

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

BELLA HEALTH AND WELLNESS
et al.,

Plaintiffs,

v.

PHIL WEISER, in his official capacity as
Attorney General of Colorado, et al.,

Defendants.

Case No. 1:23-cv-939-DDD-SKC

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

I, Monique Chireau Wubbenhorst, pursuant to 28 U.S.C. § 1746, hereby declare
as follows:

1. 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 and my 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 joined the faculty at the Duke University School of Medicine in the Department of Obstetrics and Gynecology in 2003, a position I held until 2018. While at Duke I was a member of the Duke Institutional Review Board (IRB) for 15 years. I subsequently served as Senior Deputy Assistant Administrator in the Bureau for

Global Health at the United States Agency for International Development. I am currently a Senior Public Policy Fellow at the De Nicola Center for Ethics and Culture at the University of Notre Dame. I also serve as a visiting consultant in Obstetrics and Gynecology at Tenwek Mission Hospital in Bomet, Kenya. I am licensed to practice medicine in North Carolina and Indiana and am certified by the American Board of Obstetrics and Gynecology, a certification I have held since 1997.

2. 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, as well as in Kenya, India, the Philippines, Kazakhstan, Ghana, South Sudan, Uganda, Nepal, and Cameroon.

3. I am a fellow of the American College of Obstetricians and Gynecologists and a fellow of the American Heart Association. I have authored over 20 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 One*, *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 veterans' health, and ethics in epidemiology and reproductive health.

4. My experience and qualifications are set forth in further detail in my curriculum vitae, which is attached hereto as Attachment A.

5. I have been asked by Plaintiffs to opine regarding *Bella Health and Wellness v. Weiser*, No. 1:23-cv-939-DDD-SKC, a legal action challenging the constitutionality of SB 23-190, a Colorado law that bans providing or publicizing abortion pill reversal. I have reviewed the declaration submitted by Dr. Rebecca Cohen dated October 3, 2023, and am responding to it.

6. The opinions I express in this declaration are based on my education, training, experience, and ongoing familiarity with medical literature. These opinions are my own and do not represent the opinion of my employer or of any professional or other group.

OPINIONS

I. There is scientific evidence that supports the clinical use of progesterone to counteract the effects of mifepristone.

7. There are multiple lines of scientific evidence that support the use of progesterone to attempt to reverse the abortifacient action of mifepristone. These include, but are not limited to, the biochemistry of progesterone and its role in female fertility and pregnancy; studies on progesterone's effectiveness in treating threatened miscarriage; basic science evidence about how mifepristone works and the interactions be-

tween a receptor antagonist and receptor agonist; animal studies indicating that progesterone can counteract the effects of mifepristone; and reports on the use of progesterone following the administration of mifepristone for abortion.

A. Progesterone and its role in female fertility and pregnancy

8. To understand how abortion pill reversal works, it is necessary to begin with the biochemistry of progesterone.

9. Progesterone is a naturally occurring hormone, so named because it promotes gestation, among other functions.¹ It plays an essential role in regulating the reproductive function of the uterus, ovaries, mammary glands, and brain, and is particularly critical to achieving and maintaining a healthy pregnancy.²

10. During the first ten weeks of pregnancy, progesterone is secreted by a highly specialized structure in the ovary (the corpus luteum), which forms after ovulation and is the main source of progesterone while the placenta develops. Once the placenta has grown to a certain size, it is the main source of progesterone during the remainder of pregnancy.³

11. Progesterone binds to the progesterone receptor in cells, and when it does, specific pathways in these cells are activated. Among other things, progesterone stim-

¹ See W. M. Allen et al., *Nomenclature of Corpus Luteum Hormone*, 136 *Nature* 303, 303 (1935) <https://perma.cc/DV4P-W5BL> (discussing identification of the “progestational hormone”).

² See generally Lucie Kolatorova et al., *Progesterone: A Steroid with Wide Range of Effects in Physiology as Well as Human Medicine*, 23 *Int’l J. Molecular Scis.*, July 2022, <https://perma.cc/V3JE-CGXF>.

³ Jessie K. Cable, *Physiology, Progesterone*, StatPearls Publishing (Michael H. Grider ed., 2022), <https://perma.cc/VB6D-JY72>.

ulates the formation of glands in the endometrium (the lining of the uterus), preparing it for the implantation of the developing embryo (blastocyst).⁴ It also stimulates the endometrium to produce glucose, proteins, and other nutrients that support the developing embryo. In late pregnancy, progesterone plays a role in the relaxation of smooth muscle cells, promoting uterine relaxation prior to delivery.⁵

12. Bioidentical progesterone, which is synthesized from steroid precursors, has the same chemical structure as naturally produced progesterone and has been used to support female fertility in a variety of ways for more than 50 years.⁶ There are numerous and well-known indications for bioidentical progesterone therapy in both obstetrics and gynecology, including treatment of recurrent miscarriages, prevention of preterm birth, treatment of secondary amenorrhea (lack of menstrual cycles), treatment of excessive blood loss during menstruation, treatment of premenstrual syndrome, hormonal therapy after surgical or natural menopause, and prevention and treatment of endometrial hyperplasia (thickening of the uterine lining).⁷ Notably, progesterone is routinely used to treat luteal phase defect, a type of infertility, and is

⁴ See Arri Coomarasamy et al., *PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages – a randomised, double-blind, placebo-controlled, international multicentre trial and economic evaluation*, Health Tech. Assessment, May 2016, at 1, <https://perma.cc/4BZH-NUUN>.

⁵ See N.E. Simons et al., *The long-term effect of prenatal progesterone treatment on child development, behaviour and health: a systematic review*, 128 BJOG: Int'l J. Obstet. & Gyn. 964, May 2021, <https://perma.cc/8F83-EMSB>.

⁶ See Gian Carlo Di Renzo et al., *Progesterone: History, facts, and artifacts*, 69 Best Practice & Rsch. Clinical Obstetrics & Gynaecology 2 (2020), <https://perma.cc/XKF3-CF4D>.

⁷ See Kolatorova et al., *supra* note 2.

also used during in vitro fertilization (IVF) treatment, where it is part of routine care to both support endometrial function and help prevent miscarriage.

13. All uses of supplemental progesterone except for treatment of endometrial hyperplasia (pathological thickening of the lining of the uterus) and secondary amenorrhea (lack of menstrual cycles) are “off-label” uses, meaning that they do not appear on the FDA-approved labeling. In my experience, obstetricians and other physicians frequently prescribe drugs for off-label uses during pregnancy. Such drugs include tocolytics (*i.e.*, drugs used to delay preterm labor) such as terbutaline, magnesium sulfate, nifedipine, non-steroidal anti-inflammatory drugs (NSAIDs), as well as ampicillin in preterm labor and diabetic medications such as glyburide and metformin for diabetes in pregnancy. In fact, the use of misoprostol for abortion is an off-label use.

14. Several recent studies and a host of older studies have evaluated the use of progesterone to prevent or treat unexplained recurrent miscarriage or early pregnancy bleeding.⁸

⁸ See, *e.g.*, Hassan Shehata et al, *FIGO Good Practice Recommendations on the use of progesterone in the management of recurrent first-trimester miscarriage*, 161 Int’l J. Gyn. & Obstet. 3 (2023), <https://perma.cc/YYB9-9FV9>; Arri Coomarasamy et al., *Progesterone to prevent miscarriage in women with early pregnancy bleeding: the PRISM RCT*, Health Tech. Assessment, June 2020, at 1, <https://perma.cc/QNY6-DBSQ>; Arri Coomarasamy et al., *Micronized vaginal progesterone to prevent miscarriage: a critical evaluation of randomized evidence*, 223 Am. J. Obstetricians Gynecologists 167, 167-76 (2020), <https://perma.cc/G5ZN-3727>; CB Okeke Ogwulu et al., *The cost-effectiveness of progesterone in preventing miscarriages in women with early pregnancy bleeding: an economic evaluation based on the PRISM trial*, 127 BJOG: Int’l J. Obstet. & Gyn. 757 (2020), <https://perma.cc/Z7VQ-TWH2>; Arri Coomarasamy et al., *A Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy*, 380 New Eng. J. Med. 1815 (2019), <https://perma.cc/Z4F6-PXR7>; David M. Haas et al., *Progesterone for preventing miscarriage in women with recurrent miscarriage of unclear etiology*, Cochrane Database Systematic Revs. (2018), <https://perma.cc/2D4R-YCDJ>; Hayfaa A. Wahabi et al., *Progestogen for treating threatened miscarriage*, Cochrane Database Systematic Revs. (2018), <https://perma.cc/7GH2-FRHQ>; Hee Joong Lee et al., *The Influence of Oral Dydrogesterone and Vaginal*

15. One of the most recent studies, known as the Progesterone in Spontaneous Miscarriage (PRISM) study, examined the use of progesterone in prevention of recurrent miscarriage. The PRISM study followed over 4,000 women at 48 hospitals in the United Kingdom—and found a 3% greater live birth rate among the women who received progesterone therapy. The study concluded that “[p]rogesterone therapy did not result in a significantly higher rate of live births among women with threatened miscarriage *overall*.”⁹ But it did identify a differential benefit among women with prior miscarriages, showing a 15% greater live birth rate among women with early pregnancy bleeding and three or more prior miscarriages.¹⁰ Arri Coomarasamy, lead author of the PRISM study, stated that “[o]ur research has shown that progesterone is a robust and effective treatment option” that “could prevent 8[,]450 miscarriages a year in the UK.”¹¹

16. Dr. Cohen misreads these results, selectively claiming that the PRISM study “did not find any statistically significant increase in live births.”¹² But she ignores the “increasing live birth rates according to the number of previous miscarriages”

Progesterone on Threatened Abortion: A Systematic Review and Meta-Analysis, 2017 BioMed Research Int’l, <https://perma.cc/H699-NJEP>; Arri Coomarasamy et al., *PROMISE: first-trimester progesterone therapy in women with a history of unexplained recurrent miscarriages – a randomised, double-blind, placebo-controlled, international multicentre trial and economic evaluation*, Health Tech. Assessment, May 2016, at 1, <https://perma.cc/4BZH-NUUN>.

⁹ See Coomarasamy et al., *Progesterone to prevent miscarriage in women with early pregnancy bleeding: the PRISM RCT*, *supra* note 8 (emphasis added).

¹⁰ *Id.*

¹¹ Jacqui Wise, *NICE recommends progesterone to prevent early miscarriage*, British Med. J. (Nov. 24, 2021), <https://perma.cc/HLD7-7Y8J>.

¹² Cohen Decl. ¶ 16.

among women who received progesterone therapy.¹³ As the study authors explained in a follow-up analysis, PRISM in fact shows a “small but positive treatment effect” from progesterone therapy among women with a history of miscarriage.¹⁴ The authors therefore recommended that “the information [about progesterone] should be communicated to women at high risk of miscarriages,” concluding that “[w]e believe that a woman at high risk of having a miscarriage may not need absolute scientific certainty to choose to have a treatment. If she is informed about the uncertainty around treatment effects and available safety data, then she could decide for herself the right course of action.”¹⁵

17. Dr. Cohen goes on to quote a 2019 editorial by Dr. Michael Greene that claims the PRISM study as proof that the “enthusiasm” for progesterone therapy to treat threatened miscarriage “was driven by overestimation of the incidence of pregnancy loss in the absence of therapy and *by reports of seeming success in uncontrolled case series.*”¹⁶ But as noted above, the authors of PRISM rebutted Greene’s view of the study—that the only effects of progesterone are “small” and “statistically insignificant”—in a subsequent publication. And the purportedly “uncontrolled case series” cited by Greene is a 1948 study on the use of the estrogen diethylstilbestrol (DES) to prevent complications of pregnancy. DES is a semisynthetic estrogen once used by

¹³ Arri Coomarasamy et al., *Micronized vaginal progesterone to prevent miscarriage: a critical evaluation of randomized evidence*, 223 Am. J. Obstetricians Gynecologists 167, 167-76 (2020), <https://perma.cc/G5ZN-3727>.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ Cohen Decl. ¶ 16 (emphasis in original) (quoting Michael F. Greene, Editorial, *Progesterone for Threatened Abortion*, 380(19) N. Eng. J. Med. 1867 (2019) (Cohen Decl. Ex. L)).

clinicians to try to reduce the risk of miscarriage in women prone to pregnancy loss, among other reasons. It was pulled from the market after a generation of women who were exposed to it *in utero* developed vaginal cancer. That study does not use progesterone to treat threatened miscarriage.

18. In November 2021, the UK’s National Institute of Health and Care Excellence (NICE) published new guidelines recommending progesterone therapy for women with early pregnancy bleeding and at least one previous miscarriage.¹⁷ The recommendation followed a Cochrane review of studies on progesterone use, including the PRISM study. Gillian Leng, NICE’s chief executive, stated that “progesterone will not be able to prevent every miscarriage,” but “will be of benefit to some women and, as an inexpensive treatment option, can be made available to women on the NHS from today.”¹⁸

19. Importantly, there is no evidence that progesterone poses a safety risk to pregnant women or to their embryos or fetuses. The NICE committee found “no evidence of harms for women or babies” from the use of progesterone, including “no increase in risk of stillbirth, ectopic pregnancy, congenital abnormalities or adverse drug reactions.”¹⁹ The American Society for Reproductive Medicine (ASRM) has similarly concluded: “The weight of available evidence indicates that the most common forms

¹⁷ *Ectopic pregnancy and miscarriage: diagnosis and initial management*, National Institute for Health and Care Excellence (NICE) (updated Nov. 24, 2021), <https://perma.cc/Y9TE-KCY5> (Guideline NG126, Recommendation 1.5.2).

¹⁸ Wise, *supra* note 11.

¹⁹ *Ectopic pregnancy and miscarriage: diagnosis and initial management*, National Institute for Health and Care Excellence (NICE), 16 (November 2021), <https://perma.cc/4W4X-Q95Y> (Guideline NG126 Update).

of [progesterone] supplementation during early pregnancy pose no significant risk to mother or fetus.”²⁰

20. Progesterone received FDA approval in 1998.²¹ It is classified as a “Category B” drug for pregnant women—in the same risk category as Tylenol, the most commonly used pain reliever during pregnancy.²²

B. The abortion pill

21. What is commonly known as the abortion pill refers to the use of prescribed drugs to terminate pregnancy. This procedure is also sometimes known as “medication abortion,” “medical abortion,” or “chemical abortion.”

22. The current abortion-pill regimen involves two drugs, mifepristone (marketed originally as “RU-486” and now as “Mifeprex”) and misoprostol. Under the current protocol, a woman takes 200 milligrams of mifepristone orally, followed up to 48 hours later by 800 micrograms of misoprostol buccally (i.e., in the cheek).²³

23. Mifepristone is a synthetic steroid developed in the 1980s by a research team led by Etienne-Emile Baulieu at the French pharmaceutical company Roussel-Uclaf.²⁴ Mifepristone is a progesterone antagonist that works by binding to—and blocking—the progesterone receptors on the nuclear membranes of cells in the uterus

²⁰ Prac. Comm. of the Am. Soc. for Reprod. Med., *Progesterone Supplementation During the Luteal Phase and in Early Pregnancy in the Treatment of Infertility: an Educational Bulletin*, 89 Fertility & Sterility 789, 791 (2008), <https://perma.cc/X39A-VMRH>.

²¹ FDA, Approval Letter (Dec. 16, 1998), <https://perma.cc/M7T7-VSDL>.

²² FDA, Prometrium Label at 15, <https://perma.cc/CR46-2FTS>; *Prometrium Prescribing Information*, Drugs.com, <https://perma.cc/RDN3-WNQ8>.

²³ FDA, Mifeprex Label at 1, <https://perma.cc/JW69-KNND>.

²⁴ See generally *The Antiprogesterin Steroid RU 486 and Human Fertility Control* (Etienne-Emile Baulieu & Sheldon J. Segal eds., 1985), <https://perma.cc/UCT3-CS3T>.

and throughout the body.²⁵ As Baulieu put it, the progesterone receptors are like a keyhole, and mifepristone is the “false key” that fits the lock but cannot open it.²⁶

24. By blocking progesterone receptors, mifepristone causes disruption of the developing human embryo’s implantation site and suppresses the production of hCG (human chorionic gonadotropin) and progesterone by the placenta. This prevents oxygen and nutrition from being transported to the developing embryo, eventually resulting in the death of the embryo and its detachment from the endometrium.²⁷ Mifepristone also softens the cervix and increases for the sensitivity of the uterus to agents that cause uterine contractions.²⁸

25. As Dr. Cohen correctly acknowledges, mifepristone alone is not always effective in ending a pregnancy.²⁹ Misoprostol is included in the abortion pill regimen to improve its overall efficacy rate and achieve complete expulsion of the embryo. Misoprostol works by binding to smooth muscle cells in the uterine lining, causing contractions that mechanically expel the embryo, placenta, and membranes from the uterus.

²⁵ See *id.* at 276 (“Our results confirm that RU 486 behaves as a progesterone antagonist at the receptor level.”).

²⁶ Cristine Russell, *Chemical Found by French Could Lead to Monthly Birth Control Pill*, Washington Post (Apr. 20, 1982), <https://perma.cc/6VA5-5ZXJ>.

²⁷ Marja-Liisa Swahn & Marc Bygdeman, The effect of the anti-progestin RU486 on uterine contractility and sensitivity to prostaglandin and oxytocin, 95 BJOG: Int’l J. Obstet. & Gyn. 126-134, Feb. 1988, <https://t.ly/BI-OK>.

²⁸ Mary L. Davenport et al., *Embryo Survival After Mifepristone: A Systematic Review of the Literature*, 32 Issues L. & Med. 3 (2017), <https://perma.cc/9YXB-9HGR>.

²⁹ Cohen Decl. ¶ 9.

26. According to a scoping review (DeBeasi) published in July 2023, the continuing pregnancy rate for women who take mifepristone alone is generally 25% or less for gestational ages of 49 days or less.³⁰ This result is consistent with a 2017 paper (Davenport) that analyzed data from early mifepristone studies and concluded that the continuing pregnancy rate after mifepristone alone was up to 23%.³¹

27. Dr. Cohen's response to the DeBeasi study is to complain that the journal that published it is a publication of the Catholic Medical Association, and "not a journal that is typically utilized by OB/GYNs for dissemination of clinically relevant data."³² But whether a journal is devoted to the "dissemination" of OB-GYN clinical data is irrelevant to the strength or accuracy of a particular study. Indeed, numerous other non-OB-GYN journals—including *PLOS One*, on which Dr. Cohen serves as a reviewer³³—can and do publish articles of interest to OB-GYNs.

28. Dr. Cohen goes on to denigrate the credentials of the study author, Paul DeBeasi, complaining that he is "not a physician" and that he graduated from "a small Catholic university."³⁴ It is worth noting that Mr. DeBeasi is the former chief of research for Gartner, one of the most prestigious research organizations not just in the country, but in the world. And as Dr. Cohen also admits, "[t]he purpose of a scoping

³⁰ Paul L.C. DeBeasi, *Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review*, The Linacre Quarterly (July 2023), <https://perma.cc/27RP-8HU5>.

³¹ Davenport et al., *supra* note 28; see also Mitchell Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial*, 135(1) *Obstetrics & Gynecology* 158 (2020), <https://perma.cc/6H6B-KUXS> (estimating that "only 25%" of patients receiving mifepristone and placebo would have continuing pregnancies).

³² Cohen Decl. ¶ 31.

³³ *Id.* ¶ 3.

³⁴ *Id.* ¶ 31.

review is to *synthesize evidence*”—and she offers no critique of either the review’s data analysis (which is sound) or its conclusion confirming the 25% or less continuing pregnancy rate for women who take mifepristone alone.³⁵ Instead, she cites a statistic that appears to be irrelevant to a discussion of Mr. DeBeasi’s paper, from an article on outcomes following medication abortion.³⁶

29. Dr. Cohen’s claim that “as many as 46%” of women who take mifepristone without misoprostol will continue their pregnancies is not supported by solid data.³⁷ The 46% figure rests on a single study with important flaws (Zheng) that defined “persisting pregnancy” as “no expulsion of the conceptus” and “gradual” increase of serum or urine hCG.³⁸ The Zheng study failed to use an ultrasound to verify the presence of a living embryo—and thus failed to distinguish between a continuing pregnancy (i.e., a living fetus) and retained fetal and placental parts (i.e., an incomplete abortion) or ectopic pregnancy.³⁹ The 2017 Davenport paper carefully analyzed data from early mifepristone studies and concluded that the Zheng study was “not reliable for determining the rate of embryo survival.”⁴⁰

³⁵ *Id.* at ¶ 32 (emphasis added).

³⁶ *Id.* (citing Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121(1) *Obstetrics & Gynecology* 166-71 (2013) (Cohen Decl. Ex. P)).

³⁷ Cohen Decl. ¶ 9 (citing Zheng Shu-rang, *RU 486 (Mifepristone): Clinical Trials in China*, 149 *Acta Obstetrica Gynecologica Scand. Suppl.* 19, 21 (1989) (Cohen Decl. Ex. E)).

³⁸ Zheng Shu-rang, *RU 486 (Mifepristone): Clinical Trials in China*, 149 *Acta Obstetrica Gynecologica Scand. Suppl.* 19, 21 (1989) (Cohen Decl. Ex. E).

³⁹ DeBeasi, *supra* note 30.

⁴⁰ *See, e.g.*, Davenport et al., *supra* note 28; *cf.* Creinin et al., *supra* note 31 (estimating that “only 25%” of patients receiving mifepristone and placebo would have continuing pregnancies).

C. Abortion pill reversal

30. When a woman has taken mifepristone and then decides that she wishes to continue her pregnancy, it no longer makes sense for her to take misoprostol. The first step in halting the abortion pill process is for the patient not to take misoprostol.

31. Health care providers may then help the woman by prescribing progesterone in an attempt to overcome the progesterone-blocking effects of mifepristone and maintain the pregnancy. Administering progesterone in these circumstances is commonly known as “abortion pill reversal.”

32. Dr. Cohen opines at length about the importance of decisional certainty, claiming that it is “exceedingly rare” for women to change their mind about abortion, and that “somewhere between 0.005% and .3% of patients change their mind after taking mifepristone.”⁴¹ But the policy guideline paper she cites for that statistic—by Alice Mark of the National Abortion Federation—states that “[i]n most clinical trials of early medication abortion, *the number of subjects taking mifepristone without misoprostol is not reported.*”⁴² In other words, the statistic Dr. Cohen touts for the proposition that “patients ... rarely change their minds after taking mifepristone” derives

⁴¹ Cohen Decl. ¶ 11; *see also id.* ¶ 40 (“the data suggests far fewer than 1% of women elect to continue their pregnancies after taking mifepristone”).

⁴² Alice Mark et al., *When Patients Change Their Minds After Starting an Abortion: Guidance from the National Abortion Federation’s Clinical Policies Committee*, *Contraception* 101(5):283-285 (2020) (emphasis added), <https://perma.cc/JVL7-7SH9>.

from a policy guideline document disclosing that no such data is reported in most clinical trials.⁴³

33. Like most other uses of supplemental progesterone, the use of progesterone in abortion pill reversal is an “off-label” use.

34. The basic biochemical premise of abortion pill reversal is that the activity of a receptor antagonist can be inhibited by increasing the concentration of the receptor agonist.⁴⁴ Put differently, it is well established that the effect of competitive inhibitors (*e.g.*, mifepristone) that block substrates (*e.g.*, progesterone) can be thwarted by adding more substrate.⁴⁵ Abortion pill reversal—which involves administering a surplus of progesterone to outcompete the effects of the mifepristone—is modeled on these basic principles of biochemistry.

35. Counteracting the effects of a receptor antagonist by introducing higher doses of the receptor agonist is not a new idea. One example is treatment of carbon monoxide poisoning. In normal respiration, oxygen in the lungs binds to the hemoglobin

⁴³ Cohen Decl. at 5. Dr. Cohen further relies on the rigor of her own initial consultation with abortion patients, stating that she “ensure[s] they are not under duress, being coerced into obtaining an abortion, or uncertain about their decision,” and that she “take[s] a detailed history from the patient,” “screen[s] for risk factors for domestic violence,” and “separate[s] the patient” from any family members or intimate partners present “to make sure they are not being coerced or under threat of harm.” *Id.* ¶ 12. But even assuming all that is true, Dr. Cohen does not—and cannot—testify that comparable practices are followed in every clinic in Colorado. More importantly, Dr. Cohen fails to acknowledge that the FDA’s 2016 REMS for mifepristone “[r]emov[ed] ... the instruction that administration of misoprostol must be done in-clinic,” *i.e.*, in person with a physician. FDA Summary Review of 2016 Amendments at 2 (Mar. 29, 2016), <https://perma.cc/D2HE-KSD5>. It is simply not possible to follow the screening mechanisms Dr. Cohen identifies when the doctor-patient relationship is limited to a single telehealth appointment.

⁴⁴ See generally Barbara J. Pleuvry, *Receptors, agonists and antagonists*, 5 *Neurosurgical Anaesthesia and Intensive Care*, Pharmacology 350 (2004), <https://perma.cc/9N6R-X4XA>.

⁴⁵ See John W. Pelley, *Elsevier’s Integrated Review Biochemistry* (2d ed. 2011) 33-34, <https://perma.cc/4EVE-G6Y6>.

molecule in red blood cells in the lungs, and then is carried to tissues throughout the body. Carbon monoxide causes hypoxia (low oxygen) because it binds more tightly to hemoglobin than oxygen—its affinity for hemoglobin is more than 200 times that of oxygen.⁴⁶ But when a patient with carbon monoxide poisoning arrives in the emergency room, she is treated with high-flow oxygen therapy. That is because, even though carbon monoxide binds more tightly to hemoglobin than oxygen, carbon monoxide binding to the hemoglobin molecule is reversible. In other words, oxygen can effectively compete with, and outcompete, carbon monoxide for hemoglobin binding sites.

36. Dr. Cohen states that “there is no reliable scientific evidence supporting the use of exogenous progesterone to break mifepristone’s bind to the progesterone receptors.”⁴⁷ This statement is false. Below are some of the studies, from both the basic science and clinical literature, showing that progesterone can effectively compete with and outcompete mifepristone for progesterone binding sites.

37. Animal studies indicate that administering additional progesterone can counteract the effects of mifepristone. In 1989, researchers designed a study (Yamabe) to investigate “the role of progesterone in the maintenance of pregnancy” using a population of pregnant rats.⁴⁸ After four days, only 33.3% of the rats who received mife-

⁴⁶ Lindell K. Weaver, *Carbon Monoxide Poisoning*, 360(12) New Eng. J. Med. (2009), <https://perma.cc/D6AA-CTXB>.

⁴⁷ Cohen Decl. ¶ 17.

⁴⁸ Shingo Yamabe et al., *The Effect of RU486 and Progesterone on Luteal Function During Pregnancy*, 65 Folia Endocrinologica Japonica 497 (1989), <https://perma.cc/FY3C-ADAD>.

pristone remained pregnant—but 100% of the rats who were given progesterone simultaneously with mifepristone remained pregnant. The Yamabe study therefore indicates that progesterone can counteract mifepristone’s effectiveness in blocking progesterone receptors.

38. Another animal study (Camilleri & Sammut) published in July 2023 supports that same conclusion. Researchers designed a follow-on to the Yamabe study to evaluate the “non-simultaneous, subsequent administration” of progesterone following mifepristone in a population of pregnant rats.⁴⁹ No rats who received mifepristone alone at first-trimester human equivalent (approximately 4-6 weeks human gestation) remained pregnant, while 81.3% of rats who received mifepristone followed by progesterone at the same stage remained pregnant. The study concludes that “[t]he administration and actions of the natural agonist, progesterone, in the presence of the antagonist, mifepristone, appears to be in concordance with the literature and our understanding of the pharmacological functioning of reversible competitive antagonism, where sufficient levels of the agonist can override a given concentration of an antagonist.”⁵⁰

⁴⁹ Christina Camilleri & Stephen Sammut, *Progesterone-mediated reversal of mifepristone-induced pregnancy termination in a rat model: an exploratory investigation*, 13 Scientific Reports 10942 (2023), <https://perma.cc/4SAL-DDP3>.

⁵⁰ *Id.*

39. In 2012, Dr. George Delgado and Dr. Mary Davenport published a small case series that followed seven women who had taken mifepristone and then received progesterone therapy after seeking medical assistance to maintain their pregnancies.⁵¹ Four of the six women (66%) who completed the study carried their pregnancies to term and delivered live infants. No birth defects were observed.

40. A similar small case series out of Australia (Garratt & Turner) was published in the *European Journal of Contraceptive and Reproductive Health Care* in 2017.⁵² In that series, two out of three women (66%) who received progesterone therapy after ingesting mifepristone carried their pregnancies to term and delivered healthy live infants.

41. In 2018, Dr. George Delgado and his co-authors published a larger case series that followed 754 pregnant women who had taken mifepristone, but had not yet taken misoprostol, and were interested in reversing its effects. The 2018 study analyzed the charts of 547 women who had ingested mifepristone within the last 72 hours and then received progesterone therapy.⁵³ The study found an overall fetal survival rate of 48%.⁵⁴

⁵¹ George Delgado & Mary L. Davenport, *Progesterone use to reverse the effects of mifepristone*, 46 *Annals of Pharmacotherapy* 1723 (2012), <https://perma.cc/EKF3-R8QA>.

⁵² Deborah Garratt & Joseph V. Turner, *Progesterone for preventing pregnancy termination after initiation of medical abortion with mifepristone*, 22 *Eur. J. Contraceptive & Reprod. Health Care* 472 (2017), <https://perma.cc/WTG8-3DDX>.

⁵³ George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 *Issues L. & Med.* 21, 25-26 (2018), <https://perma.cc/4WZM-5EWU>.

⁵⁴ *Id.* at 26-27.

42. The 2018 Delgado study showed even higher survival rates when the patients were divided into treatment subgroups. The subgroup that received progesterone intramuscularly showed fetal survival rates of 64%, and the subgroup that received a high dose of oral progesterone followed by daily oral progesterone until the end of the first trimester had survival rates of 68%.⁵⁵

43. The 2018 Delgado study used data from a previous study as a historical control to determine how these fetal survival rates compared to those of women who took mifepristone alone. That data was derived from a systematic review, published by Dr. Davenport in 2017, that surveyed the existing literature on outcomes for women who had taken mifepristone but not misoprostol and found fetal survival rates that ranged from 10% to 23.3%.⁵⁶ In the 2018 study, Dr. Delgado and his co-authors chose to use a number for historical controls (25% survival) that was higher than Dr. Davenport's highest number (23.3% survival). Even so, the fetal survival rates for women who received progesterone therapy—48% up to 68%—compare favorably to the baseline number.

44. Notably, the 2018 Delgado study found no increased risk of birth defects after progesterone therapy. This result is consistent with other studies that have found no increased incidence in birth defects in infants born after exposure to mifepristone in

⁵⁵ *Id.* at 26-27.

⁵⁶ Davenport et al., *supra* note 28.

the first trimester.⁵⁷ The 2018 Delgado study also found that the rate of preterm delivery among women who received progesterone therapy was 2.7%, compared with a 10% average in the general population in the United States.⁵⁸

45. Even before the 2018 Delgado study was published, Dr. Harvey Kliman, the director of the reproductive and placental research unit at the Yale School of Medicine, told the *New York Times* that using progesterone to reverse the effects of mifepristone “makes biological sense” and is “totally feasible.”⁵⁹ Dr. Kliman further stated that “if one of his daughters came to him and said she had somehow accidentally taken mifepristone during pregnancy ... he would tell her to take 200 milligrams of progesterone three times a day for several days, just long enough for the mifepristone to leave her system: ‘I bet you it would work.’”⁶⁰

46. Even more telling is the 2020 ACOG joint practice bulletin. As discussed below, *infra* at ¶64, Dr. Cohen cites the joint bulletin in support of her claim that “there is no evidence suggesting that using progesterone after taking mifepristone increases the likelihood of a pregnancy continuing.”⁶¹ But that same bulletin also warns that “[p]atients who select depot medroxyprogesterone acetate (DMPA)” —a synthetic progesterone-like steroid—“for contraception should be counseled that administration of

⁵⁷ See, e.g., FDA, Mifeprex Label at 9, <https://perma.cc/JW69-KNND> (noting that no teratogenic effects have been noted in experiments with rats and mice).

⁵⁸ Delgado et al., *supra* note 53.

⁵⁹ Ruth Graham, *A New Front in the War Over Reproductive Rights: ‘Abortion-Pill Reversal’*, N.Y. Times, July 18, 2017, <https://perma.cc/CN75-8YEU>.

⁶⁰ *Id.*

⁶¹ Cohen Decl. ¶ 35 (citing Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 *Obstetrics & Gynecology* 1, 3 (2020) (Cohen Decl. Ex. S)).

DMPA on day 1 of the medication abortion regimen *may increase the risk of ongoing pregnancy*.”⁶² It goes on to state:

Concern has been raised that the immediate use of hormonal contraception that contains progestins could theoretically interfere with medication abortion efficacy ... DMPA injection at the time of mifepristone administration may slightly increase the risk of an ongoing pregnancy. In a randomized trial that evaluated the effects of DMPA injection timing on medication abortion outcomes, ongoing pregnancy was more common among those randomized to receive DMPA injection on the day of mifepristone administration compared with those who received DMPA at a follow-up visit (3.6% versus 0.9%; 90% CI, 2.7 [0.4–5.6]).⁶³

Thus, ACOG itself warns patients that using a progestin—a synthetic progesterone-like compound—on the same day as mifepristone decreases the effectiveness of mifepristone and “increase[s] the risk of ongoing pregnancy.” That warning is consistent with the overall body of scientific evidence that supports abortion pill reversal.

47. Finally, the same study cited by Dr. Cohen—and ACOG, and the National Abortion Federation, and many others—in support of alleged safety concerns about abortion pill reversal in fact shows progesterone’s effectiveness to reverse the effects of mifepristone. As discussed below, *infra* at ¶¶ 65-67, Dr. Mitchell Creinin attempted to conduct a randomized study on the “efficacy and safety” of abortion pill reversal.⁶⁴ The study was designed to enroll 40 pregnant women in two control groups—one receiving mifepristone followed by progesterone, and the other receiving mifepristone followed by a placebo. But the study was halted after 12 women were enrolled, and

⁶² Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 225: Medication Abortion up to 70 Days of Gestation*, 136 *Obstetrics & Gynecology* 1, 8 (2020) (emphasis added) (Cohen Decl. Ex. S).

⁶³ *Id.* at 8-9.

⁶⁴ Creinin et al., *supra* note 31.

only 10 women completed it. Notably, four of the five women (80%) in the progesterone group of the Creinin study successfully maintained their pregnancies, as documented by fetal cardiac activity. In contrast, only two of the women in the placebo group (40%) maintained their pregnancies. These results are also consistent with the overall body of scientific evidence that supports abortion pill reversal.

D. Dr. Cohen’s summary of the scientific evidence is selective and inaccurate

48. Dr. Cohen opines that “there is no scientific support for so-called ‘medication abortion reversal.’”⁶⁵ But she bases this erroneous conclusion on an incomplete review of the relevant literature and a selective and inaccurate summary of the scientific evidence.

49. Notably, Dr. Cohen does not acknowledge—much less dispute—the animal studies indicating that progesterone can counteract the effects of mifepristone, or the Australian case series, or the efficacy results of the Creinin study. Nor does she address the ACOG Practice Bulletin warning that use of a progestin on the same day as mifepristone “increase[s] the risk of ongoing pregnancy.” And as noted above at ¶¶ 16-17, her attempt to downplay the effects of progesterone in the PRISM study misreads the relevant results and is rebutted by the PRISM authors themselves.

50. Instead, Dr. Cohen focuses all of her attention and criticisms on the two studies by Dr. George Delgado. These critiques—many of which are flawed or overstated or both—fail to show that there is “no scientific support” for abortion pill reversal.⁶⁶

⁶⁵ Cohen Decl. at 8 (cleaned up).

⁶⁶ *Id.* at 8; *id.* ¶¶ 15, 18-30.

51. To begin, many of Dr. Cohen’s critiques boil down to the fact that Dr. Delgado’s studies are case series rather than randomized controlled trials. In a randomized controlled trial, study participants are carefully selected to minimize differences between patient groups. They are then randomly assigned either to a treatment group or a control group. The treatment group receives the treatment at issue, and the control group receives either a placebo or standard treatment. By contrast, a case series involves a collection of reports on the treatment of individual patients with the same condition. A randomized controlled trial is generally considered the “gold standard” in medical research.

52. In some clinical situations, case series and observational studies are the only appropriate source of data, since randomizing one group of patients to a placebo would be unethical. For example, it would be unethical to use a placebo arm in a study of abortion pill reversal where the women have ingested mifepristone but then decided to continue their pregnancies.

53. Physicians can and do use the results of case series to integrate innovative therapeutic treatments into their practices. Case series are commonly used in studies involving pregnant women. Many drugs used in obstetrics and gynecology came into clinical usage based on data from case series. These include magnesium sulfate for prevention of preterm labor and eclampsia (seizures with high blood pressure in pregnancy); terbutaline for prevention of preterm birth; nifedipine for prevention of preterm birth; hydralazine for control of hypertension in pregnancy; and methotrexate for treatment of ectopic pregnancy, among others. Notably, mifepristone itself was

approved by the FDA based on non-blinded, non-randomized studies.⁶⁷ None of these studies were randomized controlled trials.

54. Dr. Cohen critiques the 2012 Delgado study because “[a] six-person sample size is far too small to draw any statistically significant generalizations.”⁶⁸ But the 2012 Delgado study, like most case series, does not present any statistical analyses.

55. Dr. Cohen further claims that the 2018 Delgado study failed to “adhere[] to any ethical and regulatory standards of clinical trials,” failed to “use a concurrent control group,” and failed to use a single progesterone regimen.⁶⁹ But the 2018 Delgado study was not a “clinical trial[].” Rather, the study makes clear that its analysis is based on data collected from the abortion pill reversal hotline: “Subjects called an informational hotline linked to an informational website and staffed by nurses and a physician assistant. After receiving information about the reversal process, those who decided to proceed with reversal were referred to physicians and mid-level practitioners in their respective geographic areas for treatment.”⁷⁰ The study did not use a concurrent control group because it was not a case-control study. And because the authors were collecting real-world data on different protocols in use, it is not surprising that different regimens were included.

⁶⁷ Irving M. Spitz et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338(18) N. Eng. J. Med. 1241 (1998), <https://perma.cc/P2RV-C6GC>.

⁶⁸ Cohen Decl. ¶ 19.

⁶⁹ See, e.g., *id.* ¶¶ 20, 25, 29-30.

⁷⁰ Delgado et al., *supra* note 53.

56. Dr. Cohen further states that Dr. Delgado and his co-authors originally labeled the 2018 study an “observational case study,” which she claims—without citation—is “not a study design generally used in medical research.”⁷¹ This is not true. The term “observational case study” is a legitimate study design documented in the medical literature.⁷²

57. Dr. Cohen further alleges “selection bias” because patients were included in the Delgado studies after an ultrasound screening confirmed a living embryo prior to the first progesterone dose.⁷³ But the purpose of the studies was to evaluate the use of progesterone in reversing the effects of mifepristone and continuing the pregnancy. It would make no sense to administer progesterone to a woman with a dead embryo or to include those patients in the analysis.

58. Dr. Cohen also criticizes the Institutional Review Board (IRB) approval of the 2018 Delgado study.⁷⁴ But the final version of the 2018 Delgado study clearly states that “[t]he study was reviewed and approved by an institutional review board.”⁷⁵

⁷¹ Cohen Decl. ¶ 24.

⁷² See, e.g., Sonya J. Morgan et al., *Case Study Observational Research: A Framework for Conducting Case Study Research Where Observation Data Are the Focus*, 27 Qualitative Health Rsch. 1060, 1060-1068 (2017), <https://perma.cc/QN9Z-P48E>; Assad A Rezigalla, *Observational Study Designs: Synopsis for Selecting an Appropriate Study Design*, 12 Cureus (2020), <https://perma.cc/5UT2-EBVM>; Julia FM Gilmartin-Thomas et al., *Observational studies and their utility for practice*, 41 Australian Prescriber 82 (2018), <https://perma.cc/UR2X-VZZH>.

⁷³ Cohen Decl. ¶¶ 21, 30.

⁷⁴ *Id.* ¶ 26.

⁷⁵ Delgado et al., *supra* note 53.

59. I disagree with Dr. Cohen’s statement that the 2018 Delgado study “violated several ethical standards of medical research.”⁷⁶ She does not state what those violations are. Based on my decades of experience as a reviewer and IRB member, I see no ethical violations in this research, which is a straightforward observational case series.

60. After criticizing the Delgado studies—and ignoring the balance of the scientific evidence—Dr. Cohen proceeds to cite two studies by Dr. Daniel Grossman for the proposition that “[s]cientifically valid research finds insufficient data to support progesterone therapy over expectant management.”⁷⁷ Neither of the cited studies supports this conclusion.

61. To begin, Dr. Grossman’s 2015 literature review concluded that the “evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.”⁷⁸ But that conclusion was based solely on an analysis of the 2012 Delgado study, which of course predates the 2017 Australian study, the 2018 Delgado study, the 2020 PRISM study, the 2020 Creinin study, the 2023 DeBiasi study, and the 2023 Camilleri & Sammut study.

62. Moreover, Dr. Grossman’s conclusion—that there was insufficient evidence to show that progesterone therapy improved fetal survival—was based on the reportedly

⁷⁶ Cohen Decl. ¶ 28.

⁷⁷ *Id.* at 16.

⁷⁸ Daniel Grossman et al., *Continuing Pregnancy after Mifepristone and “Reversal” of First-Trimester Medical Abortion: A Systematic Review*, 92(3) *Contraception* 206 (2015), <https://perma.cc/ZPB5-KKNY>.

high continuing pregnancy rates from a series of studies in the 1980s. Based on these studies, Dr. Grossman claimed that the continuing pregnancy rate for women who take mifepristone alone is up to 46%.⁷⁹ But Dr. Grossman’s “systematic review” of 11 studies included four studies—among them the Zheng study discussed *supra* at ¶ 29—that failed to distinguish between continuing pregnancy and retained “products of conception” (*i.e.*, an incomplete abortion).⁸⁰ In other words: four of the 11 studies included in Dr. Grossman’s literature review estimated embryo survival rates without using an ultrasound to verify the presence of a living embryo. Further, Dr. Grossman failed to include five more studies that *did* report on whether there was a live embryo after the use of mifepristone.⁸¹ These methodological flaws seriously undermine both Dr. Grossman’s estimates of continuing pregnancy rate and his evaluation of the efficacy of progesterone therapy relative to expectant management following mifepristone.⁸²

63. Dr. Cohen then states that “Dr. Grossman published a second article, this time in the *New England Journal of Medicine*.”⁸³ She fails to note that this piece was

⁷⁹ *Id.* at 208.

⁸⁰ DeBeasi, *supra* note 30.

⁸¹ Davenport et al., *supra* note 28.

⁸² Dr. Cohen touts *Contraception*, the journal in which the 2015 Grossman review was published, as a “highly cited journal regularly relied upon by OB/GYNs and clinicians in the reproductive health field.” Cohen Decl. ¶ 33. She fails to mention that it is the official journal of the Society of Family Planning, which is openly committed to a “vision of just and equitable abortion” and has signed onto numerous amicus briefs in court cases concerning abortion access. Society of Family Planning, *Diversity, Equity, and Inclusion*, <https://perma.cc/G69Q-HN99>. Nor does she mention that Dr. Grossman has served as a paid advisor to Planned Parenthood. Daniel Grossman ICMJE Form for Disclosure of Potential Conflicts of Interest, May 23, 2018, at 2-3, <https://perma.cc/V7GZ-3SXQ>.

⁸³ Cohen Decl. ¶ 34 (citing Daniel Grossman & Kari White, *Abortion “Reversal”—Legislating Without Evidence*, 379(16) N. Eng. J. Med. 1401 (2018) (Cohen Decl. Ex.Q)).

published in the “Perspective” section of the journal—and is therefore clinical commentary or opinion, not a research study. In the article, Dr. Grossman criticizes various aspects of the 2018 Delgado study. He goes on to claim that “a randomized, placebo-controlled trial is the most appropriate study design” for research on abortion pill reversal—with no apparent concern for the ethical problems posed by assigning women who wish to continue their pregnancies to a placebo group.⁸⁴

64. Dr. Cohen cites a joint practice bulletin from ACOG and the Society of Family Planning and the National Abortion Federation clinical policy guidelines as further support for her opinions.⁸⁵ Both publications claim that there is “no evidence” that using progesterone after taking mifepristone increases the likelihood of a continuing pregnancy.⁸⁶ But both rely exclusively on Grossman’s 2015 study (critiqued above at ¶¶ 61-62) and Creinin’s 2020 study (discussed below at ¶¶ 65-67) and address none of the other relevant literature.

65. Dr. Cohen next claims that the *other* off-label uses of progesterone “that meet generally accepted standards of medical practice have been subjected to the research, data collection, analysis, and reporting in journals commonly relied upon by practitioners.”⁸⁷ But she does not identify which of the many off-label uses are “generally accepted” in her view and which are not. The only example she offers is “the study

⁸⁴ Daniel Grossman & Kari White, *Abortion “Reversal”—Legislating Without Evidence*, 379(16) N. Eng. J. Med. 1401, 1493 (2018), <https://perma.cc/8XAV-CQ7A>.

⁸⁵ Cohen Decl. ¶ 35.

⁸⁶ Am. Coll. of Obstetricians & Gynecologists, Practice Bulletin No. 225, *Medication Abortion up to 70 Days of Gestation*, 136 *Obstetrics & Gynecology* 1, 3 (2020) (Cohen Decl. Ex. S); 5 Nat’l Abortion Fed’n, *Clinical Policy Guidelines for Abortion Care* 18 (2020) (Cohen Decl. Ex. T).

⁸⁷ Cohen Decl. ¶ 36.

[that] ... specifically explored the efficacy of progesterone for patients with threatened miscarriages in the first trimester”—an apparent reference to PRISM, the same study she previously misread as finding no statistical significance for progesterone therapy in patients with threatened miscarriage.⁸⁸ Moreover, Dr. Cohen is wrong to suggest that all other off-label uses for progesterone were subjected to randomized controlled trials prior to widespread use within obstetrics. For example, OB-GYNs began using progesterone in the 1940s, long before any clinical trials were conducted. The assertion that off-label drugs can only be legitimately used after clinical trials have been performed is false. Finally, Dr. Cohen claims that a 2020 study by Dr. Mitchell Creinin raised “significant safety concerns.”⁸⁹ Dr. Creinin attempted to conduct a randomized study on the “efficacy and safety” of abortion pill reversal. The study was designed to enroll 40 pregnant women in two control groups—one receiving mifepristone followed by progesterone, and the other receiving mifepristone followed by a placebo. But Dr. Creinin stopped the study after 12 women were enrolled, and only 10 women completed it.

66. Dr. Cohen obliquely claims that the Creinin study was halted “because three participants experienced severe hemorrhage that required emergency medical care.”⁹⁰ What she fails to mention is that two of those women were in the placebo group, so the only drug they had received was mifepristone. Those women required emergency curettage/suction procedures to control bleeding, and one of them required

⁸⁸ *Id.* ¶ 36 (referring to “the study described in paragraph 15 above”); *see id.* ¶ 16.

⁸⁹ Cohen Decl. ¶ 37 (citing Creinin et al., *supra* note 31).

⁹⁰ Cohen Decl. ¶ 38.

a blood transfusion. But for the one woman who had received progesterone and had significant bleeding, no intervention was required.⁹¹ Nowhere in the study does Dr. Creinin contend that progesterone itself is the danger, focusing instead on the purported danger of not taking misoprostol.

67. What Dr. Cohen also fails to mention is that four of the five women (80%) in the progesterone group of the Creinin study successfully maintained their pregnancies, as documented by fetal cardiac activity. In contrast, only two of the women in the placebo group (40%) maintained their pregnancies. These results directly undermine her conclusion that progesterone therapy is “no more effective than watchful waiting.”⁹²

68. In summary, there is scientific evidence that supports the clinical use of progesterone to counteract the effects of mifepristone. Progesterone in a variety of formulations has well established clinical uses and an extensive track record of safety and is used off label for several clinical purposes. Multiple studies over time have evaluated the use of progesterone to prevent or treat unexplained recurrent miscarriage or early pregnancy bleeding. Research indicates that the continuing pregnancy rate after mifepristone alone for abortion is 23-25%. There is evidence that abortion pill reversal is a safe and effective option for women who change their minds after ingesting mifepristone for abortion. Abortion pill reversal is based on sound basic science and biochemistry and evidence suggests that it is safe and reduces the risk of

⁹¹ Creinin et al., *supra* note 31 (“Heavy bleeding lasted about 3 hours overall, and no intervention was needed.”).

⁹² Cohen Decl. ¶ 40.

completed induced abortion after mifepristone alone. Importantly, evidence suggests that abortion pill reversal is a compassionate, safe, and effective response to support a woman's reproductive autonomy as well as her desire to keep her child.

69. Based on the foregoing, I conclude that there is scientific evidence to support the use of progesterone to reverse the effects of mifepristone.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on this 9 day of October, 2023.



Monique Chireau Wubbenhorst

Attachment A

CURRICULUM VITAE

Updated: 4-04-2023

Name: Monique Chireau Wubbenhorst, MD, MPH, FACOG, FAHA
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Medical licensure: North Carolina License # XXXXXX, 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:

<u>Institution</u>	<u>Degree</u>	<u>Date (Year)</u>
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):

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

Past and Present Hospital and Clinical Affiliations:

<u>Institution</u>	<u>Position/Title</u>	<u>Dates</u>
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 (<i>locum tenens</i>)	1998-1999
Mt. Auburn Hospital Cambridge, MA	Staff obstetrician-gynecologist (<i>locum tenens</i>)	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 (<i>locum tenens</i>)	2000-2017
Chinle Indian Hospital Chinle, AZ	Staff obstetrician-gynecologist (<i>locum tenens</i>)	2000
Fallon Clinic Leominster, MA	Staff obstetrician-gynecologist (<i>locum tenens</i>)	2000-2001
WW Hastings Indian Hospital Tahlequah, OK	Staff obstetrician-gynecologist (<i>locum tenens</i>)	2001-2002
Alamance Regional Hospital Burlington, NC	Staff obstetrician-gynecologist (<i>locum tenens</i>)	2003
Pine Ridge Indian Hospital Pine Ridge, SD	Staff obstetrician-gynecologist (<i>locum tenens</i>)	2003
Rosebud Indian Hospital Rosebud, SD	Staff obstetrician-gynecologist (<i>locum tenens</i>)	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 (<i>locum tenens</i>)	2005-2014
Chowan Hospital Edenton, NC	Staff obstetrician-gynecologist (<i>locum tenens</i>)	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

Publications:

1. Refereed journals:

1. Harrison D, Buskmiller C, **Chireau M**, Ruppertsberger 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, Guadalajara, 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) <i>ad hoc</i> 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, <i>pLOS 1</i>
2014-2018	Member, Advisory Committee for Arts, Sciences and University Transfer, Durham Technical Community College, Durham, NC
2013-2018	Reviewer, <i>Public Health</i>
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, <i>Issues in Law and Medicine</i>
2021-	Reviewer, <i>Journal of Medical Ethics</i>

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.
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- 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.
- 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:

On sabbatical

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