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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026-TOR DECLARATION OF COURTNEY SCHREIBER, M.D., M.P.H.

I, Courtney Schreiber, M.D., M.P.H., declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am a board-certified obstetrician/gynecologist and a Professor in the Department of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania. I am also a Fellow of the American College of Obstetricians and Gynecologists ("ACOG"), the nation's leading group of physicians providing health care for women, which has more than 58,000 members representing more than 90% of all obstetrician/gynecologists in the United States. At Penn Medicine and the Perelman School of Medicine, I am Chief of the Division of Family Planning, the Program Director of the Fellowship in Family Planning and the Clinical Director of the Pregnancy Early Access Center ("PEACE"), and an attending physician at the Hospital of the University of Pennsylvania. In addition to being an obstetrician/gynecologist, I hold a master's degree in public health with a concentration in epidemiology (the study of the incidence, distribution, and possible control of diseases and other factors relating to health).

3. I am licensed to practice in the State of Pennsylvania. I am board certified in both Obstetrics and Gynecology and Complex Family Planning (American Board of OBGYN).

4. I have published over 90 peer-reviewed research articles on a wide range of reproductive health issues. In addition, I have been the principal investigator or co-investigator on approximately 60 research studies relating to

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early pregnancy, abortion, pregnancy loss (miscarriage), contraception, and sexually transmitted infections.

5. I currently serve on the editorial board of *Contraception*, and serve or have served as a reviewer for *Fertility and Sterility*, *Pharmacoepidemiology*, and the *American Journal of Obstetrics and Gynecology*. A copy of my curriculum vitae is attached hereto as Exhibit A.

6. At Penn Medicine, I provide both clinical and didactic (i.e., lectures) training to medical students as well as residents in obstetrics/gynecology and family medicine, among other specialties. Among the subjects I teach is abortion, training students and residents in both medication and surgical abortion methods. In addition, as Director of the Fellowship in Family Planning at Penn, I teach advanced family planning and abortion techniques to doctors who have completed their residencies and want to further specialize in this area.

7. I am an expert in the provision of abortion services, having provided this procedure for over 5,000 patients as an integral component of my practice. I use a variety of abortion techniques, including medication abortion, vacuum aspiration, and dilation and evacuation. I provide a wide spectrum of general gynecology care and have particular expertise in contraceptive management as well as care for early pregnancy loss. This has been my practice as an attending physician for 18 years at the Perelman School of Medicine.

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Abortion Care in the United States

8. Abortion is one of the safest and most common outpatient services provided in the United States. Approximately one in four women in the United States will have an abortion by age 45.[1]

9. Carrying a pregnancy to term carries much higher risks of both morbidity and mortality than abortion. A patient's risk of death associated with continued pregnancy and childbirth is approximately 14 times higher than the risk of death associated with abortion.[2] The mortality rate for abortion is also much lower than that for other outpatient procedures, such as colonoscopy and tonsillectomy, both of which have a mortality rate more than four times higher than the rate associated with abortion.[3]

10. As indicated above, there are both surgical and non-surgical (i.e., medication) abortion methods available in the United States. While abortion is extremely safe, medication abortion is safer and/or preferable for some patients given their individual circumstances. The best (and FDA-approved) regimen of

[1] Guttmacher Inst., Induced Abortion in the United States (Sept. 2019), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states (last visited March 14, 2023). I use the term "women" in this report to refer to patients seeking abortion care, but note that gender non-binary and transgender patients also use these services.

[2] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (2012).

[3] Committee on Reproductive Health Servs., Health and Med. Division, *The Safety and Quality of Abortion Care in the United States*, Nat'l Acad. of Sci., Engineering, and Med. 75 (2018), https://doi.org/10.17226/29450.

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medication abortion for early pregnancies entails taking two medications: mifepristone (also known as RU-486 or by its trade name in the U.S., Mifeprex) and misoprostol (available as a generic or under the brand name Cytotec®). Together they cause the patient to undergo a pregnancy termination within a predictable period of time. The process is very similar to an early miscarriage.

11. As detailed below, the FDA subjects Mifeprex and its generic to a Risk Evaluation and Mitigation Strategy ("REMS") that significantly limits where and how patients can obtain it. By contrast, misoprostol—which is part of the FDA-approved regimen for medication abortion listed on the Mifeprex label, although it is itself labeled only for ulcer treatment—is not subject to a REMS. Misoprostol is available by prescription at retail and mail-order pharmacies. Misoprostol alone is also an abortifacient, but the combination of the two drugs is a superior regimen.

12. The great majority of abortions in the United States occur in the first 70 days of pregnancy (as dated from the first day of a patient's last menstrual period, or "LMP"). Medication abortion with the mifepristone-misoprostol combination now accounts for more than half of all abortions in the United

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States.[4] Since the FDA approved Mifeprex in 2000, more than four million women in the U.S. have used this medication to end an early pregnancy.[5]

The Medication Abortion Regimen

13. I am familiar with the drug mifepristone. I prescribe mifepristone for my patients and have done so since approximately 2003.

14. I understand that the U.S. Food and Drug Administration ("FDA") subjects Mifeprex® (as well as its generic counterpart) to REMS, including Elements to Assure Safe Use ("ETASU"), which restricts how, where, and by whom the drug can be distributed. I use "Mifeprex REMS" as shorthand to refer to both the REMS and the ETASU it includes, for both Mifeprex and its generic counterpart.[6]

15. The Mifeprex REMS provides no medical or safety benefit. I base this opinion on my expertise in the fields of obstetrics and gynecology; my experience providing a broad range of reproductive health care, including abortions; my expertise as a clinical researcher in the field of reproduction; and my familiarity with the body of scientific literature concerning medication abortion.

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[4] Rachel K. Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, Guttmacher Inst. (Feb. 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions (last visited March 14, 2023).

[5] *Mifeprex Effectiveness & Advantages*, Danco Laboratories, LLC (last visited March 14, 2023), https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/.

[6] The FDA regulates both Mifeprex and its generic, Mifepristone, identically.

16. The labeling for Mifeprex that the FDA approved in 2016 outlines an evidence-based regimen for medication abortion with mifepristone and misoprostol: On day 1, at a location of her choosing, the patient takes 200 mg of mifepristone orally; 24 to 48 hours later, and also at a location of her choosing, the patient takes 800 mcg of misoprostol buccally (i.e., she lets it dissolve in her mouth, in the pocket of her cheek). The success rate for medication abortion in the U.S. using this protocol is above 95%.[7] As the FDA emphasized in the updated 2016 label, clinical trials have demonstrated that this protocol is safe and extremely effective through 70 days LMP.[8] ACOG, the nation's leading professional association of physicians providing health care for women, has endorsed the dosage, timing, and route of administration of this regimen,[9] and this is the regimen I use to provide early medication abortion and miscarriage management in my own practice and in my teaching. It is the standard of care.

17. When used in a medication abortion, mifepristone blocks the body's receptors for progesterone, a hormone necessary to sustain pregnancy, which

[7] Committee on Practice Bulletins – Gynecology and the Society of Family Planning, *Practice Bulletin Number 143: Medical Management of First-Trimester Abortion*, American College of Obstetricians and Gynecologists 7 (Mar. 2014), https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins----Gynecology/Public/pb143.pdf; BeverlyWinikoff et al., *Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial*, 112 Obstetrics & Gynecology 1303-10 (2008); *see also* Eric A. Schaff et al., *Comparison of misoprostol plasma concentrations following buccal and sublingual administration*, 71 Contraception 225 (2005).

[8] Danco Laboratories, LLC, *Mifeprex (mifepristone) Medication Guide* (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (detailing studies regarding the safe and effective use of Mifeprex through 70 days LMP).

[9] *Practice Bulletin Number 143*, *supra* note 7.

prompts the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall.[10] Mifepristone also triggers the body to release endogenous prostaglandins that soften and open the cervix,[11] and increases uterine contractility (capacity to contract).[12]

18. Misoprostol is a prostaglandin which, on its own, causes uterine contractions that expel the contents of the uterus. Misoprostol is capable of causing an abortion even without Mifeprex, and is also used to empty the uterus in cases of miscarriage. Some providers offer misoprostol alone to patients as a means of pregnancy termination if they cannot access Mifeprex, or if a contraindication for Mifeprex is present (which is relatively rare). But as explained below, uniform medical opinion is that the superior regimen, in terms of both safety and efficacy, combines the two medications.

19. In combination, mifepristone and misoprostol work synergistically to terminate an early pregnancy with high efficacy.[13] The mifepristone helps the pregnancy to detach from the endometrial lining, and boosts the strength and

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[10] N.N. Sarkar, *Mifepristone: Bioavailability, Pharmokinetics, and Use-Effectiveness*, 101 European J. of Obstetrics & Gynecology and Reproductive Biology 113, 115-16 (2002); Regine Sitruk-Ware & Irving M. Spitz, *Pharmacological Properties of Mifepristone: Toxicology and Safety in Animal and Human Studies*, 68 Contraception 409, 410-11 (2003); Beatrice Couzinet et al., *Termination of Early Pregnancy by the Progesterone Antagonist RU486 (Mifepristone)*, 315 New England J. Med. 1565, 1568 (1986).

[11] Couzinet et al., *supra* note 10, at 1568; Christian Fiala & Kristina Gemzel-Danielsson, *Review of Medical Abortion Using Mifepristone in Combination With a Prostaglandin Analogue*, 74 Contraception 66, 76 (2006).

[12] Couzinet et al., *supra* note 10, at 1568; Fiala & Gemzel-Danielsson, *supra* note 11, at 68; Sitruk-Ware & Spitz, *supra* note 10, at 411-12.

[13] Fiala & Gemzel-Danielsson, *supra* note 11, at 66-67.

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efficacy of the contractions that misoprostol induces.[14] Mifepristone also prompts the body to release both natural prostaglandins and additional prostaglandin receptors, priming the body to respond to misoprostol, a synthetic prostaglandin. Hence, the combination of the two drugs is more likely than misoprostol alone to result in pregnancy termination and complete emptying of the uterus. For this reason, medical providers generally use the term "medication abortion" to refer not to either mifepristone or misoprostol on their own, but rather to the combination of the two drugs. As noted above, this is also how the FDA has approved the use of mifepristone for medication abortion.

No Medical or Safety Benefit Justifies the REMS

The Restrictions on Mifeprex

20. The Mifeprex REMS provides that a patient must receive the mifepristone prescription from a health care provider who has attested to their ability to safely prescribe mifepristone, and then either arranged to order and stock mifepristone in their health care facility or sends the prescription to a specially certified pharmacy. In addition, the patient must sign a "Patient Agreement" form confirming that she has received counseling on the risks associated with mifepristone.

[14] *Id*. at 66.

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Mifeprex is Safe

21. Hundreds of scientific studies, both cumulatively and on their own, demonstrate that mifepristone is an extremely safe drug. These studies include clinical trials, post-marketing studies, epidemiological studies, and real-world studies. These studies have tested mifepristone with a variety of formulations and doses, and have evaluated mifepristone used alone and in conjunction with other drugs, such as misoprostol. *All* of these studies concluded that mifepristone is extremely safe for clinical use.[15]

22. Mifepristone's chemical structure itself supports the conclusion that mifepristone is extremely safe. It is chemically similar to norethindrone, which was the original progestin formulation used in early oral contraceptive pills and which is still widely used today. Because it is so similar in structure to a widely used progestin, mifepristone is unlikely to be toxic to patients.

23. As the FDA labeling for Mifeprex discusses, cramping, uterine bleeding, and abdominal pain are expected in all medication abortion patients: Treatment with mifepristone and misoprostol is intended to cause uterine cramping and bleeding to induce pregnancy termination.[16]

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[15] *See, e.g.*, Elizabeth G. Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 Contraception 26, 32 (2013); Regina Kulier et al., *Medical methods for first trimester abortion*, Cochrane Database Sys. Rev. Issue 11 Article Number CD002855, 2 (2011); *Practice Bulletin Number 143*, *supra* note 7, at 11.

[16] That expected uterine bleeding, which is the intended result of the regimen, is distinct from heavy uterine bleeding, which is considered a complication if the amount of blood lost in the process of emptying the uterus is more than a person's body can tolerate, given that person's particular physiology.

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24. Any process that empties the pregnant uterus—medication abortion, surgical abortion, miscarriage (i.e., spontaneous abortion), or childbirth—poses the two categories of risk that the Mifeprex labeling identifies: "Serious or sometimes fatal infections or bleeding."[17] The Mifeprex labeling acknowledges that "rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth" and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and these events has been established."[18]

25. In other words, all pregnancy outcomes carry a risk of heavy bleeding and a risk of infection. Heavy bleeding typically results from the uterus not contracting well enough to compress blood vessels and stop bleeding at the site where the placenta was attached to the uterine wall; much less frequently, it occurs when strong contractions cause the uterine muscle to rupture as a result of a prior uterine scar. The typical cause of infection is that a miscarriage, surgical abortion, medication abortion, or childbirth does not completely empty the uterus, and the tissue that remains there becomes infected. As the FDA acknowledges, there is no evidence that Mifeprex *causes* either of these complications.[19]

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[17] Danco Laboratories, LLC, *supra* note 8, at 2.

[18] *Id*.

[19] The FDA has likewise acknowledged that there is no evidence that mifepristone caused the handful of deaths from *Clostridium sordelli* infection among medication abortion patients a number of years ago, and that the underlying pregnancy was a more plausible explanation. Letter from Janet Woodcock, M.D., Director, Ctr. for

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26. Moreover, according to the FDA, serious adverse events among Mifeprex patients are "exceedingly rare, generally far below 0.1% for any individual adverse event."[20]

27. The mifepristone-misoprostol regimen for early medical abortion otherwise carries a risk of very minor side effects, many of which are common among pregnant people, and which may not actually be caused by mifepristone use. For any FDA clinical trial, side effects are reported without any determination of causation. According to the FDA, the most commonly reported (i.e., occurring in more than 15% of patients) side effects following use of the mifepristone-misoprostol regimen are nausea, weakness, fever and/or chills, vomiting, headache, diarrhea, and dizziness.[21] These symptoms are common and non-dangerous, and can occur even without using medication. Further, mifepristone is a drug used as a treatment for pregnant patients, and many of the side effects listed on the Mifeprex label, such as headaches and nausea, are extremely common among pregnant patients. Thus, it is not surprising that patients using mifepristone might report experiencing nausea and/or headache around the time that they take mifepristone.

Drug Evaluation & Research, to Donna Harrison, M.D., et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex 25-26 n.69 (Mar. 29, 2016), https://www.regulations.gov/document?D=FDA-2002-P-0364-0002.

[20] Ctr. For Drug Evaluation & Res., *Application Number 020687Orig1s020: Medical Reviews* 47 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

[21] Danco Laboratories, LLC, *supra* note 8, at 7, Table 1.

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28. The Mifeprex labeling lists only a few contraindications: (1) a confirmed or suspected ectopic pregnancy (i.e., a pregnancy located outside the uterus); (2) chronic adrenal failure and/or long-term steroid therapy; (3) previous allergic reactions to mifepristone, misoprostol, or drugs with similar chemical compositions; (4) hemorrhagic disorders or concurrent use of anticoagulants (commonly known as "blood thinners"); and (5) inherited porphyrias, a type of rare blood disorder. All of these contraindications are easily ascertained by simply asking a patient about their medical history.[22]

29. There are no new or emerging safety concerns for mifepristone. Indeed, in 2016, the FDA dropped the REMS requirement that Mifeprex prescribers report serious adverse events other than death because such events were so rare and the safety profile for Mifeprex had remained stable for so long.

30. In sum, extensive data from the past two decades, including both clinical studies and mandatory reporting of serious adverse events for the more than four million U.S. women who have taken Mifeprex, demonstrate that Mifeprex does not have a risk profile warranting regulatory limitations on its prescription.

[22] *Practice Bulletin Number 143*, *supra* note 7, at 6.

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The FDA Does Not Impose a REMS for Less Safe Drugs, and Among Drugs with Comparable REMS, the Restrictions on Mifeprex are Uniquely Illogical

31. The FDA's differential treatment of Mifeprex is all the more apparent when Mifeprex is compared to drugs that pose similar or greater levels of risk, but for which the FDA does not impose a REMS.

32. First, Korlym® is another mifepristone product which the FDA has approved for the treatment of Cushing's syndrome under certain circumstances. Cushing's syndrome is a disorder that can result when the body produces too much of the cortisol hormone. When using mifepristone to treat Cushing's syndrome, patients take between one and four 300 mg tablets of mifepristone—1.5 to 6 times the recommended dose for Mifeprex—on a daily, long-term basis.

33. The most commonly reported side effects for Korlym are nausea, fatigue, headache, decreased blood potassium, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite, and endometrial hypertrophy (thickening of the uterine lining).[23] Unsurprisingly, the most commonly reported side effects for Mifeprex are very similar: nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.

34. Yet, Korlym is not subject to a REMS. Under a voluntary arrangement with the manufacturer, a patient's clinician submits a patient enrollment form and prescription for Korlym to a specialty pharmacy, which

[23] Corcept Therapeutics, Inc., *Korlym Prescribing Information*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf (last visited March 14, 2023).

delivers the drug to the patient's home. The patient is then responsible for taking the recommended dose every day at home according to their prescription.

35. In addition, other drugs that present similar or greater risks of bleeding than mifepristone are nonetheless unregulated by REMS. For example, warfarin (also known under the brand name Coumadin) is an anticoagulant (often referred to as a "blood thinner") commonly prescribed for patients with atrial fibrillation to reduce the risk of blood clot and stroke. Warfarin is what is referred to as a "first-line" drug because it is used by providers as a first line of defense. Like Korlym, it is often taken on a chronic (i.e., long-term) basis. Warfarin acts by decreasing the number of clotting factors in the blood, thereby reducing the likelihood of a blood clot forming. I often treat patients who take warfarin to address a variety of cardiovascular disorders, including atrial fibrillation and history of venous thromboembolism. Typically, first-line drugs achieve that status after having been shown to be highly effective with a relatively low risk of adverse effects. But despite its status as a first-line drug, warfarin's labeling carries a black box warning stating that it can cause "major or fatal bleeding."[24] For patients with certain underlying conditions, such as atrial fibrillation, the risk of such "major bleeding" is particularly high: for instance, among patients with atrial fibrillation, the incidence of "major bleeding" associated with warfarin

[24] Bristol-Myers Squibb Co., *Coumadin (warfarin sodium) Prescribing Information*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf (last visited March 14, 2023).

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ranged from 0.6% to 2.7% in clinical trials.[25] By comparison, the FDA acknowledges that for Mifeprex, the risk of any individual serious adverse event is exceedingly rare, and under 0.1%.[26]

36. Misoprostol, the second drug in the FDA-approved medical abortion regimen, does not have a REMS and is available by prescription at virtually any retail pharmacy. The disparate treatment of Mifeprex and misoprostol is counterintuitive given that misoprostol poses similar categories of risks as those associated with miscarriage, childbirth, surgical abortion, or Mifeprex.

37. The heightened regulation of Mifeprex is particularly medically unjustified given that the two drugs used in combination are more effective—and, in turn, safer—than misoprostol alone in evacuating the contents of a patient's uterus. Indeed, building on the robust body of evidence confirming the enhanced efficacy of the two-drug regimen in the context of early abortion care, I published a study in the New England Journal of Medicine ("NEJM") that evaluated the efficacy of the two-drug regimen in the context of early *miscarriage* care. The study concluded that misoprostol was likewise more successful in managing first-trimester pregnancy loss (i.e., in effectively completing the evacuation of all uterine contents) when patients received pretreatment with

[25] *Id.* at 24.

[26] Ctr. For Drug Evaluation & Res., *supra* note 20.

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mifepristone.[27] But, because the REMS limits access to Mifeprex, some clinicians are compelled to prescribe misoprostol alone for abortion and/or miscarriage care. As discussed above, while a misoprostol-only regimen is an option for medication abortions, the two-drug regimen of mifepristone-misoprostol remains the gold standard.

38. When a woman uses mifepristone and misoprostol together, the extremely rare complications of heavy bleeding or infection are significantly more likely to occur after she takes the misoprostol, rather than after she takes the Mifeprex alone. This is because, as discussed above, in the two-drug regimen, it is the misoprostol, not the mifepristone, that causes the uterus to contract and expel its contents. These contractions cause the bleeding and cramping that is the intended function of the medication abortion; in extremely rare cases, such contractions could result in heavy bleeding. Similarly, the very low risk of infection generally arises in the event that the misoprostol causes the patient's uterus to contract and expel *some but not all* of its contents.

39. Treating the patient with mifepristone before she takes the misoprostol likely *increases* the safety of medical uterine evacuation for miscarriage management and abortion care. While difficult to do a comparative safety study given the extremely low rates of serious adverse events with either the two-drug regimen or misoprostol alone, the evidence showing that the

[27] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New England J. Med. 2161 (2018).

mifepristone-misoprostol regimen is more effective than misoprostol alone carries clear implications for patient safety: Because the uterine lining has already started to separate and the body is more sensitive to misoprostol after mifepristone pretreatment, the uterine contractions caused by misoprostol are more productive, and the patient's uterus is evacuated more quickly. The less time it takes to evacuate a patient's uterus, the less likely she is to experience heavy bleeding. In the same way, because the mifepristone-misoprostol combination is more effective than misoprostol alone in *fully* evacuating the patient's uterus, it is less likely that the patient will retain any tissue in her uterus after the initial treatment. This, in turn, reduces the likelihood that she would need an additional intervention (such as a clinical procedure with instruments or an additional dosage of misoprostol) to complete the uterine evacuation, and reduces the risk of retained tissue that could lead to infection.

40. Based on my research and clinical experience, I cannot conceive of a situation in which a prescriber with access to Mifeprex would choose to prescribe misoprostol alone for a medication abortion or early miscarriage treatment, unless the patient had one of the relatively rare contraindications described above. If Mifeprex is removed from the market, I suspect the complications related to abortion will increase, and I am concerned that patients will commonly seek emergency care in the setting of incomplete abortion and other complications.

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41. The FDA's treatment of misoprostol underscores that Mifeprex's labeling alone should suffice to alert patients and providers to any potential risks, without the additional layer of REMS restrictions. Misoprostol's labeling notes "[p]elvic pain, retained placenta, severe genital bleeding, shock, fetal bradycardia, and fetal and maternal death have been reported" relating to the use of misoprostol, all of which are also risks endemic to childbirth, miscarriage or abortion. The misoprostol labeling also notes that the drug has abortifacient effects, but simply states that "[p]atients must be advised of the abortifacient property and warned not to give the drug to others."[28] In my medical opinion, the same approach to risk management would be appropriate for Mifeprex. In sum, the absence of any REMS for misoprostol, and the safety benefits that Mifeprex provides when compared to misoprostol alone, further undermine any rationale for the Mifeprex REMS.

Leading Medical and Public Health Authorities Support Eliminating the Mifeprex REMS

42. Leading medical and public health organizations support eliminating the Mifeprex REMS because it has no medical justification and burdens access. The American Medical Association and the American Academy of Family Physicians (AAFP) both passed resolutions in 2018 to support

[28] G.D. Searle & Co., *Cytotec (misoprostol) Medication Guide*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf (last visited March 14, 2023).

eliminating the Mifeprex REMS because it is medically unfounded.[29] AAFP resolved to engage in such efforts upon finding that "the REMS restrictions on mifepristone are not based on scientific evidence and cause significant barriers to accessing abortion care."[30]

43. I understand that medical and public health authorities were making such recommendations to the FDA before the agency reexamined and reimposed the Mifeprex REMS in March 2016. For instance, the American Public Health Association's Population, Reproductive, and Sexual Health Section joined a letter to the FDA in November 2015 recommending that the REMS be "discontinued in its entirety" because "the immense volume of data about and experience with mifepristone…have demonstrated that this drug is extremely safe and…standard professional labeling is clearly sufficient to ensure that its benefits outweigh its risks."[31] The same month, ACOG provided the FDA with a statement that the organization "finds evidence regarding the safety of the drug over the past 15 years of use in the United States to be a compelling argument for the removal or substantial modification of the [REMS]" and that the REMS are

[29] Congress of Delegates, American Acad. of Family Physicians, *Resolution No. 506 (Co-Sponsored C) Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* 2 (May 24, 2018), https://www.reproductiveaccess.org/wpcontent/uploads/2019/02/Resolution-No.-506-REMS.pdf; House of Delegates, American Med. Ass'n, *Memorial Resolutions Adopted Unanimously* (2018), https://www.amaassn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a18-resolutions.pdf.

[30] Congress of Delegates, *supra* note 29.

[31] Letter from Kelly Blanchard, President, Ibis Reproductive Health et al., to Robert M. Califf, Deputy Commissioner for Med. Products and Tobacco, & Janet Woodcock, Director of Ctr. for Drug Evaluation and Res., Food and Drug Admin. et al. 4 (Nov. 3, 2015) (Administrative Record (FDA 1248)).

"inappropriately unique to the provision of abortion and . . . mandate procedures and care that are not evidence-based."[32] And the Society of Family Planning signed on to a February 2016 letter to the FDA stating that "today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and [REMS]" and describing "the numerous burdens on patients' access to abortion care that would be greatly alleviated if the REMS were eliminated."[33]

44. The Mifeprex REMS as a whole is without medical justification, is arbitrary, and does nothing to promote the safe use of this medication.

None of the Individual REMS Elements Decreases the Risks of, or Facilitates the Treatment of, Mifeprex's Very Rare Complications

The Prescriber Agreement Requirement

45. Under the REMS, all clinicians who prescribe Mifeprex must be specially certified by completing a "prescriber agreement" and submitting it to the drug distributor or specially certified pharmacies.

46. The prescriber agreement requires the individual completing the form to certify that they meet certain qualifications for prescribing mifepristone.

[32] Letter from Hal C. Lawrence, III, Executive Vice President and Chief Executive Officer, American Congress of Obstetricians and Gynecologists, to Robert M. Califf, Deputy Commissioner for Med. Products and Tobacco & Janet Woodcock, Director of Ctr. for Drug Evaluation and Res., Food and Drug Admin. (Nov. 4, 2015) (Administrative Record (FDA 1264)).

[33] Letter from Advancing New Standards in Reproductive Health, Dep't of Obstetrics, Gynecology & Reproductive Sci., U.C. San Francisco et al., to Stephen Ostroff, Acting Commissioner of Food and Drugs, U.S. Food and Drug Admin. et al. 2 (Feb. 4, 2016) (Administrative Record (FDA 1255)).

Specifically, they must certify that they are able to accurately assess the duration of pregnancy, diagnose ectopic pregnancies, provide surgical intervention in the event of incomplete abortion and/or heavy bleeding or are able to make plans to provide care through others, and assure patient access to medical facilities equipped to provide blood transfusions and resuscitation. The individual must also certify that they have read and understood the distributor's prescribing information for mifepristone.

47. By signing the form, the individual also agrees to follow an enumerated list of guidelines for mifepristone use, which include: reviewing the patient agreement form with the patient, fully explaining the risks of the mifepristone treatment regimen, and answering any patient questions; signing and obtaining the patient's signature on the patient agreement form; providing the patient with a copy of the patient agreement form and mifepristone medication guide; placing the signed patient agreement form in the patient's medical record; recording the serial number from each package of mifepristone in each patient's medical record (if the provider dispenses mifepristone); and reporting deaths to the distributor by identifying the patient by a non-identifying patient reference and the serial number from each package of mifepristone. The individual completing the form must provide their name and medical license number, and the address and phone number for each facility where they intend to prescribe mifepristone.

48. The prescriber agreement is unnecessary for the safe provision of mifepristone and deters qualified clinicians from prescribing this medication.

49. *First*, clinicians are already governed by strict clinical, ethical, and legal standards, such as licensure requirements and scope of practice statutes, that direct the safe prescription and dispensing of any and all prescription drugs. It is a basic tenet of medical ethics and the regulation of clinical care that clinicians may prescribe a drug only if they have the skills to properly and safely do so, and only if they can ensure appropriate surveillance as needed. For example, the ACOG Code of Professional Ethics dictates that "the obstetrician-gynecologist should recognize the boundaries of his or her particular competencies and expertise and must provide only those services and use only those techniques for which he or she is qualified by education, training, and experience."[34] All clinicians are bound by analogous requirements, and any who fail to adhere to those ethical and legal standards risk license investigation and revocation by state licensure boards as well as medical malpractice liability. Thus, the FDA does not generally require any provider certification for clinicians to dispense drugs: there is no prescriber certification requirement for misoprostol, and even drugs that carry "black box" warnings from the FDA indicating that they present serious or life-threatening risks typically do not require special certification. A requirement

[34] *Code of Professional Ethics of the American College of Obstetricians and Gynecologists*, American College of Obstetricians and Gynecologists 2 (Dec. 2018), https://www.acog.org/About-ACOG/ACOG-Departments/Committees-and-Councils/Volunteer-Agreement/Code-of-Professional-Ethics-of-the-American-College-of-Obstetricians-and-Gynecologists.

that physicians self-certify that they are qualified to prescribe mifepristone does not enhance the preexisting protections that these ethical, legal, and clinical standards provide.

50. Even if in 2000, when the FDA first approved mifepristone, there was reason to fear that clinicians could not readily obtain training in providing early medication abortion, that is no longer the case. The procedure is common, and I am aware that clinicians can now obtain the needed training online.

51. Speaking from my extensive experience training residents in medication abortion, the provision of medication abortion does not require highly specialized clinical skills.

52. Within clinical training and competencies, it is relatively easy for a provider to determine an individual patient's eligibility for mifepristone. Typically, to determine eligibility for any medication, clinicians must review a predetermined list of a medication's indications and contraindications against a patient's self-reported medical history. This is an extremely common process among all clinicians. The additional clinical skills required to determine a patient's eligibility for mifepristone are skills common to any sort of care for pregnant patients. A clinician must determine whether a patient has an intrauterine pregnancy and assess how far along the pregnancy has progressed based on standard methods of evaluation such as an ultrasound, blood work, and/or the patient's self-reported history. When I train my own students in

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medication abortion, they learn these skills as threshold competencies for providing any treatment for pregnant patients. It is my understanding from years of attending national meetings and conferences that all or virtually all clinicians who care for pregnant patients and issue prescriptions as part of their scope of practice are trained in the skills of diagnosing an intrauterine pregnancy and dating the pregnancy.

53. Medication abortion and surgical abortion require the same diagnostic skills (diagnosing and dating an intrauterine pregnancy), but medication abortion does not require additional procedural skills. Thus, a clinician already trained in safely providing surgical abortion care can safely prescribe medication abortion after reading the mifepristone prescribing information and medication guide.

54. The same is true for clinicians trained in miscarriage management or prenatal care, who also have the skills necessary to diagnose and date a pregnancy and, of course, to prescribe a pill. All obstetrician-gynecologists and most if not all family practice, internal medicine, and emergency medicine physicians have these skills and clinical competencies, as do advanced practice registered nurses and physician assistants trained in caring for pregnant patients. And, if for some reason a clinician is not comfortable diagnosing and dating a pregnancy, they can easily obtain this information by ordering an ultrasound.

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55. Further, the requirement that the prescriber certify their ability to provide surgical intervention or ensure patient access to surgical intervention and blood transfusions and resuscitation, if necessary, is simply a requirement that the prescriber is able to refer a patient to the nearest Emergency Department. All clinicians are able to direct patients to emergency care as needed.

56. Similarly, all health providers are qualified to read and understand the prescribing information for mifepristone, just as they are all qualified to read and understand prescribing information for any drug.

57. *Second*, the prescriber agreement does not meaningfully enhance safety by requiring prescribers to certify that they will follow certain guidelines.

58. Requiring providers to agree to provide and discuss the patient agreement form and medication guide is essentially an additional layer on top of the existing requirement to provide informed consent. Laws and ethical standards already require abortion providers, like all clinicians, to obtain informed consent from patients before providing treatment, and every institution at which I have practiced medicine has mandatory protocols and processes in place to obtain patient informed consent. The prescriber agreement form is duplicative because it requires prescribers to certify that they will act in accordance with laws that already govern their conduct.

59. *Third*, the prescriber agreement requirement deters or restricts providers from providing medication abortion care. Because of anti-abortion

terrorism and harassment in the United States, many clinicians are concerned about filling out a form that may register or identify them as an abortion provider, fearing that doing so could expose them and their families to violence and/or harassment.

60. I have heard these concerns from colleagues at professional conferences. I have also had many one-on-one conversations with physicians who would like to implement mifepristone in their gynecological practices, but are concerned that by completing the prescriber agreement, they might enable anti-abortion activists to access their information and target them for harassment or worse.

61. When I discuss mifepristone with my students, they often vocalize concerns about completing the prescriber agreement and therefore adding their name to a list of abortion providers that could somehow be made public. As my students think about their future careers as physicians, they often discuss the tradeoffs between offering mifepristone, which is part of safe and effective patient care, and fulfilling the prescriber agreement requirement and potentially becoming the target of harassment and violence.

62. The prescriber agreement form is also problematic in the miscarriage management context. As noted earlier, I authored a study that concluded that misoprostol was more successful in managing first-trimester

pregnancy loss when patients received pretreatment with mifepristone.[35] Since the NEJM publication, the Mifeprex and misoprostol regimen has become the standard of care for miscarriage management. By adding mifepristone to the treatment regimen for early pregnancy loss, clinicians may be able to expedite the completion of the miscarriage and avoid having the patient undergo an invasive procedure to aspirate the contents of the uterus. In addition to the medical benefits of this more effective regimen, I and many other clinicians who have adopted this treatment since the publication of my study have observed a meaningful emotional and psychological benefit for our miscarriage patients, who are often experiencing acute grief and are eager to complete the process as quickly as possible so that they can begin to heal.

63. But miscarriage management is provided in a wide variety of clinical settings, by a wide variety of clinicians with various medical backgrounds. Because of fears of violence and harassment or individual views of abortion care, clinicians who seek to provide miscarriage management care may be deterred from prescribing mifepristone, even though it increases the safety and efficacy of misoprostol for miscarriage management, because of the requirement that they complete the prescriber agreement form identifying as an abortion provider.

[35] Schreiber et al., *supra* note 27.

64. Thus, by requiring providers to attest to their decision to prescribe mifepristone, the prescriber agreement requirement creates a barrier to providing mifepristone as part of safe, effective abortion care and miscarriage management.

The Patient Agreement Form

65. Under the REMS, a patient cannot receive mifepristone before completing and signing a "patient agreement form," a copy of which her provider must place in the medical record. The patient agreement form provides information about potential risks of mifepristone and general procedures for seeking any necessary follow-up care. The patient agreement form specifically discusses the use of mifepristone to terminate a pregnancy.

66. The FDA does not generally require patient agreement forms for prescription drugs, and does not require a patient agreement form for misoprostol.

67. As I stated above, informed consent laws and practices, as well as professional practice guidelines, already require that clinicians (1) provide patients with information on the nature and risks of treatment, alternatives to the treatment, and how to seek any necessary follow-up care (including how to address any complications), and then (2) obtain the patient's consent before providing any treatment. The patient agreement form is thus duplicative of standard (and legally mandated) informed consent procedures and creates unnecessary labor for the provider and patients without enhancing the informed consent process or decreasing the risk of complications.

68. Moreover, the counseling that clinicians provide as part of their informed consent process should be tailored to include *all* clinically relevant information specific to that patient, and *only* clinically relevant information, given the provider's actual practice and the specific patient's circumstances.

69. The patient agreement form does not enhance this informed consent—it undermines it by creating confusion, and in some cases even trauma, for patients.

70. The patient agreement form is based on the science that existed in 2016 and does not evolve alongside evidence-based clinical practice. It contains information that may be irrelevant to an individual patient and/or inconsistent with a clinician's practice or preferred counseling. It is understandably confusing for patients, and undermines the clinician-patient relationship, when their provider tells them one thing, but they must then sign an official FDA form saying something different.

71. For instance, many years before the 2016 Mifeprex label change and REMS approval, evidence confirmed that the 600 mg dosage of Mifeprex that the FDA originally authorized in 2000 was unnecessarily high. Off-label use of drugs—using a medication for a different indication or in a different regimen than that listed on an FDA-approved label, in accordance with the medical evidence—is extremely common and widely accepted within the United States health care system. Thus, for years, I and most other abortion providers utilized the superior

200 mg regimen instead. Nevertheless, we had to have our patients sign a form describing the 600 mg dosage, which understandably confused them and made some question whether to trust the medical judgment of their provider or of the FDA.

72. In some states, laws specific to abortion also require patients to complete yet another informed consent form, certifying that they have received certain state-mandated disclosures about abortion. The patient agreement form only adds to the confusion of patients in these states, who must participate in three informed consent processes before receiving care: the process clinicians go through in order to practice good, ethical medicine; the state-mandated process; and the REMS-mandated process.

73. The patient agreement form can be particularly distressing for patients using mifepristone for a non-abortion indication, including miscarriage management. As discussed above, pretreatment with mifepristone followed by misoprostol results in a higher likelihood of successful management of first trimester pregnancy loss than misoprostol alone. This is excellent news for patients, who in my experience often prefer to have their miscarriage managed through medication, and completed as quickly and effectively as possible. But the REMS requires my patients experiencing pregnancy loss to sign a document that states, inaccurately, that they are having an abortion. The patient agreement

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form thus creates confusion and potential distress for such patients and fails to reflect innovations in safe and effective patient care.

CONCLUSION

74. The Mifeprex REMS provides no medical benefit. There is no valid scientific reason for the FDA to single out this safe and effective medication for onerous restrictions. Far from improving patient care, the REMS diminishes it by erecting numerous barriers to the provision of abortion care that ultimately limit where medication abortion is available. For instance, a recent nationally representative survey of ACOG fellows (who are currently practicing, board certified obstetrician/gynecologists) found that only 14% of the 655 respondents reported providing medication abortion care during the past year, and those who had provided any abortion care were disproportionately located in urban areas. Of the approximately 86% of respondents who had not provided a medication abortion in the past year, 28% said they *would* – if it were just a matter of writing a prescription.[36] That is, they would do so, but for the REMS.

75. By reducing the number of providers offering the FDA-approved medication abortion regimen, the REMS forces many women to travel farther to access this care. That, in turn, delays their abortion care. While abortion is very safe, delay increases risk because the risks associated with abortion increase as pregnancy advances. Further, the experience of remaining pregnant after making

[36] Daniel Grossman et al., *Induced Abortion Provision Among a National Sample of Obstetrician–Gynecologists*, 133 Obstetrics & Gynecology 477-83 (2019).

the decision to have an abortion can have a tremendously negative impact on a patient's medical and emotional well-being. Abortion is also more expensive in the second trimester—both because the procedure is more costly and because it may require an overnight stay.

76. Some patients who are unable to access an abortion provider engage in potentially dangerous measures to try to self-induce an abortion. The FDA restrictions put safe medical care out of reach for patients in this country with no legitimate medical justification.

I declare under penalty of perjury under the laws of the Commonwealth of Pennsylvania and the United States of America that the foregoing is true and correct.

DATED this 19th day of March, 2023, at 8:29 am.

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

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EXHIBIT A

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 01/27/2023

Courtney Anne Schreiber, MD, MPH

Address: Department of Obstetrics and Gynecology
3737 Market Street, 12th floor
Philadelphia, PA 19104 United States

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

Education:

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

Postgraduate Training and Fellowship Appointments:

1999-2003	Resident, Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Philadelphia, PA
2003-2005	Fellow, Contraceptive Research and Family Planning, University of Pittsburgh, Dept of Obstetrics, Gynecology and Reproductive Sciences, Pittsburgh, PA
2013	Leading Success Certificate Program, Office of Organization Effectiveness, Perelman School of Medicine
2023	Dr. Edward S. Cooper Leadership Development Program., The Wharton School, University of Pennsylvania

Faculty Appointments:

2006-2014	Assistant Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2014-2020	Associate Professor of Obstetrics and Gynecology at the Hospital of the University of Pennsylvania, University of Pennsylvania School of Medicine
2020-present	Stuart and Emily B.H. Mudd Professor in Human Behavior and Reproduction, University of Pennsylvania School of Medicine

Hospital and/or Administrative Appointments:

2005-present	Attending in Obstetrics and Gynecology, Hospital of the University of Pennsylvania, Department of Obstetrics and

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

Other Appointments:

2015-present	Expert Witness, Center for Reproductive Rights
2015-present	Expert Witness, American Civil Liberties Union
2017-present	Expert Witness, Planned Parenthood Federation of America
2018-present	Research Director, Building Interdisciplinary Research Careers in Women's Health K-12 Program, Perelman School of Medicine, University of Pennsylvania
2018-present	Senior Fellow, Leonard Davis Institute of Health Economics (LDI Amplify dissemination training program, 2021)
2021-present	Executive Director, FOCUS on Health and Leadership for Women

Specialty Certification:

2007	Obstetrics and Gynecology, American Board of Obstetrics and Gynecology
2022	Complex Family Planning, American Board of Obstetrics and Gynecology

Licensure:

2003-present	Pennsylvania Medical Licensure

Awards, Honors and Membership in Honorary Societies:

1996	Reproductive Health Fellowship, Medical Students for Choice, San Francisco, CA
1998	National Abortion Federation Early Achievement Award
1999	Dr. Martin Gold Visionary Provider Award, Diana Foundation, NY, NY
1999	James E Constantine Award in Obstetrics and Gynecology, NYU School of Medicine
2001	Resident Teaching Award, Hospital of the University of Pennsylvania
2004	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Philip F. Williams Prize Award, American College of

	OB/GYN
2005	Donald F. Richardson Memorial Prize Paper Award Nominee, American College of Obstetricians and Gynecologists
2010	Women's Way Unsung Heroine Award: Turning Talk into Action
2011	The Penn Medicine "Penn Pearls" Award for Excellence in Teaching
2011	Emily B. Hartshorne Mudd Award for Contributions to the Field of Family Health
2015	Penn Center for Innovation Accelerator Award Phase I
2016	Penn Center for Innovation Accelerator Award Phase II
2019	Clinical Research Forum Top 10 Clinical Research Achievement Award
2020	Women's Medical Fund Abortion Hero Award (Awarded to PEACE) For Compassion, Dedication, and Resiliency
2022	Penn Medicine Difference Maker
2022	Penn Medicine Award for Excellent Service and Seamless Patient Care (Awarded to PEACE)

Memberships in Professional and Scientific Societies and Other Professional Activities:

National:

1995-1999	Medical Students for Choice (Board of Directors)
1997-2002	American Medical Women's Association
1997-present	Physicians for Reproductive Choice and Health (Board of Directors 1997-1999)
1999-present	American College of Obstetricians and Gynecologists (Physician Member, Committee on Health Care for Underserved Women (2012-13) Fellow (2002-present) Junior Fellow (1999-2008)
2001-2006	American Society for Reproductive Medicine
2003-2018	Association of Reproductive Health Professionals
2003-present	National Abortion Federation
2004-2012	American Public Health Association
2005-present	Society of Family Planning (Complex Family Planning Fellowship Executive Committee (Chair, 2017-2019)
2008-present	Peer Health Exchange (Curriculum Advisory Board)
2012-present	Center for Disease Control Teen Pregnancy Prevention Project, Family Planning

Council of Pennsylvania (Consultant)

2014 NIH (Study Section Reviewer: Female Contraceptive Development Program (U01)

2019-present American Board of Obstetrics and Gynecology (Member at Large, Board of Directors
Credentials Committee 2020-pesent
Audit Committee 2020-present
Certifying Examination Development Committee 2021-present)

2019-present American Board of Obstetrics and Gynecology (Complex Family Planning Committee Chair 2019
Complex Family Planning Division Chair 2020-present)

2019-present The Accreditation Council for Graduate Medical Education, Complex Family Planning Task Force

2021-Present American Association of Academic Medical Centers (AAMC) (Group on Women in Medicine Steering Committee (elected, 2022-present))

2021-present American Gynecological and Obstetrical Society (AGOS) (Steering Committee, Women First Research Coalition (WFRC) 2021-present)

Local:

2008-2016 Family Planning Council (Board Member of the Medical Committee)

2008-2016 Women's Medical Fund Medical Advisory Committee

2010-2016 American Civil Liberties Union of Pennsylvania, Clara Bell Duvall Reproductive Freedom Project (Advisory Council Member)

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

2021-Present Leonard Davis Institute, University of Pennsylvania Gender Equity Special Interest Group (Founder)

2021-Present Leonard Davis Institute, University of Pennsylvania Reproductive and Maternal Health Special Interest Group (Founder)

2022-Present Penn Medicine Post-Roe Task Force (Founder)

Editorial Positions:

2005-present	Reviewer, Contraception
2007-present	Reviewer, American Journal Obstetrics and Gynecology
2008-2010	Reviewer, Pharmacoepidemiology
2011-present	Associate Editor, Contraception

2017-present	Section Editor, Contraception, UpToDate
2018-present	Section Editor, Ectopic Pregnancy, UpToDate
2018-present	Deputy Editor, Contraception

Academic and Institutional Committees:

2002-2003	House Officer Committee, Hospital of the University of Pennsylvania
2005-2010	Resident Curriculum Development Committee
2009-2019	Operating Room Committee
2010-2012	Grant Reviewer Penn CFAR Pilot Grants Program
2011-2014	Chair, Management of Early Pregnancy Failure Working Group
2012-2018	Center for AIDS Research Committee on Women and HIV
2013-2018	Core Member, Women's Health Scholar Certificate
2014-2015	Member, Department of Obstetrics and Gynecology Executive Committee
2014-present	Medical School Admissions Interview Committee, Perelman School of Medicine of the University of Pennsylvania.
2018-2019	Member, Review Committee for the Department of Biostatistics, Epidemiology, and Informatics
2018-present	Department of Obstetrics and Gynecology Executive Committee
2022	Chair, Maternal-Fetal Medicine Division Chief Search Committee, PennMedicine
2022-Present	Leader, Post-Roe Task Force Penn Medicine

Major Academic and Clinical Teaching Responsibilities:

2002-2003	Organizer, Ob/Gyn resident journal club, Hospital of the University of Pennsylvania
2002-present	Lecturer, Ob/Gyn resident didactics and journal club
2005-2015	Lecture on Family Planning, Core Clinical Clerkship in Ob/Gyn (OG200), (8x/yr)
2005-2016	Faculty preceptor, Core Clinical Clerkship in Ob/Gyn (OG200), (1-2x/yr)
2006-2017	Lecturer "Contraception", Reproduction module (1 lecture/yr)
2006-2016	"Bridging the Gaps" Academic Mentor for one student each summer
2006-2017	Director, Family Planning Rotation for Ob/Gyn residents
2006-2017	Course Director, Family Planning and Abortion Care Elective (OG300), medical students
2006-2017	Small group discussion leader on abortion and contraception, Reproduction Module II (2 sessions/yr), medical students
2006-present	Attending Physician, Family Planning, supervise and teach medical students, residents, and fellows
2006-2016	Attending physician, Resident Gynecology service (4 weeks/yr)
2006-present	Research mentor for resident research projects
2006-2017	Lecture "Abortion," Reproduction Module II (1 lecture/yr), medical students
2006-2007	Mentor, Sabrina Sukhan, MD, Resident in Obstetrics and

	Gynecology "Is exposure to prenatal care associated with improved pregnancy outcomes and post-partum contraception continuation in a teenage population?"
2006	Hospital of The University of Pennsylvania Department of Obstetrics and Gynecology Grand Rounds: "The Characterization and Treatment of Early Pregnancy Failure"
2007	Division of Cardiology, University of Pennsylvania Medical Center, "Contraception in Women with Congenital Heart Disease",
2008-2010	Mentor, Monika Goyal, MD, Pediatric Emergency Fellow "Prevalence of Trichomonas vaginitis in a symptomatic adolescent ED population
2009-present	Program Director, Fellowship in Complex Family Planning
2010-2012	Fellowship Mentor: Sara Pentlicky, MD
2010-2013	Mentor, Holly Langmuir, MD, Resident in Obstetrics and Gynecology "Immediate postpartum IUD placement: a decision analysis"
2010-2013	Mentor, Peter Vasquez, MD, Resident in Obstetrics and Gynecology "Factors that decrease morbidity among women undergoing second trimester uterine evacuation at an urban academic medical center"
2010-2013	Mentor, Ericka Gibson, MD, Resident in Obstetrics and Gynecology "Risk Factors for pregnancy during contraceptive clinical trials"
2010-2012	Mentor, Sara Pentlicky, MD, Fellow in Family Planning "Weight Loss in the postpartum: impact of different contraceptive methods"
2010-2013	Mentor, Corina Tennant, MD, Resident in Obstetrics and Gynecology "Uptake, acceptability, and continuation of the Implanon contraceptive implant immediately postpartum in an urban medical center"
2011-2013	Mentor, Lily Pemberton, MD, Resident in Obstetrics and Gynecology "establishment of an academic family planning outpatient facility increases uptake of LARC among inner-city women"
2011-2017	Public Health Perspectives in Family Planning Instructor and course co-director (offered through the MPH program)
2011-2012	Doris Duke Clinical Research Fellowship Mentor (Mentee - Kelly Quinley - Awarded Society of Academic Emergency Medicine Medical Student Excellence Award)
2011-2013	Fellowship Mentor: Stephanie Sober, MD
2011	Mentor, Valerie Colleselli, medical student, University of Innsbruck, Austria "Medical management of early pregnancy failure (EPF): a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice"
2012-2014	Fellowship Mentor, Susan Wilson, M.D.
2012-2015	Mentor, Andrea Roe, MD, Resident in Obstetrics and Gynecology "Cystic Fibrosis and Fertility"
2012-2015	Mentor, Joni Price, MD, Resident in Obstetrics and Gynecology

	"Risk of unplanned pregnancy by cycle day among contracepting women"
2012-2016	Clinician Trainings for the Family Planning Council's CDC Teen Pregnancy Prevention Project
2014-2015	Mentor, Pooja Mehta, MD, ACOG Industry-Funded Research Fellowship in Contraceptive Access within Low-Resource Populations
2014-2016	Mentor, Elizabeth Gurney, MD, Fellow in Family Planning "Six-month Retention Rates of Copper IUDs Placed Immediately Post-placentally"
2014-2016	Mentor, Alyssa Colwill, MD, Resident in Obstetrics and Gynecology "Immediate Post-placental IUD Expulsion - a Retrospective Cohort Study"
2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology, Pennsylvania Hospital, Philadelphia PA
2015-2017	Mentor, Elizabeth Greenstein, MD, Resident in Obstetrics and Gynecology "Doctor-Patient Communication at the Time of Miscarriage Management"
2015-2018	Mentor, Maryl Sackheim, MD, Resident in Obstetrics and Gynecology: "Rapid Repeat Pregnancy at Penn Medicine: Prevalence and Risk Factors"
2015-2017	Mentor, Alhambra Frarey, MD, Fellow in Family Planning "Referral and Delay in Abortion Care: a Cross-sectional Study"
2015	"Contraception for women with rheumatologic disease," Division of Rheumatology of Penn Medicine, Philadelphia Pa.
2016-2018	Mentor, Sarah Horvath, MD, Fellow in Family Planning "Quantifying Feto-Maternal Hemorrhage in the First Trimester of Pregnancy" *Winner, Society of Family Planning Young Investigator Award, 2018
2016	"History of Contraception in the US," Master of Public Health Program, University of Pennsylvania, Philadelphia PA
2016	"Academic Medicine as an Instrument of Change," Master of Science of Health Policy, University of Pennsylvania, Philadelphia PA
2017	"The role of public health practice and research in reproductive health" Master of Public Health Program, University of Pennsylvania Perelman School of Medicine. Philadelphia, PA
2017-2019	Mentor, Divyah Nagendra, MD, Fellow in Family Planning "Pain Control for Uterine Evacuation: a Non-Inferiority Trial"
2017	"Academic Medicine as an Instrument of Change," University of Pennsylvania MSHP Program
2017-2020	Mentor, Dr. Sarita Sonalkar, Perelman School of Medicine NIH/NICHD K12--HD-001265 WRHR Scholar, "Feasibility and acceptability of the mobile PPFP Compendium among obstetrical

	providers, and to pilot-test the effectiveness of a provider-based postpartum family planning intervention that incorporates both use of the WHO PPFP Compendium mobile application and LARC method availability, using a hybrid implementation-effectiveness design."
2018	Pediatric Grand Rounds: Children's Hospital of Philadelphia, "Progress and Opportunities in Adolescent Reproductive Health"
2018-2020	Mentor, Jade Shorter, MD, Fellow in Family Planning "Disparities in Reproductive Health: The Patient Experience with Miscarriage Management"
2018-Present	Mentor, Dr. Andreas Roe, "Maximizing reproductive health outcomes for patients with cystic fibrosis and sickle cell anemia"
2019-2021	Mentor, Anne Flynn, MD. "Early Pregnancy Loss Patient Decision Aid"
2020-2022	Mentor, Sarah Gutman, MD, Fellow in Complex Family Planning "Centering Contraceptive Counseling"
2021-2023	Mentor, Emma Gilmore MD, Rh-Immunoglobulin administration for patients with first trimester bleeding: estimating the cost to the healthcare system
2021-Present	Mentor, Dr. Jamie Krashin University of New Mexico K-L2, "Implementation of evidence-based pregnancy loss care practices in rural settings."
2022-Present	Mentor, Dr. Sarah Horvath, Penn State University Clinical and Translational Science Institute's Early-Stage Investigator Training Program (KL2), "Reducing barriers to patient-centered delivery of contraceptive care"

Lectures by Invitation:

Mar, 2004	Instructor, Early pregnancy ultrasound course, Planned Parenthood, Philadelphia, PA: "Introduction to Ultrasound"
Jun, 2004	Invited discussant for the trial development to evaluate the use of ultrasound in medical abortion care. Gynuity, New York, NY: "Medical Abortion Protocol Development"
Jul, 2004	Speaker, Pennsylvania Pharmacist Association, Harrisburg, PA: "Emergency Contraception"
Sep, 2004	Grand Rounds Presenter, University of Buffalo Department of Gynecology-Obstetrics, Buffalo, NY: "Medical Abortion" and "Emergency Contraception"
Feb, 2005	HIV Prevention Trials Network Annual Meeting Plenary Session, Washington DC: "The significance of subclinical pregnancy for clinical trails"
Mar, 2005	Medical Students for Choice Annual Meeting Philadelphia, PA: "Practitioners' Perspectives"
Nov, 2005	Medical Students for Choice Regional Meeting Philadelphia, PA: "Practitioners' Perspectives"
Mar, 2006	HIV Prevention Trial Network Microbicides Safety Meeting,

	Washington DC: "Pregnancy concerns in microbicide trials"
May, 2006	Temple University Hospital Department of Obstetrics and Gynecology Grand Rounds Presenter: "Preventing and Managing the Complications of Second Trimester Abortion"
Jun, 2006	Penn State University School of Medicine Grand Rounds Presentation: "Second Trimester Abortion"
Oct, 2008	ASRM Postgraduate Course: Contraceptive Use in Reproductive Endocrinology. Lecture Title: "Contraceptive Use in the Treatment of PMS; Emergency Contraception"
Mar, 2009	"Uterine Evacuation: Medical Management of Early Abortion and Early Pregnancy Failure" Drexel University Department of Obstetrics and Gynecology
Mar, 2010	"Uterine Evacuation: Medical Management" Duke University School of Medicine Department of Obstetrics and Gynecology. Durham, North Carolina
Mar, 2010	"Challenges in Family Planning." Duke University School of Medicine Department of Obstetrics and Gynecology, Durham, North Carolina
May, 2010	"Contraception for Medically Complicated Patients." American College of Obstetricians and Gynecologists Annual Meeting, Ryan Program Annual Meeting, San Francisco, CA
Jun, 2011	"Second Trimester Abortion: Management of Complications," Department of Obstetrics and Gynecology, Jefferson College of Medicine, Philadelphia PA
Jun, 2011	"Medical Management of Uterine Evacuation," Department of Obstetrics and Gynecology Brown University, Providence, RI
Apr, 2012	"Contraception for Women with Complex Heart Disease," 2012 Heart Disease in Pregnancy Symposium Philadelphia, PA
Apr, 2012	"Birth Control," Department of Obstetrics and Gynecology, Crozer-Chester Medical Center, Upland, PA
May, 2012	"Controversies in Family Planning," Fellowship in Family Planning Annual Meeting, San Diego, CA
May, 2012	"Establishing and Sustaining Second Trimester Procedure Services," Ryan Program Meeting, San Diego, CA (Moderator)
May, 2012	"Legislative Updates in Pennsylvania," Fellowship in Family Planning Annual Meeting, San Diego, CA
Sep, 2012	Invited discussant: "A Critical Look at Lowest Dose Oral Contraception: Experts Consensus Roundtable," Medtelligence, Chicago, IL
Nov, 2012	"Lessons Learned from Medical Abortion: Larger Implications for Women's Health," Medical Students for Choice Conference on Family Planning, St. Louis, MO
May, 2013	"Controversies in Family Planning," Fellowship in Family Planning Annual Meeting, New Orleans, LA
Jul, 2013	"Office Based Management of Early Pregnancy Failure," two hour training, Department of Obstetrics and Gynecology Residency

	Program, Mayo Clinic, Rochester, MN
Oct, 2013	"Early Pregnancy Failure: a specialty for the Family Planning Specialist" Plenary Session, North American Forum on Family Planning, Seattle, WA
Oct, 2013	"Immediate Post-Partum LARC: Limited Access to Reliable Contraception," Concurrent Session, North American Forum on Family Planning, Seattle, WA
Oct, 2013	"Contraception after Medical Abortion" North American Forum on Family Planning, Concurrent Session, Seattle, WA
Mar, 2014	"The management of early pregnancy complications," University of Innsbruck, Innsbruck, Austria
Apr, 2014	Controversies in Family Planning, Fellowship in Family Planning Annual Meeting. Chicago, IL.
May, 2014	Miscarriage Management in the Emergency Department, Grove Foundation Advancing Miscarriage Management Symposium. San Francisco, CA
Oct, 2014	Demystifying hCG: What hCG is and patterns in normal and abnormal pregnancy. North American Forum on Family Planning, Miami FL
Nov, 2014	The Patient's Voice in the Management of Early Pregnancy Loss. V. Chavez, A. Agha, E. Easley, C.A. Schreiber, Association of Early Pregnancy Units (AEPU), Winchester, UK
Nov, 2014	"Individulaized Care of Early Pregnacy Loss" Washington University Departmetn of Obstetrics and Gynecology, St Louis, Mo.
Apr, 2015	"Prevention and Management of Early Pregnancy Complications," Department of Obstetrics and Gynecology of Jefferson Hospital, Philadelphia PA
Jul, 2015	"Immediate Postpartum Long Acting Reversible Contraception." Philadelphia Board of Health, Department of Health
Mar, 2016	"Increasing Access to Long-Acting Reversible Contraception for Philadelphia Women." Public Health and Preventive Medicine Section at the College of Physicians of Philadelphia, PA
Apr, 2016	Liletta: Challenges and Advantages of a New LNG IUD. Moderated a webinar for the Fellowship in Family Planning and Ryan Program Nationally
Apr, 2016	"Immediate Postpartum LARC: Evidence and Implementation." Department of Obstetrics & Gynecology Grand Rounds. WellSpan / York Hospital, York PA
Oct, 2016	"Unpacking Complex Contraception," University of British Columbia Interdisciplinary Grand Rounds, Vancouver, BC
Dec, 2016	"LARC for the medically complex patient," ACOG LARC Program, CME accredited webinar
Oct, 2017	"Climbing the career ladder and lifting others as you climb." Society for Family Planning Career Development Seminar, Atlanta, GA
Nov, 2017	"Pregnancy of Unknown Location" Early Pregnancy Symposium. Philadelphia, PA

Nov, 2017	"Personalized Approaches to Early Pregnancy Loss Care" Early Pregnancy Symposium. Philadelphia, PA
Jan, 2018	"Patient-Centered Early Pregnancy Loss Care," UC San Diego Obstetrics and Gynecology Grand Rounds, San Diego, CA
Apr, 2018	"Hormonal Contraception and the Risk of Mood Symptoms," North American Society for Psychosocial Obstetrics and Gynecology, Philadelphia, PA
Oct, 2018	"Advances in the Care of Patients with Early Pregnancy Loss," Magee-Women's Hospital Alumni Day, Pittsburgh, PA
Nov, 2018	"Advances is Early Pregnancy Loss Care" Einstein Healthcare Network, Obstetrics and Gynecology Departmental Grand Rounds
Nov, 2018	"Miscarriage Management: Updates and Innovations" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of ACOG, Santiago, Chile
Nov, 2018	"Healthy Child-Spacing, Healthy Families: Best Practices in Postpartum Contraception" Plenary session, Chilean Society of Obstetrics and Gynecology (SOCHOG) and the Chilean Section of ACOG, Santiago, Chile
Jan, 2019	"Advances in the Care of Patients with Early Pregnancy Loss," Obstetrics and Gynecology Grand Rounds, MedStar Washington Hospital Center and MedStar Georgetown University Hospital, Washington, DC
Mar, 2019	"Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss" Ob/Gyn Grand rounds, Beth Israel Deaconess Medical Center, Boston MA
Mar, 2019	"The Medical Management of Early Pregnancy Loss," Translational Science 2019 Conference, Washington, DC
Jul, 2019	"Abortion in the United States," Department of Obstetrics and Gynecology University of Helsinki, Helsinki, Finland
Jul, 2019	"Biomarkers of Human Reproduction," Department of Obstetrics and Gynecology, Karolinska Institute, Stockholm, Sweden.
Jan, 2020	"Advances in the Care of Patients with Early Pregnancy Loss," Columbia University Medical Center Obstetrics and Gynecology Grand Rounds, New York, NY.
May, 2020	"Academic Medicine as an Instrument of Social Change" Invited Professorship University of Pennsylvania Obstetrics and Gynecology Resident Research Day
Oct, 2020	"The Integration of Early Pregnancy Care into Family Planning Services," Closing Plenary, Society of Family Planning Annual Scientific Meeting
Feb, 2021	"The Long and Winding Road," Family Planning Symposium Visiting Professor, University of Utah
Feb, 2021	"High-value Early Pregnancy Care," Family Planning Symposium Visiting Professor, University of Utah
Apr, 2021	"Advancing the care of early pregnancy loss patients." Highland OBGYN City Grand Rounds. Rochester, New York (virtually)

Oct, 2021	"The Other Fifty Percent" New York Obstetrical Society, The Yale Club, New York City
Apr, 2022	"Innovations and Opportunities for Sex and Gender Equity in Academic Medicine," Association of Senior & Emeritus Faculty-PSOM President's Distinguished Speaker
May, 2022	"Innovations and Opportunities for Sex and Gender Equity in Academic Medicine," Joanne Decker Memorial Lectureship, Children's Hospital of Philadelphia

Organizing Roles in Scientific Meetings:

Apr, 2010	Chair, National Abortion Federation 2010 Postgraduate course: "Team Work and Patient Safety" Philadelphia, PA
2011	Co-Chair HIV and Women subgroup of the Penn Center For Aids Research Philadelphia, PA
Apr, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Chicago, IL
May, 2013	Co-Chair, Penn CFAR Women and HIV Symposium: "Biobehavioral approaches to HIV prevention and management in adolescent women" Perelman School of Medicine, Philadelphia PA
May, 2013	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting Denver, CO
May, 2014	Facilitator: Controversies in Family Planning. Fellowship in Family Planning Annual Meeting New Orleans, LA
Apr, 2015	Moderator, second year family planning fellows' research presentations on contraception San Francisco, CA
Apr, 2017	Organizer and Panel Moderator, "Moving Forward: Protecting and Promoting Reproductive Health" University of Pennsylvania, Phila, PA
May, 2019	Chairperson, Directors' Meeting, Fellowship in Family Planning Boston, Mass
Sep, 2022	Co-Chair, AGOS Plenary Session "Tired and Inspired: Notes for Leaders on a Post-Roe abortion Landscape" Chicago, Ill

Grants:

Pending:

Genetics of Pregnancy Loss in a Diverse Population (GOAL), NIH/NICHD, 1R01HD108256-01, 9/2022-8/2027 (Schreiber, PI: Bucan, Co-Investigator), $811,078/annual direct costs, 12.5% effort (Role in grant: PI)

Mycoplasma genitalium, Social Determinants of Health, and Infertility (Peipert), Indiana University/NIH, R01, 4/2022-3/2027 (Schreiber/Peipert, PI), $107,478/annual direct costs, 7.5% effort (Role in grant: PI)

Current:

Integration of early pregnancy care into family planning service delivery, Independence Blue Cross, Clinical Care Innovation, 1/2022-12/2022 (Schreiber, PI), $166,666/annual direct costs, 10% effort (Role in grant: PI, The major goal of this project is to, ...)

Fellowship in Family Planning 923.12, Anonymous Foundation, 923.12, 7/2021-6/2022 (SCHREIBER, PI: SONALKAR, Co-Investigator), $45,000/annual direct costs, 1% effort (Role in grant: PI, The main goal of this project is to train experts in family planning and clinical research.)

Facilitated group contraceptive counseling for patients presenting to abortion care (Gutman), Society of Family Planning, SFPRF21-14, 1/2021-6/2022 (Gutman, PI), $14,913/annual direct costs (Role in grant: Mentor)

Contraceptive Development Program NICHD Contraceptive Clinical Trials Network - Female Sites (Task Order 1), Eunice Kennedy Shriver National Institute of Child Health and Human Development, 75N94020F00001, 8/2020-7/2027 (Schreiber, PI: Barnhart, Co-Investigator), $66,000/annual direct costs, 1% effort (Role in grant: PI, The primary goal of this task order is to collaboratively generate comprehensive, scientifically sound research protocols in order to develop effective and safe contraception for women, including (a) obese women and (b) women with contraindications to current contraceptive products.)

The RhIMAB Study: A Prospective Trial to Evaluate the Value of Rh Immune Globulin in Medication Abortion Service Provision (Schreiber), Society of Family Planning, SFPRF12-MA11, 10/2018-4/2023 (Schreiber, PI), $378,199/annual direct costs, 20% effort (Role in grant: PI, Generating Evidence that Contributes to Increasing Access toMedication Abortion in the United States)

Population Health Research Support: Start Trial (Barnhart), NIH/NICHD, NIH-NICHD-DIPHR-2018-12, 9/2018-9/2023 (Schreiber, PI), $110,888/annual direct costs, 2.5% effort (Role in grant: PI, To establish geographically diverse research sites capable of implementing sophisticated initiatives, from preconception through adulthood, using scientifically valid and rigorous methodologies, to assist in the conduct of population health research initiatives. It is anticipated that initially new research (observational cohorts and/or intervention trials) initiatives could be implemented each year)

Contraceptive Clinical Trials Network-Female Sites (CCTN013C), NIH/NICHD, HHSN275201300020I, 1/2018-12/2021 (Schreiber, PI), $48,064/annual direct costs, 5% effort (Role in grant: PI, A multi-center, randomized study to evaluate the

pharmacokinetic and pharmacodynamics profile, contraceptive efficacy and safety of daily oral low dose ulipristal acetate)

Multi-center, open-label, uncontrolled study to assess contraceptive efficacy and safety of Mirena during extended use beyond 5 years in women 18 to 35 years of age including a subgroup evaluation of treatment effect on heavy menstrual bleeding, BAY 86-5028 (Schreiber), Bayer Healthcare Pharmaceuticals Inc., BAY 86-5028/18649, 2/2017-10/2021 (Schreiber, PI), $26,616/annual direct costs, 6% effort (Role in grant: PI, The major goal of this project is to assess the contraceptive efficacy of Mirena beyond 5 years up to 8 years of use.)

A multi-center, single-blind, randomized clinical trial to compare two copper IUDs: Mona Lisa NT Cu380 Mini and ParaGard (Schreiber), Gates Foundation/FHI360, OPP1200867, 11/2015-6/2022 (Schreiber, PI), $238,292/annual direct costs, 11% effort (Role in grant: PI, The major goal of this project is to obtain valid and reliable data to determine the contraceptive effectiveness, bleeding patterns, side effects and safety of novel LARC methods that can provide safe and effective contraception for women.)

A Phase 3, Randomized, Multi-Center, Open-Label Study of a Levonorgestrel-Releasing Intrauterine System (20 mcg/day) and Mirena for Long-Term, Reversible Contraception up to Five Years, M360-L102 (Schreiber), Medicines360 (L102), M360-L102, 5/2010-12/2021 (Schreiber, PI), $55,886/annual direct costs, 10% effort (Role in grant: Principal Investigator, The major goal of this project is to test the safety and efficacy of a new levonorgestrel intrauterine system)

Past:

Fellowship in Family Planning, FPF.11 , Anonymous Foundation, 923.11, 7/2020-6/2021 (Schreiber, PI), $385,000/annual direct costs, 11% effort (Role in grant: PI, The main goal of this project is to train experts in family planning and clinical research.)

Fellowship in Family Planning, FPF.10 (Schreiber), Anonymous Foundation, FPF 923.10, 7/2019-6/2020 (Schreiber, PI: Sonalkar, Co-Investigator), $389,000/annual direct costs, 11% effort (Role in grant: PI, The main goal of this project is to train experts in family planning and clinical research.)

Disparities in Reproductive Health: The Patient Experience with Miscarriage Management (Shorter), Society of Family Planning, SFPRF19-02, 1/2019-6/2020 (SCHREIBER, PI: SHORTER, Co-Investigator), $15,000/annual direct costs (Role in grant: Mentor, Fellowship Research Award, No Salary, Mentor)

Building Interdisciplinary Research Careers In Women's Health, BIRCWH K-12 (Oquendo), NIH/NICHD, 5 K12 HD085848-05, 9/2018-8/2020 (OQUENDO, PI: SCHREIBER, Co-Investigator), $24,743/annual direct costs, 10% effort (Role in grant: Research Director, The major goal of this mentored career-development project is to support and develop junior faculty with a focus in women's health and sex-differences research)

Fellowship in Family Planning, FPF.09 (Schreiber), Anonymous Foundation, FPF.09, 7/2018-6/2019 (Schreiber, PI), $389,000/annual direct costs, 11% effort (Role in grant: PI, The main goal of this project is to train experts in family planning and clinical research.)

A Feasibility, Open-Label, Postcoital, Safety, Release, Fit, and Acceptability Study of Ovaprene, Dare Bioscience Inc, DR-OVP-001, 6/2018-6/2020 (Schreiber, PI), $118,391/annual direct costs, 2.5% effort (Role in grant: PI, The major goal of this project is to evaluate the Safety and Acceptability Study of a Non-Hormonal Ring for contraception)

A Pilot Randomized Non-inferiority Trial of Ibuprofen versus Oxycodone for Overnight Pain Control During Second-Trimester Abortion Care (Nagendra), Society of Family Planning, SFPRF18-19, 5/2018-6/2019 (Nagendra, PI: Schreiber, Co-Investigator), $96,827/annual direct costs (Role in grant: Mentor, Fellowship Research Award, No Salary, Mentor)

Mid-Career Mentoring Grant (Schreiber), Society of Family Planning, 7/2017-6/2020 (Schreiber, PI), $66,667/annual direct costs, 10% effort (Role in grant: PI, no cost extension)

Fellowship in Family Planning (FPF.08), Buffett Susan Thompson Foundation, 7/2017-6/2018 (Schreiber, PI), $380,694/annual direct costs, 11.65% effort (Role in grant: PI)

Flow Cytometry Quantification of Feto-Maternal Hemorrhage Following Uterine Aspiration in the First Trimester (Horvath), Society of Family Planning, SFPRF17-6, 2/2017-6/2018 (Schreiber , PI: Sarah Horvath (fellow), Co-Investigator), $100,000/annual direct costs, 1% effort (Role in grant: Mentor)

Evaluation of the Effectiveness, Safety and Tolerability of LevoCept (Levonorgestrel-Releasing Intrauterine System) for Long-Acting Reversible Contraception, CMDOC-0022 (Schreiber), CONTRAMED INC., CMDOC-0022 (LevoCept), 1/2017-1/2021 (SCHREIBER, PI), $75,750/annual direct costs, 2.5% effort (Role in grant: PI)

Family Planning Service Delivery Integration for HIV Positive and At-Risk Women in Botswana: A Hybrid Type 2 Clinical Intervention and Implementation Strategy, NIH/NIAID & Penn Center for AIDS Research (CFAR) Pilot, P30-AI-45008-21, 9/2016-12/2019 (COLLMAN, R., PI: Doreen Ramogola-Masire, Co-Investigator), $40,000/annual direct costs, 1% effort (Role in grant: Pilot Study PI, The major goal of this project is to implement and evaluate the feasibility and acceptability of an approach to contraceptive care within the context of a cervical cancer prevention program.)

Fellowship in Family Planning (Yr. 07), Anonymous Foundation, 923.07, 7/2016-6/2017

(Schreiber, PI), $356,970/annual direct costs, 15% effort (Role in grant: PI, The main goal of this project is to train experts in family planning and clinical research.)

Pregnancy Early Assessment CEnter (PEACE), University of Pennsylvania/Penn Center for Health Care Innovation, 4/2016-12/2017 (Schreiber, PI), $107,700/annual direct costs, 2% effort (Role in grant: PI, The major goal of this project is to optimize the care offered to women with early pregnancy loss within the University of Pennsylvania Health System.)

Referral and delay in abortion care: A cross-sectional study (Frarey), Society of Family Planning, SFPRF16-16, 2/2016-6/2017 (Schreiber, PI: Frarey (fellow), Co-Investigator), $94,921/annual direct costs, 1% effort (Role in grant: Mentor)

Evaluation of the Effectiveness, Feasibility, Safety and Tolerability of the ContraMed Intrauterine Copper Contraceptive for Long Acting Reversible Contraception, CMDOC-0008 (Schreiber), CONTRAMED INC., CMDOC-0008 (Veracept), 7/2015-6/2019 (Schreiber, PI), $89,000/annual direct costs, 2.5% effort (Role in grant: PI, The major goal of this project is to assess the effectiveness, feasibility, safety, and tolerability of an investigational copper intrauterine device over a three year period.)

Family Planning Service Delivery Integration for HIV Positive and At-Risk Women in Botswana: A Hybrid Type 2 Clinical Intervention and Implementation Strategy, University of Pennsylvania Center for AIDS Research, 7/2015-6/2016 (Schreiber, PI), $40,000/annual direct costs, 1% effort (Role in grant: PI)

Fellowship in Family Planning (Yr. 06) , Anonymous Foundation, 923.06, 7/2015-6/2016 (Schreiber, PI), $340,044/annual direct costs, 15% effort (Role in grant: Principal Investigator, The main goal of this project is to train experts in family planning and clinical research)

Expulsion of Immediate Postplacental Copper Intrauterine Devices at Six Months: A Prospective Cohort Study (Gurney), Society of Family Planning, SFPRF15-15, 4/2015-2/2017 (Schreiber, PI: (Gurney, mentee), Co-Investigator), $100,000/annual direct costs, 1% effort (Role in grant: Mentor)

Contraceptive Clinical Trials Network-Task Order 3 (CCTN), NIH/NICHD, HHSN275201300020I, 9/2014-9/2019 (Barnhart, PI: Schreiber, Co-Investigator), $159,050/annual direct costs, 1% effort (Role in grant: Co-Investigator, The major goals of this project is to determine the contraceptive effectiveness, pharmacokinetics, bleeding patterns, side effects and safety of novel products that can provide safe and effective contraception for women.)

Contraception in Women with Cystic Fibrosis: Satisfaction and Effects on Disease (Traxler), Society of Family Planning, SFPRF14-13, 4/2014-6/2015 (Schreiber, PI: Sarah Traxler, Co-Investigator), $35,000/annual direct costs, 1% effort (Role in grant: Mentor, Role: Mentor (no salary))

The Impact of Doulas in the Surgical Management of Early Pregnancy Failure and Abortion care (Wilson), Society of Family Planning, SFPRF14-3, 3/2014-12/2014 (Schreiber, PI), $29,761/annual direct costs, 1% effort (Role in grant: Mentor, Role: Mentor (no salary))

A Phase 1, Multi-Center Study to Assess the Performance of a LNG20 Intrauterine System Inserter, Medicines360 (L104), L104, 12/2013-12/2014 (Schreiber, PI), $94,000/annual direct costs, 3% effort (Role in grant: Principal Investigator)

Comparative Effectiveness of Pregnancy Failure Management Regimens, Pre-Fai-R (Schreiber), NIH/NICHD (R01), R01-HD-071920-05 (N.C.E.), 8/2013-4/2020 (Schreiber, PI: Barnhart, Sammel, Co-Investigator), $335,751/annual direct costs, 7.5% effort (Role in grant: Principal Investigator, Early Pregnancy Failure (EPF) is the most common complication in pregnancy, but safe and effective management options are limited. Up to 60% of women who choose medical management of EPF with prostaglandins ultimately require multiple doses or surgery. Our goal is to improve upon the effectiveness of medical management of EPF by adding a progesterone receptor modulator, and to study the biological and clinical predictors of success among women who choose medical management.)

Fellowship in Family Planning (Yr. 04), Anonymous Foundation, 923.04, 7/2013-6/2014 (Schreiber, PI), $366,800/annual direct costs, 15% effort (Role in grant: Principal Investigator, The main goal of this project is to train experts in family planning and clinical research)

Core Function Activities Task Order #1 (Barnhart), NIH/NICHD (CCTN), HHSN275201300020I, 6/2013-6/2015 (Barnhart, PI), $88,683/annual direct costs, 5% effort (Role in grant: Co-Investigator, To assist in the protocol review, protocol development and activities associated with past, present and future CCTN activities.)

Fertility After Contraceptive Termination (FACT Pilot), WASHINGTON UNIVERSITY IN ST. LOUIS/BAYER, Pilot Study, 3/2013-6/2016 (Creinin, PI), $12,500/annual direct costs, 1% effort (Role in grant: Subcontract PI)

Impact Of Peer Counseling On Long Acting Reversible Contraception Uptake Among Adolescents And Duration Of Contraceptive Use (Wilson), Society of Family Planning, SFP - Wilson, 1/2013-7/2014 (Schreiber, PI), $69,931/annual direct costs, 1% effort (Role in grant: Principal Investigator, Role: Mentor (no salary))

Study Of Uptake, Continuation And Removal Of Intra-Uterine Contraception (Iuc), University Of California - San Francisco, 7272sc, 8/2012-6/2013 (COURTNEY SCHREIBER, PI), $8,182/annual direct costs, 1% effort (Role in grant: PI)

Fellowship in Family Planning (Yr. 03), Anonymous Foundation, 923.03, 7/2012-6/2013 (Schreiber, PI), $366,800/annual direct costs, 15% effort (Role in grant: Principal

Investigator, The main goal of this project is to train experts in family planning and clinical research)

Evaluation of a Brief Standardized Postpartum Counseling Intervention's Effect on Repeat Pregnancy Rates and Contraceptive Choice/Use/Continuation/Satisfaction in Adolescents (Sober), Society of Family Planning, SFP, 2/2012-3/2014 (Sober, PI), $49,144/annual direct costs, 1% effort (Role in grant: Principal Investigator, Role: Mentor (no salary))

A Phase 1, Multi-Center Study to Assess the Safety and Performance of an Novel LNG20 Intrauterine System Inserter, Medicines360 (L103), M360-L103, 11/2011-12/2012 ((Schreiber), PI), $38,170/annual direct costs, 1% effort (Role in grant: Principal Investigator, The major goal of this project is to ...)

Fellowship in Family Planning (Yr. 02), Anonymous Foundation, 923.02, 7/2011-6/2012 (Schreiber, PI), $323,520/annual direct costs, 16% effort (Role in grant: Principal Investigator, The main goal of this project is to train experts in family planning and clinical research)

The Impact of Contraception on Post Partum Weight Loss: A Prospective Study (Pentlicky), Anonymous Foundation, 3643, 7/2011-6/2012 ((Pentlicky), PI), $46,548/annual direct costs (Role in grant: Principal Investigator)

Pharmacokinetic And Pharmacodynamic Study Of Tenofovir 1% Gel Using The Bat 24 Regimen Versus Daily And Pericoital Dosing, CONRAD/Eastern Virginia Medical School, PPA-11-115, 6/2011-12/2013 (Schreiber, PI), $127,508/annual direct costs, 2% effort (Role in grant: PI, The main goal is to evaluate the effectiveness of different Tenofovir 1% Gel dosing regimens)

AMP001 - A Multicenter, Open-Label, Randomized Study of the Contraceptive Efficacy and Safety of Amphora Gel Compared to Conceptrol Vaginal Gel (Barnhart), EvoFem Inc., AMP001, 5/2011-8/2013 (Barnhart, PI), $56,891/annual direct costs, 1% effort (Role in grant: Co-Investigator, The major goal of this project is to study the Contraceptive Efficacy and Safety of Amphora Gel Compared to Conceptrol Vaginal Gel)

Clinical Evaluation of Nestoronel Estradiol-Releasing Vaginal Ring for Female Contraception - Task 6 (Barnhart), NIH/NICHD contract, HHSN275201100041U-Task6, 3/2011-1/2014 (Barnhart, PI), $705,379/annual direct costs, 5% effort (Role in grant: Co-Investigator, The proposed study will be conducted in women of reproductive age in order to evaluate contraceptive efficacy, pharmacokinetics, bleeding patterns and the safety and side effects of this new contraceptive product.)

Core Function Activities Task Order 8 (Barnhart), NIH/NICHD contract, HHSN275201100068U Task 8, 3/2011-7/2013 (Barnhart, PI), $114,253/annual direct costs, 5% effort (Role in grant: Co-Investigator, To assist in the development of new

contraceptive products by providing services related to protocol review, protocol development and activities associated with past, present and future CCTN activities)

Clinical Evaluation of Levonorgestrel Butaoate for Female Contraception - Task 7 (Barnhart), NIH/NICHD contract, HHSN275201100071U-Task7, 3/2011-8/2012 (Barnhart, PI), $64,704/annual direct costs, 5% effort (Role in grant: Co-Investigator, There is a demand for estrogen-free contraception in order to reduce the risk of venous thromboembolism (VTE) particularly for obese women)

Contraceptive Efficacy and Safety of Two Progestin Patches - Task 5 (Barnhart), NIH/NICHD contract, HSN275201000022U-Task5, 1/2010-7/2012 (Barnhart, PI), $183,073/annual direct costs, 2% effort (Role in grant: Co-Investigator, To evaluate in obese and non-obese women the pharmacokinetics, effects, cycle control, and safety of progestin-only patches containing defined doses of levonorgestrel.)

Uptake And Acceptability Of Home Use Of Mifepristone, Gynuity Health Projects, GYNUITY, 12/2009-11/2010 (COURTNEY SCHREIBER, PI), $34,808/annual direct costs, 4% effort (Role in grant: PI, The major goal of this project is to test the safety and acceptability of home administration of mifepristone)

Penn Family Planning And Pregnancy Loss Center Database Proposal, Society of Family Planning, SFP3-18, 10/2009-3/2011 (COURTNEY SCHREIBER, PI), $15,000/annual direct costs, 2% effort (Role in grant: PI, The main goal of this project is to develop a family planning database and pilot its use as a model for nation-wide registry.)

Contraceptive Efficacy Evaluation Of The Path Female Condom, National Institutes Of Health, HHSN275200900083U, 9/2009-12/2012 (Kurt T. Barnhart, PI), $0/annual direct costs, 18% effort (Role in grant: Co-PI, To compare the safety and contraceptive efficacy of a new female condom in women of reproductive age. The PATH condom is a new version of the female condom that appeared to have greater acceptability in a small comparative study)

Women In Steady Exercise Research (WISER) Sister Substudy - Contraceptive use in Women at Increased Risk for Breast Cancer, Teva Women's Health Research, Teva CT, 8/2009-5/2013 (Schreiber, PI), $10,000/annual direct costs, 1% effort (Role in grant: Principal Investigator, The main goal of this project is to evaluate contraceptive decision making and the uptake, safety and acceptability of the TCu380A IUD in this clinical trial population at increased risk for breast cancer)

A Plan B 1.5 Emergency Contraception Actual Use Study - Dr-Lev-302, Duramed Research, 4/2009-7/2011 (COURTNEY SCHREIBER, PI), $20,476/annual direct costs, 12% effort (Role in grant: PI, The main goal of this project is to assess use of an emergency contraceptive pill under simulated over-the-counter conditions)

A Pilot Study To Evaluate Precision And Accuracy Of Smart Applicator For Microbicide Clinical Trials, International Partnership For Microbicides, IPM 022, 8/2008-7/2009

(COURTNEY SCHREIBER, PI), $0/annual direct costs, 10% effort (Role in grant: PI)

Kenneth J. Ryan Residency Training Program In Abortion and Family Planning, Anonymous Foundation, 296.03, 1/2008-10/2011 ((Schreiber), PI), $499,996/annual direct costs, 20% effort (Role in grant: Principal Investigator, The main goal of this project is to institute resident training in family planning)

How to avoid pregnancies in HIV prevention trials: A case control study and point-of-care questionnaire, Penn Center for AIDS Research (CFAR), 7/2007-6/2008 (Courtney Schreiber, MD, MPH, PI), $40,000/annual direct costs, 5% effort (Role in grant: PI)

Clinical Trials Unit: Microbicide Trials Network, NIH/NIAID, U01-AI-069534, 2/2007-6/2009 ((Metzger, D.), PI), $1/annual direct costs, 10% effort (Role in grant: Co-Investigator)

Contraceptive Clinical Trials Network (Female Contraceptive Trials Topic Area) Task Order 3: A Multi-Center, Open-Label Trial on the Efficacy, Cycle Control, and Safety of a Contraceptive Vaginal Ring Delivering a Daily Dose Nestoron and Ethinyl Estradiol, NIH/NICHD, RFTOP#:003 , 8/2006-1/2010 (Kurt Barnhart, M.D., PI), $170,518/annual direct costs, 5% effort (Role in grant: co-investigator, The main goal of this project is to evaluate the efficacy and safety of a new contraceptive vaginal ring.)

Contraceptive Effectiveness Diaphragm and Safety Study of the SILCS with Nonoxynol-9: The Pivotal Study, Eastern Virginia Medical School (CONRAD), CSA-06-430 , 7/2006-12/2009 (Kurt Barnhart, M.D., PI), $243,820/annual direct costs, 5% effort (Role in grant: Co-investigator, CONRAD is a research organization funded by USAID and Foundation. The main goal of this project is to Estimate the safety and effectiveness among users of the SILCS diaphragm used with contraceptive gel over 6 months of typical use.)

A Pilot Randomized Controlled Trial of Advanced Supply of Levonorgestrel Emergency Contraception vs. Routine Postpartum Contraceptive Care in the Teenage Population, University Research Foundation, 7/2006-1/2008 (CA Schreiber, PI), $0/annual direct costs (Role in grant: PI)

A Study of Mucosal and Inflammatory Effects of Vaginal Gels on Reproductive Tract, Magee Women's Health Corp. VIA NIH, 6/2006-5/2007 (Kurt Barnhart, M.D., PI), $0/annual direct costs, 1% effort (Role in grant: co-investigator)

Mifepristone and Misoprostol for the Treatment of Early Pregnancy Failure: a Pilot Clinical Trial, Anonymous, 9/2004-10/2005 (Courtney A. Schreiber, MD, MPH, PI), $0/annual direct costs, 20% effort (Role in grant: PI, no salary support)

University Of Pennsylvania Center For Aids Research:, National Institutes Of Health, 5-P30-AI-045008-10, 7/2004-9/2009 (JAMES A HOXIE, PI), $1,822,128/annual direct

costs, 5% effort (Role in grant: Co-PI)

A multicenter, randomized, double masked, comparator study of the safetyand contraceptive efficacy of C31G vaginal gel compared to 15% Conceptrol® vaginal gel, NICHD, N01-HD-4-3372, 7/2004-10/2005 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

An Evaluation of NuvaRing® for the Treatment of Abnormal Patterns Bleeding in the Perimenopause, Organon, 7/2004-6/2005 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator, no salary support)

Contraceptive Clinical Trials Network (Female Contraceptive Trials Topic Area): Task Order 2- Female Contraceptive Clinical Trial: A Randomized Controlled Study of the Efficacy, Safety and Acceptability of C31G, NIH, 4/2004-3/2011 (Kurt Barnhart, M.D., PI), $1/annual direct costs, 5% effort (Role in grant: co-investigator)

An Open Label Study of the Contraceptive Efficacy and Safety of Tripahsic Norethindrone Acetate 1 mg/Ethinyl Estradiol 0.005, 0.030, and 0.035 mg Oral Tablets Administered for 24 Days of a 28 Day Cycle, Galen, 2/2004-6/2004 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

A Multicenter, Randomized Comparison of Mifepristone and Misoprostol Simultaneously Versus 24 Hours Apart for Abortion Through 63 Days Gestation, Anonymous, 1/2004-6/2005 (Courtney A. Schreiber, MD, MPH, PI), $0/annual direct costs, 20% effort (Role in grant: PI, no salary support)

A Survey of Contraception Knowledge and Attitudes among Graduating Residents in Pittsburgh, Anonymous, 1/2004-6/2005 (Courtney A. Schreiber, MD, MPH, PI), $0/annual direct costs, 20% effort (Role in grant: PI, no salary support)

An Evaluation of the Return to Ovulation After Treatment with Mifepristone and Misoprostol For Undesired Pregnancy., Anonymous, 1/2004-6/2005 (Courtney A. Schreiber, MD, MPH, PI), $0/annual direct costs, 20% effort (Role in grant: PI, no salary support)

Phase I Post Coital Testing and Safety Study of the SILCS Diaphragm, Prototype VI , CONRAD, A02-081, 9/2003-8/2004 ((Creinin, Mitchell D.), PI), $120,000/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

Phase III Multicenter Open Label Study to Evaluate the Safety and Efficacy of Levonorgestrel 90 micrograms and Ethinyl Estradiol 20 micrograms in a Continuous Daily Regimen for Oral Contraception, Wyeth Pharmamaceuticals, 9/2003-5/2004 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

A Randomized Controlled Study of the Efficacy,Safety and Acceptability of Buffer Gel., NICHD-N01-HD, HD-1-3319, 7/2003-6/2005 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

Randomized Clinical Trial on Management of Early Pregnancy Failure, NICHD, N01-HD-1-3322, 7/2003-7/2004 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

Same Day Initiation of the Combined Hormonal Transdermal Delivery System Traditional Initiation Method, Anonymous, 6/2003-12/2004 (Amita S. Murthy, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator, no salary support)

Mifepristone and Misoprostol Administered at the Same Time for Medical Abortion Up to 49 Days' Gestation, Anonymous , 6/2003-6/2004 (Amita S. Murthy, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator, no salary support)

Mifepristone and Misoprostol Administered at the Same Time for Medical Abortion from 50-63 Days' Gestation, Anonymous , 6/2003-5/2004 (Courtney Schreiber, MD, MPH, PI), $0/annual direct costs, 20% effort (Role in grant: PI, no salary support)

Safety Analysis of the Diaphragm in Combination with Vaginal MicrobicideGels, CDC, 6/2003-5/2004 (Mitchell D. Creinin, PI), $0/annual direct costs, 5% effort (Role in grant: Co-Investigator at study site, no salary support)

Career Development In Women's Health Research, National Institutes Of Health, 5-K12-HD-043459-05, 9/2002-7/2008 (ELLEN W FREEMAN, PI), $462,965/annual direct costs, 75% effort (Role in grant: Co-PI)

BUILDING INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH (BIRCWH), National Institutes of Health (NICHD), 5K12HD043459-05, 9/2002-12/2007 (Ellen W. Freeman, PI), $0/annual direct costs, 75% effort (Role in grant: BIRCWH Scholar)

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