipient 2023
Honors a clinical services provider team from a Planned Parenthood affiliate who, through their creativity in clinical services, have demonstrated special commitment and ingenuity in applying the PPFA mission to ensure access to reproductive and sexual health care for all.

Press Ganey Patient Experience Top Performing Provider 2020
Ranked in the top 10% of providers across the country for providing the highest level of patient experience.

2002 Roy Virak Memorial Family Practice Resident Scholarship Recipient
Awarded by the Washington Academy of Family Practice on the basis of academic achievement, excellence in patient care, and strong service to the community.

Exhibit 7

Addendum to December 2023 Report of Dr. Bane

I ordered the textbook (Paul, M.P, Lichtenberg, E.S, Borgatta, L., Grimes, D., & Stubblefield, P. (1999). A Clinician's Guide to Medical and Surgical Abortion. ChurchHill Livingstone Publishing) as part of my research for my written report but did not receive it in time to review it before submitting my report in December 2023. This is an addendum to that report based on my review of the textbook made in preparation for my deposition. The following citations support my opinion that physiological changes occur during a miscarriage that make an induced abortion riskier than a miscarriage procedure.

p. 111 "Although abortion is among the most common medical needs of women, fewer than half of graduating obstetrics/gynecology residents in the United States have ever performed a first trimester induced abortion. **Training in the management of incomplete spontaneous abortion is not an adequate substitute."**

p. 131 "The degree of softening of fetal cortical bone affects the amount of dilation needed for D&E. Softening is facilitated by fetal demise. Noticeable cortical softening begins to occur as soon as 16-24 hours after demise."

p. 158 "Uterine evacuation may be technically easier after fetal demise. Softening of cortical bone makes surgical extraction easier."

Susan Bane, MD, PhD *1/30/24*

Exhibit 8

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

INTERIM UPDATE

ACOG PRACTICE BULLETIN

Clinical Management Guidelines for Obstetrician–Gynecologists

NUMBER 193, MARCH 2018

(Replaces Practice Bulletin Number 191, February 2018)

Committee on Practice Bulletins—Gynecology. This Practice Bulletin was developed by the Committee on Practice Bulletins—Gynecology in collaboration with Kurt T. Barnhart, MD, MSCE; and Jason M. Franasiak, MD, TS (ABB).

INTERIM UPDATE: This Practice Bulletin is updated as highlighted to clarify the guidance on the assessment of hCG levels after uterine aspiration in women with a pregnancy of unknown location.

Tubal Ectopic Pregnancy

Ectopic pregnancy *is defined as a pregnancy that occurs outside of the uterine cavity. The most common site of ectopic pregnancy is the fallopian tube. Most cases of tubal ectopic pregnancy that are detected early can be treated successfully either with minimally invasive surgery or with medical management using methotrexate. However, tubal ectopic pregnancy in an unstable patient is a medical emergency that requires prompt surgical intervention. The purpose of this document is to review information on the current understanding of tubal ectopic pregnancy and to provide guidelines for timely diagnosis and management that are consistent with the best available scientific evidence.*

Background

Epidemiology

According to the Centers for Disease Control and Prevention, ectopic pregnancy accounts for approximately 2% of all reported pregnancies (1). However, the true current incidence of ectopic pregnancy is difficult to estimate because many patients are treated in an outpatient setting where events are not tracked, and national surveillance data on ectopic pregnancy have not been updated since 1992 (1). Despite improvements in diagnosis and management, ruptured ectopic pregnancy continues to be a significant cause of pregnancy-related mortality and morbidity. In 2011–2013, ruptured ectopic pregnancy accounted for 2.7% of all pregnancy-related deaths and was the leading cause of hemorrhage-related mortality (2). The prevalence of ectopic pregnancy among women presenting to an emergency department with first-trimester vaginal bleeding, or abdominal pain, or both, has been reported to be as high as 18% (3).

Etiology

The fallopian tube is the most common location of ectopic implantation, accounting for more than 90% of cases (4). However, implantation in the abdomen (1%), cervix (1%), ovary (1–3%), and cesarean scar (1–3%) can occur and often results in greater morbidity because of delayed diagnosis and treatment (4). An ectopic pregnancy also can co-occur with an intrauterine pregnancy, a condition known as heterotopic pregnancy. The risk of heterotopic pregnancy among women with a naturally achieved pregnancy is estimated to range from 1 in 4,000 to 1 in 30,000, whereas the risk among women who have undergone in vitro fertilization is estimated to be as high as 1 in 100 (5, 6).

Risk Factors

One half of all women who receive a diagnosis of an ectopic pregnancy do not have any known risk factors (3). Women with a history of ectopic pregnancy are at increased risk of recurrence. The chance of a repeat ectopic pregnancy in a woman with a history of one ectopic pregnancy is approximately 10% (odds ratio [OR] 3.0; 95% CI, 2.1–4.4). In a woman with two or more prior ectopic pregnancies, the risk of recurrence increases to more than 25% (OR, 11.17; 95% CI, 4.0–29.5) (3). Other important risk factors for ectopic pregnancy include previous damage to the fallopian tubes, factors secondary to ascending pelvic infection, and prior pelvic or fallopian tube surgery (3, 7). Among women who become pregnant through the use of assisted reproductive technology, certain factors such as tubal factor infertility and multiple

embryo transfer are associated with an increased risk of ectopic pregnancy (8, 9). Women with a history of infertility also are at increased risk of ectopic pregnancy independent of how they become pregnant (7). Other less significant risk factors include a history of cigarette smoking and age older than 35 years (7).

Women who use an intrauterine device (IUD) have a lower risk of ectopic pregnancy than women who are not using any form of contraception because IUDs are highly effective at preventing pregnancy. However, up to 53% of pregnancies that occur with an IUD in place are ectopic (10). Factors such as oral contraceptive use, emergency contraception failure, previous elective pregnancy termination, pregnancy loss, and cesarean delivery have not been associated with an increased risk of ectopic pregnancy (3, 7, 11, 12).

Clinical Considerations and Recommendations

▶ ***How is an ectopic pregnancy diagnosed?***

The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy. Serial evaluation with transvaginal ultrasonography, or serum hCG level measurement, or both, often is required to confirm the diagnosis.

Women with clinical signs and physical symptoms of a ruptured ectopic pregnancy, such as hemodynamic instability or an acute abdomen, should be evaluated and treated urgently. Early diagnosis is aided by a high index of suspicion. Every sexually active, reproductive-aged woman who presents with abdominal pain or vaginal bleeding should be screened for pregnancy, regardless of whether she is currently using contraception (13, 14). Women who become pregnant and have known significant risk factors should be evaluated for possible ectopic pregnancy even in the absence of symptoms.

Transvaginal Ultrasonography

Ultrasonography can definitively diagnose an ectopic pregnancy when a gestational sac with a yolk sac, or embryo, or both, is noted in the adnexa (15, 16); however, most ectopic pregnancies do not progress to this stage (15). The ultrasound findings of a mass or a mass with a hypoechoic area that is separate from the ovary should raise suspicion for the presence of an ectopic pregnancy; however, its positive predictive value is only 80% (15) because these findings can be confused with pelvic structures, such as a paratubal cyst, corpus luteum, hydrosalpinx, endometrioma, or bowel. Although an early intrauterine gestational sac may be visualized as early as 5 weeks of gestation (17), definitive ultrasound evidence of an intrauterine pregnancy includes visualization of a gestational sac with a yolk sac or embryo (16). Visualization of a definitive intrauterine pregnancy eliminates ectopic pregnancy except in the rare case of a heterotopic pregnancy. Although a hypoechoic "sac-like" structure (including a "double sac sign") (18) in the uterus likely represents an intrauterine gestation, it also may represent a pseudogestational sac, which is a collection of fluid or blood in the uterine cavity that is sometimes visualized with ultrasonography in women with an ectopic pregnancy (19, 20).

Serum Human Chorionic Gonadotropin Measurement

Measurement of the serum hCG level aids in the diagnosis of women at risk of ectopic pregnancy. However, serum hCG values alone should not be used to diagnose an ectopic pregnancy and should be correlated with the patient's history, symptoms, and ultrasound findings (21, 22). Accurate gestational age calculation, rather than an absolute hCG level, is the best determinant of when a normal pregnancy should be seen within the uterus with transvaginal ultrasonography (23, 24). An intrauterine gestational sac with a yolk sac should be visible between 5 weeks and 6 weeks of gestation regardless of whether there are one or multiple gestations (25, 26). In the absence of such definitive information, the serum hCG level can be used as a surrogate for gestational age to help interpret a nondiagnostic ultrasonogram.

The "discriminatory level" is the concept that there is a hCG value above which the landmarks of a normal intrauterine gestation should be visible on ultrasonography. The absence of a possible gestational sac on ultrasound examination in the presence of a hCG measurement above the discriminatory level strongly suggests a nonviable gestation (an early pregnancy loss or an ectopic pregnancy). In 50–70% of cases, these findings are consistent with an ectopic pregnancy (27–29). However, the utility of the hCG discriminatory level has been challenged (24) in light of a case series that noted ultrasonography confirmation of an intrauterine gestational sac on follow-up when no sac was noted on initial scan and the serum hCG level was above the discriminatory level (30–32). If the concept of the hCG discriminatory level is to be used as a diagnostic aid in women at risk of ectopic pregnancy, the value should be conservatively high (eg, as high as 3,500 mIU/mL) to avoid the potential for misdiagnosis and possible interruption of an intrauterine pregnancy that a woman hopes to continue (24, 32). Women with a multiple gestation have higher hCG levels than those with a single gestation at any given gestational age and may have hCG levels above traditional discriminatory hCG levels before ultrasonography recognition (24).

Trends of Serial Serum Human Chorionic Gonadotropin

A single hCG concentration measurement cannot diagnose viability or location of a gestation. Serial hCG concentration measurements are used to differentiate normal from abnormal pregnancies (21, 22, 33, 34). When clinical findings suggest an abnormal gestation, a second hCG value measurement is recommended 2 days after the initial measurement to assess for an increase or decrease. Subsequent assessments of hCG concentration should be obtained 2–7 days apart, depending on the pattern and the level of change.

In early pregnancy, serum hCG levels increase in a curvilinear fashion until a plateau at 100,000 mIU/mL by 10 weeks of gestation. Guidelines regarding the minimal increase in hCG for a potentially viable intrauterine pregnancy have become more conservative (ie, slower increase) (21, 22) and have been demonstrated to be dependent on the initial value (35). There is a slower than expected increase in serum hCG levels for a normal gestation when initial values are high. For example, the expected rate of increase is 49% for an initial hCG level of less than 1,500 mIU/mL, 40% for an initial hCG level of 1,500–3,000 mIU/mL, and 33% for an initial hCG level greater than 3,000 mIU/mL (35). In early pregnancy, an increase in serum hCG of less than a minimal threshold in 48 hours is suspicious of an abnormal pregnancy (ectopic or early pregnancy loss) because 99% of normal intrauterine pregnancies will have a rate of increase faster than this minimum. However, even hCG patterns consistent with a growing or resolving gestation do not eliminate the possibility of an ectopic pregnancy (36).

Decreasing hCG values suggest a failing pregnancy and may be used to monitor spontaneous resolution, but this decrease should not be considered diagnostic. Approximately 95% of women with a spontaneous early pregnancy loss will have a decrease in hCG concentration of 21–35% in 2 days depending on initial hCG levels (34). A woman with decreasing hCG values and a possible ectopic pregnancy should be monitored until nonpregnant levels are reached because rupture of an ectopic pregnancy can occur while levels are decreasing or are very low.

Pregnancy of Unknown Location

A pregnant woman without a definitive finding of an intrauterine or ectopic pregnancy on ultrasound examination has a "pregnancy of unknown location" (37). A pregnancy of unknown location should not be considered a diagnosis, rather it should be treated as a transient state and efforts should be made to establish a definitive diagnosis when possible (16). A woman with a pregnancy of unknown location who is clinically stable and has a desire to continue the pregnancy, if intrauterine, should have a repeat transvaginal ultrasound examination, or serial measurement of hCG concentration, or both, to confirm the diagnosis and guide management (22, 37). Follow-up to confirm a diagnosis of ectopic pregnancy in a stable patient, especially at first clinical encounter, is recommended to eliminate misdiagnosis and to avoid unnecessary exposure to methotrexate, which can lead to interruption or teratogenicity of an ongoing intrauterine pregnancy (16, 38, 39). The first step is to assess for the possibility that the gestation is advancing.

When the possibility of a progressing intrauterine gestation has been reasonably excluded, uterine aspiration can help to distinguish early intrauterine pregnancy loss from ectopic pregnancy by identifying the presence or absence of intrauterine chorionic villi. Choosing the appropriate time and intervention should be done through shared decision making, incorporating the patient's values and preferences regarding maternal risk and the possibility of interrupting a progressing pregnancy. If chorionic villi are found, then failed intrauterine pregnancy is confirmed and no further evaluation is necessary. If chorionic villi are not confirmed, hCG levels should be monitored, with the first measurement taken 12–24 hours after aspiration. A plateau or increase in hCG postprocedure suggests that evacuation was incomplete or there is a nonvisualized ectopic pregnancy, and further treatment is warranted. Although the change at which hCG is considered to have plateaued is not precisely defined, it would be reasonable to consider levels to have plateaued if they have decreased by less than 10–15%. Large decreases in hCG levels are more consistent with failed intrauterine pregnancy than ectopic pregnancy. In two small series of women undergoing uterine aspiration for pregnancy of unknown location, nearly all women with a decrease in hCG levels of 50% or greater within 12–24 hours after aspiration had failed intrauterine pregnancies (29, 40). Patients with a decrease in hCG of 50% or greater can be monitored with serial hCG measurements, with further treatment reserved for those whose levels plateau or increase, or who develop symptoms of ectopic pregnancy. Management of patients with an hCG decrease of less than 50% should be individualized, as while failed intrauterine pregnancy is more frequent, ectopic pregnancy risk is appreciable. One study (29) noted 55.6% of patients with ectopic pregnancies had an hCG decrease of more than 10%, 23.5% had a decrease of more than 30%, and 7.1% had a decrease of more than 50%. In a series of patients who had an initial decrease of hCG levels between 15% and 50% 12–24 hours after office uterine aspiration for pregnancy

of unknown location who were monitored with serial hCG measurement, 3 of 46 patients had rising or plateauing hCG levels necessitating treatment for ectopic pregnancy (41). The other patients had resolving hCG levels, and were presumed to have failed intrauterine pregnancies. Patients with an hCG decline between 15% and 50% 12–24 hours after aspiration require at least close follow-up with serial hCG measurement, with consideration of treatment for ectopic pregnancy based on clinical factors such as plateau or increase in hCG, development of symptoms, or high clinical suspicion or strong risk factors for ectopic pregnancy (29, 40, 41).

There is debate among experts about the need to determine pregnancy location by uterine aspiration before providing methotrexate (42, 43). Proponents cite the importance of confirming the diagnosis to avoid unnecessary exposure to methotrexate and to help guide management of the current pregnancy and future pregnancies (37, 42). Arguments against the need for a definitive diagnosis include concern about the increased risk of tubal rupture because of delay in treatment while diagnosis is established and the increased health-care costs associated with additional tests and procedures (43). However, with close follow-up during this diagnostic phase, the risk of rupture is low. In one large series with serial hCG measurement of women with pregnancies of unknown location, the risk of rupture of an ectopic pregnancy during surveillance to confirm diagnosis was as low as 0.03 % among all women at risk and as low as 1.7% among all ectopic pregnancies diagnosed (22). In addition, presumptive treatment with methotrexate has not been found to confer a significant cost savings or to decrease the risk of complications (44). The choice of performing a uterine aspiration before treatment with methotrexate should be guided by a discussion with the patient regarding the benefits and risks, including the risk of teratogenicity in the case of an ongoing intrauterine pregnancy and exposure to methotrexate.

▶ *Who are candidates for medical management of ectopic pregnancy?*

Medical management with methotrexate can be considered for women with a confirmed or high clinical suspicion of ectopic pregnancy who are hemodynamically stable, who have an unruptured mass, and who do not have absolute contraindications to methotrexate administration (45). These patients generally also are candidates for surgical management. The decision for surgical management or medical management of ectopic pregnancy should be guided by the initial clinical, laboratory, and radiologic data as well as patient-informed choice based on a discussion of the benefits and risks of each approach. Women who choose methotrexate therapy should be counseled about the importance of follow-up surveillance.

Methotrexate

Methotrexate is a folate antagonist that binds to the catalytic site of dihydrofolate reductase, which interrupts the synthesis of purine nucleotides and the amino acids serine and methionine, thereby inhibiting DNA synthesis and repair and cell replication. Methotrexate affects actively proliferating tissues, such as bone marrow, buccal and intestinal mucosa, respiratory epithelium, malignant cells, and trophoblastic tissue. Systemic methotrexate has been used to treat gestational trophoblastic disease since 1956 and was first used to treat ectopic pregnancy in 1982 (46). There are no recommended alternative medical treatment strategies for ectopic pregnancy beyond intramuscular methotrexate. Although oral methotrexate therapy for ectopic pregnancy has been studied, the outcomes data are sparse and indicate that benefits are limited (47).

Contraindications

Box 1 lists absolute and relative contraindications to methotrexate therapy (45). Before administering methotrexate, it is important to reasonably exclude the presence of an intrauterine pregnancy. In addition, methotrexate administration should be avoided in patients with clinically significant elevations in serum creatinine, liver transaminases, or bone marrow dysfunction indicated by significant anemia, leukopenia, or thrombocytopenia. Because methotrexate affects all rapidly dividing tissues within the body, including bone marrow, the gastrointestinal mucosa, and the respiratory epithelium, it should not be given to women with blood dyscrasias or active gastrointestinal or respiratory disease. However, asthma is not an exclusion to the use of methotrexate. Methotrexate is directly toxic to the hepatocytes and is cleared from the body by renal excretion; therefore, methotrexate typically is not used in women with liver or kidney disease.

Relative contraindications for the use of methotrexate (Box 1) do not serve as absolute cut-offs but rather as indicators of potentially reduced effectiveness in certain settings. For example, a high initial hCG level is considered a relative contraindication. Systematic review evidence shows a failure rate of 14.3% or higher with methotrexate when pretreatment hCG levels are higher than 5,000 mIU/mL compared with a 3.7% failure rate for hCG levels less than 5,000 mIU/mL (48). Of note, studies often have excluded patients from methotrexate treatment when hCG levels are greater than

Box 1. Contraindications to Methotrexate Therapy

Absolute Contraindications

- Intrauterine pregnancy
- Evidence of immunodeficiency
- Moderate to severe anemia, leukopenia, or thrombocytopenia
- Sensitivity to methotrexate
- Active pulmonary disease
- Active peptic ulcer disease
- Clinically important hepatic dysfunction
- Clinically important renal dysfunction
- Breastfeeding
- Ruptured ectopic pregnancy
- Hemodynamically unstable patient
- Inability to participate in follow-up

Relative Contraindications

- Embryonic cardiac activity detected by transvaginal ultrasonography
- High initial hCG concentration
- Ectopic pregnancy greater than 4 cm in size as imaged by transvaginal ultrasonography
- Refusal to accept blood transfusion

Modified from Medical treatment of ectopic pregnancy: a committee opinion. Practice Committee of American Society for Reproductive Medicine. Fertil Steril 2013;100:638–44.

5,000 mIU/mL based on expert opinion that these levels are a relative contraindication to medical management. Other predictors of methotrexate treatment failure include the presence of an advanced or rapidly growing gestation (as evidenced by fetal cardiac activity) and a rapidly increasing hCG concentration (greater than 50% in 48 hours) (48–50).

▶ ***What methotrexate regimens are used in the management of ectopic pregnancy, and how do they compare in effectiveness and risk of adverse effects?***

There are three published protocols for the administration of methotrexate to treat ectopic pregnancy: 1) a single-dose protocol (51), 2) a two-dose protocol (52), and 3) a fixed multiple-dose protocol (53) (Box 2). The single-dose regimen is the simplest of the three regimens; however, an additional dose may be required to ensure resolution in up to one quarter of patients (54, 55). The two-dose regimen was first proposed in 2007 in an effort to combine the efficacy of the multiple-dose protocol with the favorable adverse effect profile of the single-dose regimen (55). The two-dose regimen adheres to the same hCG monitoring schedule as the single-dose regimen, but a second dose of methotrexate is administered on day 4 of treatment. The multiple-dose methotrexate regimen involves up to 8 days of treatment with alternating administration of methotrexate and folinic acid, which is given as a rescue dose to minimize the adverse effects of the methotrexate.

The overall treatment success of systemic methotrexate for ectopic pregnancy, defined as resolution of the ectopic pregnancy without the need for surgery, in observational studies ranges from approximately 70% to 95% (55). Resolution of an ectopic pregnancy may depend on the methotrexate treatment regimen used and the initial hCG level. However, there is no clear consensus in the literature regarding the optimal methotrexate regimen for the management of ectopic pregnancy. The choice of methotrexate protocol should be guided by the initial hCG level and discussion with the patient regarding the benefits and risks of each approach. In general, the single-dose protocol may be most appropriate for patients with a relatively low initial hCG level or a plateau in hCG values, and the two-dose regimen may be considered as an alternative to the single-dose regimen, particularly in women with an initial high hCG value.

Single-Dose Versus Multiple-Dose

Observational studies that compared the single-dose and multiple-dose regimens have indicated that although the multiple-dose regimen is statistically more effective (92.7% versus 88.1%, respectively; P=.035) (single-dose

Box 2. Methotrexate Treatment Protocols

Single-dose regimen*

- Administer a single dose of methotrexate at a dose of 50 mg/m² intramuscularly on day 1
- Measure hCG level on posttreatment day 4 and day 7
  - If the decrease is greater than 15%, measure hCG levels weekly until reaching nonpregnant level
  - If decrease is less than 15%, readminister methotrexate at a dose of 50 mg/m² intramuscularly and repeat hCG level
  - If hCG does not decrease after two doses, consider surgical management
- If hCG levels plateau or increase during follow-up, consider administering methotrexate for treatment of a persistent ectopic pregnancy

Two-dose regimen†

- Administer methotrexate at a dose of 50 mg/m² intramuscularly on day 1
- Administer second dose of methotrexate at a dose of 50 mg/m² intramuscularly on day 4
- Measure hCG level on posttreatment day 4 and day 7
  - If the decrease is greater than 15%, measure hCG levels weekly until reaching nonpregnant level
  - If decrease is less than 15%, readminister methotrexate 50 mg/m² intramuscularly on day 7 and check hCG levels on day 11
  - If hCG levels decrease 15% between day 7 and day 11, continue to monitor weekly until reaching nonpregnant levels
  - If the decrease is less than 15% between day 7 and day 11, readminister dose of methotrexate 50 mg/m² intramuscularly on day 11 and check hCG levels on day 14
  - If hCG does not decrease after four doses, consider surgical management
- If hCG levels plateau or increase during follow-up, consider administering methotrexate for treatment of a persistent ectopic pregnancy

Fixed multiple-dose regimen‡

- Administer methotrexate 1 mg/kg intramuscularly on days 1, 3, 5, 7; alternate with folinic acid 0.1 mg/kg intramuscularly on days 2, 4, 6, 8
- Measure hCG levels on methotrexate dose days and continue until hCG has decreased by 15% from its previous measurement
  - If the decrease is greater than 15%, discontinue administration of methotrexate and measure hCG levels weekly until reaching nonpregnant levels (may ultimately need one, two, three, or four doses)
  - If hCG does not decrease after four doses, consider surgical management
- If hCG levels plateau or increase during follow-up, consider administering methotrexate for treatment of a persistent ectopic pregnancy

Abbreviation: hCG, human chorionic gonadotropin.

*Stovall TG, Ling FW. Single-dose methotrexate: an expanded clinical trial. Am J Obstet Gynecol 1993;168:1759-62; discussion 1762–5.

†Barnhart K, Hummel AC, Sammel MD, Menon S, Jain J, Chakhtoura N. Use of "2-dose" regimen of methotrexate to treat ectopic pregnancy. Fertil Steril 2007;87:250–6.

‡Rodi IA, Sauer MV, Gorrill MJ, Bustillo M, Gunning JE, Marshall JR, et al. The medical treatment of unruptured ectopic pregnancy with methotrexate and citrovorum rescue: preliminary experience. Fertil Steril 1986;46:811–3.

failure OR, 1.71; 95% CI, 1.04–2.82), the single-dose regimen is associated with a decreased risk of adverse effects (OR, 0.44; 95% CI, 0.31–0.63) (55). However, a more recent systematic review of randomized controlled trials showed similar rates of successful resolution with the single-dose and multiple-dose regimens (relative risk [RR], 1.07; 95% CI, 0.99–1.17) and an increased risk of adverse effects with the multiple-dose protocol (RR, 1.64; 95% CI, 1.15–2.34) (56).

Single-Dose Versus Two-Dose

A systematic review and meta-analysis of three randomized controlled trials showed similar rates of successful resolution for the two-dose and single-dose protocols (RR, 1.09; 95% CI 0.98–1.20) and comparable risk of adverse effects (RR, 1.33; 95% CI, 0.92–1.94) (56). However, in two of the three trials included in the review, the two-dose regimen was associated with greater success among women with high initial hCG levels. In the first trial, there was a nonstatistically significant trend toward greater success for the two-dose regimen in the subgroup with an initial hCG level greater than 5,000 mIU/mL (80.0% versus 58.8%, P=.279) (RR, 0.74; 95% CI, 0.47–1.16) (57). The second trial reported a statistically significant higher success rate for the two-dose regimen versus the single-dose regimen in patients with initial serum hCG levels between 3,600 mIU/mL and 5,500 mIU/mL (88.9% versus 57.9%, P=.03) (OR 5.80; 95% CI, 1.29–26.2) (58).

▶ What surveillance is needed after methotrexate treatment?

After administration of methotrexate treatment, hCG levels should be serially monitored until a nonpregnancy level (based upon the reference laboratory assay) is reached (51). Close monitoring is required to ensure disappearance of trophoblastic activity and to eliminate the possibility of persistent ectopic pregnancy. During the first few days after treatment, the hCG level may increase to levels higher than the pretreatment level but then should progressively decrease to reach a nonpregnant level (51). Failure of the hCG level to decrease by at least 15% from day 4 to day 7 after methotrexate administration is associated with a high risk of treatment failure and requires additional methotrexate administration (in the case of the single-dose or two-dose regimen) or surgical intervention (51). Methotrexate treatment failure in patients who did not undergo pretreatment uterine aspiration should raise concern for the presence of an abnormal intrauterine gestation. In these patients, uterine aspiration should be considered before repeat methotrexate administration or surgical management, unless there is clear evidence of a tubal ectopic pregnancy. Ultrasound surveillance of resolution of an ectopic pregnancy is not routinely indicated because findings do not predict rupture or time to resolution (59, 60). Resolution of serum hCG levels after medical management is usually complete in 2–4 weeks but can take up to 8 weeks (55). The resolution of hCG levels is significantly faster in patients successfully treated with the two-dose methotrexate regimen compared with the single-dose regimen (25.7+13.6 versus 31.9+14.1 days; P>.025) (57).

▶ What are the potential adverse effects of systemic methotrexate administration?

Adverse effects of methotrexate usually are dependent on dose and treatment duration. Because methotrexate affects rapidly dividing tissues, gastrointestinal problems (eg, nausea, vomiting, and stomatitis) are the most common adverse effects after multiple doses. Vaginal spotting is expected. It is not unusual for women treated with methotrexate to experience abdominal pain 2–3 days after administration, presumably from the cytotoxic effect of the drug on the trophoblastic tissue. In the absence of signs and symptoms of overt tubal rupture and significant hemoperitoneum, abdominal pain usually can be managed expectantly by monitoring a woman's hemoglobin level and intraperitoneal fluid amount with transvaginal ultrasonography.

Elevation of liver enzymes is a less commonly reported adverse effect and typically resolves after discontinuing methotrexate use (61). Alopecia also is a rare adverse effect of the low doses used to treat ectopic pregnancy. Cases of pneumonitis also have been reported, and women should be counseled to report any fever or respiratory symptoms to their physicians (62).

▶ How should women be counseled regarding the treatment effects of methotrexate?

Patients treated with methotrexate should be counseled about the risk of ectopic pregnancy rupture; about avoiding certain foods, supplements, or drugs that can decrease efficacy; and about the importance of not becoming pregnant again until resolution has been confirmed. It is important to educate patients about the symptoms of tubal rupture and to emphasize the need to seek immediate medical attention if these symptoms occur. Vigorous activity and sexual intercourse should be avoided until confirmation of resolution because of the theoretical risk of inducing rupture of the ectopic pregnancy. Additionally, practitioners should limit pelvic and ultrasound examinations when possible. Patients should be advised to avoid folic acid supplements, foods

that contain folic acid, and nonsteroidal antiinflammatory drugs during therapy because these products may decrease the efficacy of methotrexate. Avoidance of narcotic analgesic medications, alcohol, and gas-producing foods are recommended so as not to mask, or be confused with, escalation of symptoms of rupture. Sunlight exposure also should be avoided during treatment to limit the risk of methotrexate dermatitis (63).

Before treatment with methotrexate, women should be counseled about the potential for fetal death or teratogenic effects when administered during pregnancy. The product labeling approved by the U.S. Food and Drug Administration recommends that women avoid pregnancy during treatment and for at least one ovulatory cycle after methotrexate therapy (63). Methotrexate is cleared from the serum before the 4–12 weeks necessary for the resolution of the ectopic gestation and ovulation in the next cycle (64, 65). However, there are reports of methotrexate detectable in liver cells 116 days past exposure (66). Limited evidence suggests that the frequency of congenital anomalies or early pregnancy loss is not elevated in women who have become pregnant shortly after methotrexate exposure (66). However, perhaps based on the timing of methotrexate's clearance from the body, some experts continue to recommend that women delay pregnancy for at least 3 months after the last dose of methotrexate (67).

▶ *How does methotrexate treatment affect subsequent fertility?*

Patients can be counseled that available evidence, although limited, suggests that methotrexate treatment of ectopic pregnancy does not have an adverse effect on subsequent fertility or on ovarian reserve. A prospective observational study noted no difference in anti-müllerian hormone levels or reproductive outcomes after administration of methotrexate (68). Furthermore, a systematic review of women undergoing fertility treatment found no significant differences in the mean number of oocytes retrieved during the cycles before and after methotrexate administration (69).

▶ *Who are candidates for surgical management of ectopic pregnancy?*

In clinically stable women in whom a nonruptured ectopic pregnancy has been diagnosed, laparoscopic surgery or intramuscular methotrexate administration are safe and effective treatments. The decision for surgical management or medical management of ectopic pregnancy should be guided by the initial clinical, laboratory, and radiologic data as well as patient-informed choice based on a discussion of the benefits and risks of each approach. Surgical management of ectopic pregnancy is required when a patient is exhibiting any of the following: hemodynamic instability, symptoms of an ongoing ruptured ectopic mass (such as pelvic pain), or signs of intraperitoneal bleeding.

Surgical management is necessary when a patient meets any of the absolute contraindications to medical management listed in Box 1 and should be considered when a patient meets any of the relative contraindications. Surgical management should be employed when a patient who initially elects medical management experiences a failure of medical management. Surgical treatment also can be considered for a clinically stable patient with a nonruptured ectopic pregnancy or when there is an indication for a concurrent surgical procedure, such as tubal sterilization or removal of hydrosalpinx when a patient is planning to undergo subsequent in vitro fertilization.

Surgical management generally is performed using laparoscopic salpingectomy (removal of part or all of the affected fallopian tube) or laparoscopic salpingostomy (removal of the ectopic pregnancy while leaving the affected fallopian tube in situ). Laparotomy typically is reserved for unstable patients, patients with a large amount of intraperitoneal bleeding, and patients in whom visualization has been compromised at laparoscopy.

▶ *How do medical management and surgical management of ectopic pregnancy compare in effectiveness and risk of complications?*

Medical management of ectopic pregnancy avoids the inherent risks of surgery and anesthesia. However, compared with laparoscopic salpingectomy, medical management of ectopic pregnancy has a lower success rate and requires longer surveillance, more office visits, and phlebotomy. Randomized trials that compared medical management of ectopic pregnancy with methotrexate to laparoscopic salpingostomy have demonstrated a statistically significant lower success rate with the use of single-dose methotrexate (relative rate for success, 0.82; 95% CI, 0.72–0.94) and no difference with the use of multidose methotrexate (relative rate for success, 1.8; 95% CI, 0.73–4.6) (70). Comparing systemic methotrexate with tube-sparing laparoscopic surgery, randomized trials have shown no difference in overall tubal preservation, tubal patency, repeat ectopic pregnancy, or future pregnancies (70).

Medical management of ectopic pregnancy is cost effective when laparoscopy is not needed to make the diagnosis and hCG values are less 1,500 mIU/mL (71). Surgical management of ectopic pregnancy is more cost

effective if time to resolution is expected to be prolonged, or there is a relatively high chance of medical management failure, such as in cases with high or increasing hCG values or when embryonic cardiac activity is detected (72, 73).

▶ *How do salpingostomy and salpingectomy compare in effectiveness and fertility outcomes in the management of ectopic pregnancy?*

The decision to perform a salpingostomy or salpingectomy for the treatment of ectopic pregnancy should be guided by the patient's clinical status, her desire for future fertility, and the extent of fallopian tube damage. Randomized controlled trials that compared salpingectomy with salpingostomy for the management of ectopic pregnancy have found no statistically significant difference in the rates of subsequent intrauterine pregnancy (RR, 1.04; 95% CI, 0.899–1.21) or repeat ectopic pregnancy (RR, 1.30; 95% CI, 0.72–2.38) (74). In contrast, cohort study findings indicate that salpingostomy is associated with a higher rate of subsequent intrauterine pregnancy (RR, 1.24; 95% CI, 1.08–1.42) but also with an increased risk of repeat ectopic pregnancy (10% versus 4%; RR, 2.27; 95% CI, 1.12–4.58) compared with salpingectomy (74).

In general, salpingectomy is the preferred approach when severe fallopian tube damage is noted and in cases in which there is significant bleeding from the proposed surgical site. Salpingectomy can be considered in cases of desired future fertility when the patient has a healthy contralateral fallopian tube. However, salpingostomy should be considered in patients who desire future fertility but have damage to the contralateral fallopian tube and in whom removal would require assisted reproduction for future childbearing. When salpingostomy is performed, it is important to monitor the patient with serial hCG measurement to ensure resolution of ectopic trophoblastic tissue. If there is concern for incomplete resection, a single prophylactic dose of methotrexate may be considered (45).

▶ *Who are candidates for expectant management of diagnosed ectopic pregnancy?*

There may be a role for expectant management of ectopic pregnancy in specific circumstances. Candidates for successful expectant management of ectopic pregnancy should be asymptomatic; should have objective evidence of resolution (generally, manifested by a plateau or decrease in hCG levels); and must be counseled and willing to accept the potential risks, which include tubal rupture, hemorrhage, and emergency surgery. If the initial hCG level is less than 200 mIU/mL, 88% of patients will experience spontaneous resolution; lower spontaneous resolution rates can be anticipated with higher hCG levels (75). In a single small randomized trial of women with hCG levels less than 2,000 mIU/mL, expectant management was not associated with a statistically significant lower treatment success than single-dose methotrexate for the management of ectopic pregnancy (59% versus 76%, respectively) (RR, 1.3; 95% CI, 0.9–1.8) (76). Reasons for abandoning expectant management include intractable or significantly increased pain, insufficient decrease of hCG levels, or tubal rupture with hemoperitoneum.

Summary of Recommendations

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

- In clinically stable women in whom a nonruptured ectopic pregnancy has been diagnosed, laparoscopic surgery or intramuscular methotrexate administration are safe and effective treatments. The decision for surgical management or medical management of ectopic pregnancy should be guided by the initial clinical, laboratory, and radiologic data as well as patient-informed choice based on a discussion of the benefits and risks of each approach.
- Surgical management of ectopic pregnancy is required when a patient is exhibiting any of the following: hemodynamic instability, symptoms of an ongoing ruptured ectopic mass (such as pelvic pain), or signs of intraperitoneal bleeding.

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

- Serum hCG values alone should not be used to diagnose an ectopic pregnancy and should be correlated with the patient's history, symptoms, and ultrasound findings.
- If the concept of the hCG discriminatory level is to be used as a diagnostic aid in women at risk of ectopic pregnancy, the value should be conservatively high (eg, as high as 3,500 mIU/mL) to avoid the potential for misdiagnosis and possible interruption of an intrauterine pregnancy that a woman hopes to continue.
- The decision to perform a salpingostomy or salpingectomy for the treatment of ectopic pregnancy

should be guided by the patient's clinical status, her desire for future fertility, and the extent of fallopian tube damage.

- The choice of methotrexate protocol should be guided by the initial hCG level and discussion with the patient regarding the benefits and risks of each approach. In general, the single-dose protocol may be most appropriate for patients with a relatively low initial hCG level or a plateau in hCG values, and the two-dose regimen may be considered as an alternative to the single-dose regimen, particularly in women with an initial high hCG value.
- Failure of the hCG level to decrease by at least 15% from day 4 to day 7 after methotrexate administration is associated with a high risk of treatment failure and requires additional methotrexate administration (in the case of the single-dose or two-dose regimen) or surgical intervention.
- Patients can be counseled that available evidence, although limited, suggests that methotrexate treatment of ectopic pregnancy does not have an adverse effect on subsequent fertility or on ovarian reserve.
- There may be a role for expectant management of ectopic pregnancy in specific circumstances.

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

- The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy. Serial evaluation with transvaginal ultrasonography, or serum hCG level measurement, or both, often is required to confirm the diagnosis.
- A woman with a pregnancy of unknown location who is clinically stable and has a desire to continue the pregnancy, if intrauterine, should have a repeat transvaginal ultrasound examination, or serial measurement of hCG concentration, or both, to confirm the diagnosis and guide management.
- Medical management with methotrexate can be considered for women with a confirmed or high clinical suspicion of ectopic pregnancy who are hemodynamically stable, who have an unruptured mass, and who do not have absolute contraindications to methotrexate administration.
- After administration of methotrexate treatment, hCG levels should be serially monitored until a nonpregnancy level (based upon the reference laboratory assay) is reached.
- Patients treated with methotrexate should be counseled about the risk of ectopic pregnancy rupture; about avoiding certain foods, supplements, or drugs that can decrease efficacy; and about the importance of not becoming pregnant again until resolution has been confirmed.

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Tubal ectopic pregnancy. ACOG Practice Bulletin No. 193. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018; 131:e91–103.

The MEDLINE database, the Cochrane Library, and ACOG's own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and September 2017. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

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

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

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

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

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

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