Exhibit 1

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA

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

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

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

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

Introduction and Professional Background

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

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

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

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

II. Expert Opinion

A. Farris Declaration

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

i) Paragraph 9

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

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

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

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

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

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

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

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

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

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

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

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

i) Paragraph 10

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

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

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

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

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

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

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

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

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

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

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

A.4. Induced abortion is not health care.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A.6. Surgical abortion is surgery

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

65. This statement is medically inaccurate.

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

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

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

69. It requires standard surgical operative sterile technique.

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

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

72. These incisions are associated with surgical complications.

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

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

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

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

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

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

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

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

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

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

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

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

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

83. This is a medically and ethically inaccurate statement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A.9. US abortion data are incomplete.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[†] U.S. approval date

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

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

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

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

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

[†] U.S. approval date

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

130. This statement is medically and ethically inaccurate.

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

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

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

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

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

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

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

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

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

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

138. The NAS report has very significant flaws.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IAN = inferior alveolar nerve

162. Tonsillectomy: tonsillectomy involves no entry into viscera.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) Expired medications and medical supplies;

(6) Failure to purchase and maintain required equipment;

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

(8) Failure to properly handle medications:

(9) Failure to comply with physical plant standards;

(10) Failure to monitor patient vital signs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

276. The shortcomings of this protocol are evident.

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

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

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

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

iii) Paragraph 60

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

308. As noted, abortion is not health care.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Alsleben declaration

C.1. Abortion does not prevent pregnancy complications

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

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

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

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

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

C.2. Women need adequate anesthesia during abortion

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

364. What this study implies is that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

373. All 31 ectopic pregnancies were in this group.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

404. 4 patients were treated for ectopic pregnancy.

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

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

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

D. Conclusion

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

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

Monique Chireau Wubbenhorst

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

Exhibit A

CURRICULUM VITAE

Updated: 5-25-2023

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

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

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

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

Citizen of: United States

Languages spoken: English, French.

Education:

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

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

Other organizations: Board member, Americans United for Life.

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

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

Past and Present Hospital and Clinical Affiliations:

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

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

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

Publications:

1. **Refereed journals:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. Non-refereed publications:

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

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

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

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

3. Selected abstracts

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

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

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

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

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

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

Consultant appointments:

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

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

Invited Presentations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Professional awards and special recognitions:

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

Organizations and participation:

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

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

Courses taught:

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

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

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

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

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

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

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

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

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

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

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

Past and present teaching responsibilities including continuing education:

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

Areas of research interests (basic and applied):

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

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

a) **Past:**

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

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

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

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

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

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

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

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

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

Past and present participation in academic and administrative activities:

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