Exhibit A

Declaration of Courtney A. Schreiber, M.D., M.P.H.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

DECLARATION OF COURTNEY A. SCHREIBER, M.D., M.P.H., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per Dkt. 107
Trial Date: Vacated per Dkt. 82

Courtney A. Schreiber, M.D., M.P.H., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows. I am a board-certified obstetrician/gynecologist and Professor of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania. I am also a Fellow of the Society of Family Planning ("SFP") and of the American College of Obstetricians and Gynecologists ("ACOG"), both of which are nationwide membership organizations. At Penn Medicine and the Perelman School of Medicine, I serve as 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 I am 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).

2. I have published over 75 peer-reviewed research articles on a wide range of reproductive health and public health science topics. In addition, I have been the principal investigator or co-investigator on approximately 55 research studies relating to early pregnancy, abortion, pregnancy loss (i.e., miscarriage), contraception, and sexually transmitted infections.

3. I currently serve on the editorial board of *Contraception*, and serve or have served as a reviewer for the *American Journal of Obstetrics and Gynecology*, *Fertility and Sterility*, and *Pharmacoepidemiology*. A copy of my curriculum vitae is attached hereto as Exhibit 1.

4. 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 procedural 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.

5. I am an expert in the provision of abortion services, having provided this care to 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 also 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 16 years at the Perelman School of Medicine.

6. I submit this declaration in support of Plaintiffs' Motion for Summary Judgment challenging the U.S. Food and Drug Administration's ("FDA") Risk

Evaluation and Mitigation Strategy ("REMS") for Mifeprex® (as well as its generic counterpart, mifepristone). I use "Mifeprex REMS" as shorthand in this declaration to refer to both the REMS and the three Elements to Assure Safe Use ("ETASU") it includes, for both Mifeprex and its generic.[1]

7. The Mifeprex REMS provides no medical benefit. These unparalleled restrictions do not enhance the safety or efficacy of this medication, do nothing to ensure that a patient receives appropriate care in the exceedingly rare event of a serious complication, and only undermine patient counseling by interfering with the informed consent process. Far from improving patient safety, the REMS *increases* medical risks by reducing where abortion care is available in this country and thereby delaying or blocking patients' access to care.

8. I base these opinions on my expertise in the field of obstetrics and gynecology; my experience providing a broad range of reproductive health care, including medication and procedural abortions and miscarriage care; my expertise as a clinical researcher in the field of reproduction; my familiarity with the body of scientific literature concerning abortion and miscarriage; and my review of the

[1] The FDA regulates both Mifeprex and its generic mifepristone identically, and I use the terms interchangeably here. *See Mifepristone Shared System REMS*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390, (last updated Apr. 11, 2019).

prescribing information (part of the labeling) for the other drugs described below which FDA regulates less stringently than Mifeprex.

ABORTION CARE IN THE UNITED STATES

9. 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.[2] Most patients who seek abortion care are already mothers,[3] and often choose to have an abortion because the timing of the current pregnancy poses financial or other stressors that interfere with their ability to care for their existing families. But most abortion patients have several interrelated reasons motivating them to end the pregnancy. The birth of a child is a life-altering physical and emotional event. Patients who choose abortion are exercising their basic rights to control their lives and well-being.

10. Based on the most recent data available, 75% of people obtaining abortions are poor or low-income: 49% of patients have an income below 100% of

[2] *Induced Abortion in the United States*, Guttmacher Inst. (Sept. 2019), https://www.guttmacher.org/fact-sheet/induced-abortion-united-states. 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.

[3] Jenna Jerman, et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Inst. (May 2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014 (59% of abortion patients have at least one child).

the federal poverty level, and an additional 26% of patients have income between 100 and 199% of the federal poverty level. 60% are people of color, with 28% identifying as Black and 25% identifying as Hispanic.[4]

11. 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.[5] 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.[6]

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"). There are two methods of abortion available at that time: medication abortion, involving the use of prescription medications that induce a process similar

[4] *Id.*

[5] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216 (2012).

[6] 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/10.17226/24950.

to an early miscarriage, or procedural abortion (sometimes called "surgical abortion"), which is performed in a clinical setting and, in the first trimester, typically involves the use of gentle suction inserted through the vagina and cervix to empty the uterus.

13. Medication abortion now accounts for 60% of abortions in that ten-week window, and for 39% of all abortions, in the United States.[7] Since FDA approved Mifeprex in 2000, more than four million people in the U.S. have used this medication to end an early pregnancy.[8]

14. While all methods of abortion are extremely safe, medication abortion is medically indicated or otherwise more appropriate for some patients given their individual circumstances. For instance, medication abortion is a safer and more effective option for people with certain anatomic conditions, such as uterine anomalies or fibroids, that can make the uterine cavity more difficult to access for a procedural abortion. And some patients prefer medication abortion for a variety of personal reasons, including to avoid an in-clinic procedure, because medication

[7] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. 8 (Sept. 2019), https://www.guttmacher.org/sites/default/files/report_pdf/abortion-incidence-service-availability-us-2017.pdf

[8] *Mifeprex Effectiveness & Advantages*, Danco Laboratories, LLC, https://www.earlyoptionpill.com/is-mifeprex-right-for-me/effectiveness-advantages/ (last visited Apr. 14, 2021).

abortion feels more natural or private, or because they need the flexibility to have the abortion at a time that does not interfere with work, childcare, or other responsibilities, rather than during the clinician's office hours.

THE MEDICATION ABORTION REGIMEN

15. The superior, evidence-based (and FDA-approved) regimen of medication abortion for early pregnancies entails taking two medications: mifepristone (also known as RU-486 or by its trade name in the United States, Mifeprex) and misoprostol (available as a generic or under the brand name Cytotec®). The mifepristone-misoprostol regimen is FDA-approved through 70 days of pregnancy.

16. The medication abortion regimen begins with an assessment of the patient's eligibility. FDA does not dictate where or how a clinician should perform this evaluation: it may occur either through an in-person assessment or entirely through a remote telemedicine visit for clinically eligible patients, including patients with regular periods and no risk factors, based on a discussion of the patient's symptoms, medical history, and last menstrual period ("LMP") and the patient's reported results of over-the-counter urine pregnancy test(s). Data show no difference in safety or efficacy between the in-person and telemedicine eligibility assessment models, and ACOG, the leading association of women's health care providers, issued guidance during the COVID-19 pandemic specifically recommending that

health care professionals perform these assessments remotely where medically appropriate.[9]

17. If the patient is eligible for a medication abortion, the prescriber will comprehensively counsel the patient about the risks of, and alternatives to, the medication abortion regimen. The prescriber then obtains the patient's informed consent. If the patient is eligible for and has consented to a medication abortion, the clinician issues a prescription for mifepristone and misoprostol. The patient is given specific instructions for use and follow-up care, including how to obtain care in the extremely rare event of a serious complication.

18. The patient must obtain their prescription for mifepristone at a hospital, clinic, or medical office and sign a special "Patient Agreement" form, pursuant to the REMS. Under the REMS, if the clinician has already assessed the patient's eligibility and reviewed the Patient Agreement form through a telemedicine visit, the patient must nonetheless travel to a health center to obtain the pill and physically sign the form even if the patient is obtaining no in-person services. However, as discussed further below, *see* ¶26, FDA stated just this week (on April 12, 2021) that it does not intend to enforce these in-person REMS requirements for the remainder

[9] ARA Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*, BJOG Int. J. Obstetrics & Gynaecology 7-8 (Feb. 9, 2021).

of the COVID-19 Public Health Emergency, citing safety data confirming that permitting patients to obtain mifepristone by mail or through a mail-order pharmacy does *not* increase the risk of serious complications.

19. The patient then swallows the mifepristone pill at the time and place of their choosing, as FDA has long permitted (unrelated to this recent, temporary change).

20. Twenty-four to 48 hours after taking the mifepristone, and also at a location of their choosing, the patient takes the misoprostol buccally (i.e., she lets it dissolve in her mouth, in the pocket of her cheek). FDA has always permitted patients to obtain the misoprostol from a mail-order or retail pharmacy, or at the health care facility where they obtained the mifepristone.

21. Approximately two to 24 hours after taking the misoprostol, the patient will experience bleeding and cramping that expels the pregnancy. FDA's approved labeling for mifepristone advises prescribers to discuss with patients where they will be located beginning 2 hours after taking the misoprostol (i.e., 26 to 50 hours after taking the mifepristone) to ensure they are in a comfortable location for this expected bleeding and cramping.

22. Mifepristone and misoprostol work synergistically to terminate an early pregnancy with high efficacy.[10] Mifepristone blocks the body's receptors for progesterone, a hormone necessary to sustain pregnancy, which prompts the pregnancy tissue and lining of the uterus to break down and separate from the uterine wall.[11] It also softens and opens the cervix,[12] and increases uterine contractility (i.e., capacity to contract).[13] The misoprostol then causes the uterine contractions that expel the contents of the uterus.

23. Misoprostol is capable of ending a pregnancy even without Mifeprex; thus, some providers offer misoprostol alone to patients as a means of pregnancy termination (either for early abortion or for treatment of an early miscarriage). But,

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[10] Christian Fiala & Kristina Gemzel-Danielsson, *Review of Medical Abortion Using Mifepristone in Combination With a Prostaglandin Analogue*, 74 Contraception 66, 66-67 (2006).

[11] 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).

[12] Couzinet et al., *supra* note 11, at 1568; Fiala & Kristina Gemzel-Danielsson, *supra* note 10, at 76 (2006).

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

as discussed more fully below, combining the two medications is the superior regimen in terms of both safety and efficacy. Mifeprex primes the body to respond to misoprostol, a synthetic prostaglandin, by prompting the body to release both natural prostaglandins and produce additional prostaglandin receptors. The combination of the two drugs is thus more likely than misoprostol alone to end the pregnancy and completely empty the uterus, and less likely to result in an infection or require a follow-up procedure. This combined regimen is how FDA has approved the use of Mifeprex for medication abortion.

24. Finally, FDA advises patients to follow up with their clinician seven to 14 days after completing the medication abortion regimen to ensure the abortion was successful. This follow-up often occurs by phone, with termination of pregnancy confirmed by self-reported symptoms and a home urine pregnancy test.

NO MEDICAL OR SAFETY BENEFIT JUSTIFIES THE REMS

The Restrictions on Mifeprex

25. The Mifeprex REMS provides that a patient cannot obtain mifepristone by prescription at a retail or mail-order pharmacy, as is the normal course, and as is true for misoprostol. Rather, the patient must receive the Mifeprex at a clinic, medical office, or hospital ("Restricted Dispensing") under the supervision of a health care provider who has registered with the Mifeprex distributor, attested to their ability to safely prescribe Mifeprex, and then arranged to order and stock

Mifeprex in their health care facility ("Prescriber Registration"). In addition, patients must sign, in person, a special form confirming that they have received counseling on the risks associated with Mifeprex ("Patient Agreement").

26. As noted above, on April 12, 2021, FDA issued guidance stating its intention not to enforce the in-person aspects of the Restricted Dispensing and Patient Agreement requirements during the remainder of the COVID-19 Public Health Emergency. Under this temporary guidance, patients are allowed to obtain their Mifeprex prescription by mail, including through mail-order pharmacies. Based on a "thorough scientific review,"[14] FDA determined that relevant studies "do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion" in the absence of the REMS in-person requirements.[15]

27. Based on both the body of research and my experience, it is my expert opinion that *none* of the REMS elements advance patient safety. To the contrary, the REMS undermines patient safety by delaying, and in some instances entirely preventing, patients from obtaining medical abortion care.

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[14] *Questions and Answers on Mifeprex*, U.S. Food & Drug Admin., https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex#fourteen (last updated Apr. 13, 2021).

[15] 2021 FDA Non-Enforcement Guidance, Joint Stipulation of Facts Ex. J, ECF No. 140.

Mifeprex Is Safe

28. Hundreds of scientific studies 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.[16]

29. Uterine cramping and bleeding, like that of a very heavy menstrual period or miscarriage, are a normal and expected part of the medication abortion process: this is what induces the patient's desired pregnancy termination. Some patients may experience other minor side effects, such as nausea or diarrhea, many of which are extremely common among pregnant people and have not shown to be caused by mifepristone use rather than the underlying pregnancy.[17]

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[16] *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 (Review)*, Cochrane Database Sys. Rev. Issue 11 Article Number CD002855, 2 (2011); Comm. on Prac. Bulls. Gynecology, Soc'y Fam. Plan., *Medication Abortion Up to 70 Days Gestation*, Contraception 6 (2020).

[17] According to FDA, the most commonly reported side effects following use of the mifepristone-misoprostol regimen are nausea, weakness, fever and/or chills, vomiting, headache, diarrhea, and dizziness. For any FDA clinical trial, side effects are reported without any determination of causation.

30. All FDA-approved drug labeling warns of risks, and for Mifeprex there are two: "serious or sometimes fatal infections or bleeding."[18] These are the same serious risks posed by any process that empties the pregnant uterus (medication abortion, procedural abortion, miscarriage, or childbirth) and are not inherent to Mifeprex. The Mifeprex labeling acknowledges as much, stating 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.[19]

31. 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

[18] *Mifeprex Prescribing Information*, U.S. Food & Drug Admin. 1, https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf (last visited Apr. 13, 2021).

[19] *Id*.

uterine scar.[20] The typical cause of infection is that a miscarriage, procedural abortion, medication abortion, or childbirth does not completely empty the uterus, and the tissue that remains there becomes infected. As FDA acknowledges, there is no evidence that Mifeprex *causes* either of these complications.[21]

32. As FDA has found, "major adverse events [among Mifeprex users] including death, hospitalization, serious infection, bleeding requiring transfusion and ectopic pregnancy are exceedingly rare, generally far below 0.1% for any individual adverse event."[22]

33. The Mifeprex labeling states that "2-7 out of 100 patients" will obtain a follow up procedure (although the studies highlighted in the labeling in fact reflect

[20] Heavy bleeding is only 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.

[21] 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 these patients' underlying pregnancies were a more plausible explanation. Letter from Janet Woodcock, M.D., Director, Ctr. for Drug Evaluation & Research, to Donna Harrison, M.D., et al., Denying Citizen Petition Asking the FDA to Revoke Approval of Mifeprex, U.S. Food & Drug Admin. 25-26 n.69 (Mar. 29, 2016), https://www.regulations.gov/document?D=FDA-2002-P-0364-0002.

[22] Ctr. Drug Evaluation & Rsch., Application Number 020687Orig1s020: Medical Review(s) 47 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

a range from 0.3% to 3.8%).[23] Of this small fraction of patients who have a follow-up procedure, the vast majority do so for reasons *other* than a serious complication: namely, (1) ongoing pregnancy, (2) incomplete abortion, or (3) at the patient's request.

34. "Ongoing pregnancy" means that the mifepristone-misoprostol regimen did not achieve the patient's desired outcome of ending the pregnancy. "Incomplete abortion" means that the regimen was not fully effective: the pregnancy is no longer viable, but there is some tissue retained in the patient's uterus. While neither is the patient's desired outcome and follow-up intervention may be appropriate, ongoing pregnancy and incomplete abortion are not serious adverse events.[24] In addition, some patients who have used the mifepristone-misoprostol regimen may request a follow-up clinical procedure because they are uncomfortable with the bleeding that is an expected and safe outcome of medication abortion—i.e., the mechanism that empties the uterus—and wish to expedite completion of the abortion. This is simply a matter of patient preference, and is not medically indicated. For all of these reasons, the Mifeprex labeling lists "patient request,"

[23] *Mifeprex Prescribing Information*, *supra* note 18, at 17.

[24] Moreover, incomplete abortion does not necessarily require a procedure for treatment; this condition can often be resolved through an additional dose of misoprostol.

"ongoing pregnancy," and "incomplete expulsion" as potential reasons for surgical intervention *distinct* from "medical necessity."[25]

35. In all cases, this follow-up intervention is not what we typically think of as "surgery." In the first trimester of pregnancy, when all mifepristone-misoprostol abortions occur, the procedure used to evacuate the contents of a patient's uterus is known as vacuum aspiration (or "aspiration abortion"). While aspiration abortion is sometimes referred to as "surgical" abortion, this is a misnomer: the procedure involves no incisions into the patient's skin or other bodily membranes. Rather, the clinician inserts a small tube (or "cannula") through the cervix into the uterus. The tube is attached to a manual or electric pump, which evacuates the contents of the uterus with gentle suction. It is a minor procedure regularly performed on an outpatient basis that does not require anesthesia or sedation. The procedure takes about five minutes or less.

36. When a patient experiences heavy uterine bleeding—whether after childbirth, spontaneous abortion (i.e., miscarriage), or the mifepristone-misoprostol regimen—clinicians typically use this identical, safe aspiration procedure to treat the heavy bleeding. Accordingly, virtually all emergency departments have access to a

[25] *Mifeprex Prescribing Information*, *supra* note 18, at 13.

physician who can perform this procedure, and the majority of clinicians who care for pregnant patients are trained in this procedure.

37. The Mifeprex labeling lists only a few contraindications—i.e., conditions inconsistent with use of the mifepristone-misoprostol regimen: (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. According to the labeling, the use of mifepristone and misoprostol to terminate a pregnancy is also contraindicated in patients with an intrauterine device ("IUD") in place. All of these contraindications are easily ascertained by simply asking a patient about their medical history.[26]

38. There are no new or emerging safety concerns for mifepristone. To the contrary, in 2016, 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.[27]

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[26] *Id.* at 4-5.

[27] The number of deaths among the millions of patients who have used Mifeprex since its approval in 2000 is exceedingly small: 24, total (as of December 31, 2018). And even this miniscule number is misleadingly high, since FDA requires

39. Significantly, international studies demonstrate that mifepristone is equally safe and effective in the absence of FDA's REMS restrictions. For instance, a recent study of 52,142 medication abortion patients in England found that, among 18,435 patients who had mifepristone and misoprostol mailed to them after receiving all of their care and counseling through telemedicine (which would not be permissible in the United States under the REMS), 99.2% of abortions were successfully completed without a follow-up procedure (compared to 98.2% of abortions with an in-person assessment), and 99.98% experienced no serious adverse events (compared to 99.96% of abortions with an in-person assessment).[28] Indeed, FDA relied on this study in reaching its decision to suspend enforcement of the in-person requirements for the duration of the COVID-19 pandemic.[29]

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prescribers to report deaths among patients who have recently used the medication even if clearly unrelated to Mifeprex, such as in the event of confirmed or suspected homicide. Bixby Ctr. for Glob. Reproductive Health, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/21/2018*, ANSIRH Advancing New Standards in Reproductive Health (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf.

[28] ARA Aiken et al., *supra* note 9, at 6.

[29] FDA relied on several other domestic and international studies examining the provision of mifepristone by mail during the pandemic, all of which concluded that this model is safe and effective, and that there is no safety basis for maintaining in-person requirements. 2021 FDA Non-Enforcement Guidance, *supra* note 15. (citing Erica Chong, et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*,

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

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

41. Of the approximately 20,000 drugs it regulates, FDA subjects only 17 (two of which are Mifeprex and its generic) to a restricted dispensing scheme requiring that the drug be obtained only in certain designated health care settings. And of those 0.08% of FDA-approved drugs subject to restricted dispensing, all except mifepristone must also be *taken* under clinical supervision.

42. In other words, for all of these drugs but mifepristone, there is a logical relationship between the restricted dispensing scheme and the FDA-approved regimen: the drug must be both dispensed *and* administered under clinical

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Contraception (2021), https://www.sciencedirect.com/science/article/pii/S0010782421000913; Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, Contraception (2021), https://doi.org/10.1016/j.contraception.2021.03.025 John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, BMJ Sex Reprod Health (2021), https://srh.bmj.com/content/early/2021/02/04/bmjsrh-2020-200976.

supervision for a clinical reason, such as to prevent a risk of immediate, life-threatening allergic reaction, or because the dosage form (e.g., intravenous administration) is not something patients typically are capable of doing on their own.

43. No such rational explanation exists for Mifeprex. Mifeprex is administered orally; it is a single tablet taken on a single occasion for which there is no risk of addiction; and, critically, FDA allows patients to take it unsupervised at the location of their choice. Mifeprex is the only drug in the nation that can be easily self-administered, and that FDA agrees does not need to be administered in a specific health care setting or under clinical supervision, but that is nonetheless subject to a restricted distribution scheme.

44. 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 FDA does not impose a REMS.

45. First, Korlym® is another mifepristone product which 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.

46. 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).[30] Unsurprisingly, the most commonly reported side effects for Mifeprex are very similar: nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.

47. Yet, Korlym is not subject to a REMS, and patients access it outside the clinical setting. 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 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.

48. Drugs that pose comparable or greater risks of serious bleeding than Mifeprex are not subject to a REMS. For instance, warfarin (also known under the brand name Coumadin®) is an anticoagulant (i.e., "blood thinner") commonly prescribed for patients with atrial fibrillation to reduce the risk of blood clot and stroke. Warfarin is often taken on a chronic (i.e., long-term) basis, and acts by

[30] Corcept Therapeutics, Inc., *Korlym Prescribing Information,* U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf (last visited Apr. 13, 2021).

decreasing the number of clotting factors in the blood, thereby reducing the likelihood of a blood clot forming. I frequently 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."[31] 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 ranged from 0.6% to 4.6% in clinical trials.[32] By comparison, FDA acknowledges that for Mifeprex, the risk of any individual serious adverse event is exceedingly rare: less than 0.1%.[33] Yet warfarin is available by prescription in retail pharmacies.

49. Another useful example is misoprostol, the second drug in the FDA-approved medication abortion regimen, which does not have a REMS and is

[31] Bristol-Myers Squibb Co., *Coumadin (warfarin sodium) Prescribing Information*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/009218s107lbl.pdf (last visited April 13, 2021).

[32] *Id.* at 24.

[33] Ctr. Drug Evaluation & Rsch., *supra* note 22.

available by prescription at virtually any retail pharmacy.[34] The disparate treatment of Mifeprex and misoprostol is counter-intuitive given that misoprostol poses similar categories of risks as those associated with miscarriage, childbirth, procedural abortion, or Mifeprex; and that misoprostol is more effective and likely safer when prescribed in combination with Mifeprex.

50. In the mifepristone-misoprostol regimen, the extremely rare complications of heavy bleeding or infection are significantly more likely to occur after the patient takes the *misoprostol* rather than after the Mifeprex. This is because, as discussed above, it is the misoprostol that causes the uterus to contract and expel its contents. These contractions are what cause the bleeding and cramping that is the intended function of the medication abortion regimen; in extremely rare cases, such

[34] Although misoprostol is part of the FDA-approved regimen included in the mifepristone labeling, misoprostol itself is labeled only for ulcer treatment. *Cytotec misoprostol tablets*, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf (last visited Apr. 13, 2021). However, it is common and permissible to use medications "off-label" (i.e., for different indications or in a different regimen than in the FDA-approved labeling) consistent with medical evidence, and misoprostol is widely used off-label to cause contractions that empty the uterus, including to induce labor, to treat miscarriages, and for early abortion. While misoprostol is part of the FDA-approved Mifeprex regimen, FDA has never directly approved misoprostol as an abortifacient. *Id*.

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.

51. 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 off the robust body of evidence showing that the mifepristone-misoprostol regimen is more effective than misoprostol alone in the context of abortion, I published a study in the New England Journal of Medicine ("NEJM") in 2018 that found that the mifepristone-misoprostol regimen is likewise more effective than misoprostol alone in effectively completing an early miscarriage.[35] Today, the combined mifepristone-misoprostol regimen is considered the superior regimen for both medication abortion and medical treatment of early miscarriage.[36]

52. 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

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

[36] *See, e.g.*, Am. Coll. Obstetricians & Gynecologists, *Practice Bulletin No. 200 Summary: Early Pregnancy Loss*, 1311 (Nov. 2018).

alone, evidence showing that the mifepristone-misoprostol regimen is more effective than misoprostol alone also 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. And, 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, thus reducing the risk of infection.

53. 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."[37] In my medical opinion, the same approach to risk management would be appropriate for Mifeprex.

Leading Medical and Public Health Authorities Support Eliminating the Mifeprex REMS

54. Leading medical and public health organizations, including the American Medical Association, American Public Health Association ("APHA"), American Academy of Family Physicians, ACOG, and SFP, support eliminating the Mifeprex REMS because it has no medical justification and burdens access.[38]

55. I understand that medical and public health authorities were making such recommendations to FDA before the agency reexamined and reimposed the Mifeprex REMS in March 2016. For instance, APHA's Population, Reproductive, and Sexual Health Section joined a letter to 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

[37] *Cytotec misoprostol tablets*, *supra* note 34, at 1.

[38] *See., e.g.*, Cong. of Delegates, Am. Acad. of Fam. Physicians, *Resolution No. 506 (CoSponsored C) Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone*, Am. Acad. of Fam. Physicians 2 (May 24, 2018), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf; House of Delegates, Am. Med. Ass'n, *Memorial Resolutions Adopted Unanimously*, Am. Med. Ass'n (2018), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a18-resolutions.pdf.

extremely safe and… standard professional labeling is clearly sufficient to ensure that its benefits outweigh its risks."[39] The same month, ACOG provided 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 "inappropriately unique to the provision of abortion and . . . mandate procedures and care that are not evidence-based."[40] And SFP signed on to a February 2016 letter to 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."[41]

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[39] 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., U.S. Food & Drug Admin. 4 (Nov. 3, 2015) (Administrative Record (FDA 1248)).

[40] 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., U.S. Food & Drug Admin. (Nov. 4, 2015) (Administrative Record (FDA 1264)).

[41] 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 & Drug Admin. 2 (Feb. 4, 2016) (Administrative Record (FDA 1255)).

56. Moreover, I am aware that all of the leading national medical associations in the country participated in litigation last year challenging the Mifeprex REMS based on their lack of medical necessity and the specific viral risks to which Restricted Dispensing subjected patients in the context of the COVID-19 pandemic. ACOG, which represents 60,000 physicians nationwide, and the Council of University Chairs of Obstetrics and Gynecology, which represents the department chairs of obstetrics and gynecology at more than 150 universities nationwide, were among the Plaintiffs, and AMA, AAFP, and more than a dozen other medical groups (including the American Academy of Pediatrics, the American College of Nurse-Midwives, the Society of General Internal Medicine, and the Society for Maternal-Fetal Medicine) supported as *amici*.[42]

57. The uniformity of opposition to the Mifeprex REMS among leading medical experts underscores that these restrictions lack any medical justification.

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

The Restricted Dispensing Scheme

58. Under the REMS, Mifeprex may be dispensed only in certain health care settings, and not through pharmacies. However, as noted above, the REMS does

[42] Brief for Med. Assoc. as Amicus Curiae Supporting Appellees, *ACOG v. FDA*, No. 20-1824, Dkt. 66 (4th Cir. Feb. 12, 2021).

not require that the patient *take* the mifepristone in these settings. In fact, FDA specifically amended the Mifeprex labeling in 2016 to make clear that the patient need not be in their provider's office when they take the Mifeprex—FDA permits providers to give the patient the mifepristone to take at home or in a setting of their choosing. As discussed above, FDA does not require that any other drug in the nation be dispensed only in designated health care settings without also directing that the patient take the drug under clinical supervision.

59. The restricted dispensing scheme for Mifeprex does nothing to reduce the risks listed in the drug labeling: serious bleeding and infection. Requiring that patients be handed Mifeprex only in certain clinical settings, as opposed to allowing the patient to obtain the mifepristone from their prescriber by mail or by prescription from a retail or mail-order pharmacy, does not in any way diminish the (very minimal) risks of heavy bleeding or infection. There is simply no medical nexus between the location where the patient receives the medication and the likelihood of serious adverse events. Indeed, FDA itself has acknowledged that permitting patients to obtain mifepristone by mail, including mail-order pharmacies, has not resulted in increased safety concerns.

60. I am aware that FDA has asserted in the past that restricted dispensing is necessary because it helps ensure that patients initiate the abortion in a timely manner, and that this diminishes the risk of serious complications. This argument is

medically unfounded for several reasons: *First*, FDA specifically *removed* instructions in 2016 that the patient take the Mifeprex where and when it is dispensed to them, undermining any suggestion that the REMS is designed to ensure prompt administration of Mifeprex. *Second*, patients can and often do obtain the misoprostol from a pharmacy, as FDA permits—which means that many patients still will need to take further steps before they have both medications they need for the abortion. *Third*, far from expediting treatment, it is my expert opinion that the REMS *delays* access to Mifeprex by severely diminishing the number of clinicians that prescribe this medication and by requiring that patients travel in person to obtain their medication when they could otherwise obtain it by mail. Indeed, a recent study in England of tens of thousands of abortion patients found that patients who obtained mifepristone by mail following a telemedicine consultation were substantially *more* likely than patients who obtained their medication in person at a health center to complete the abortion within the first six weeks of pregnancy.[43]

61. Nor does the restricted dispensing scheme in any way increase the likelihood that any serious adverse events would be safely resolved. Any (extremely rare) heavy bleeding or infection would not occur until hours or days after the patient takes the Mifeprex—which could itself be hours or days after the patient leaves the

[43] ARA Aiken et al., *supra* note 9, at 6.

health center. As discussed above, it is perfectly logical for FDA to restrict where a medication may be dispensed if it also restricts where it must be administered, either because the route of administration requires clinical involvement (such as an intravenous drug) or because the patient needs medical oversight in the event of any immediate adverse reaction. But such a restriction makes no sense here given the timing of the physiological effects of the mifepristone-misoprostol regimen.

62. I am also aware that FDA has asserted in the past that the restricted dispensing scheme could somehow enhance patient counseling. This argument likewise has no medical basis. As an initial matter, FDA does not dictate when or where Mifeprex prescribers counsel their patients: clinicians are already permitted to provide all counseling via telemedicine and just have the patient sign the Patient Agreement form at the time they pick up their medication. But even imagining that FDA's restricted dispensing scheme led to more patient counseling around the time of dispensing, there is no evidence to suggest that this increases patient safety. In all areas of medicine, clinicians counsel their patients at the time of *prescription*, not at the time of dispensing. There is absolutely no scientific reason to believe that Mifeprex patients counseled at the time their prescription is issued—just like virtually every other patient obtaining virtually every other drug—are any less capable of understanding the counseling information, or any less capable of following up with their prescriber by phone should they have subsequent questions

that they cannot resolve by reviewing the prescribing information that comes with each prescription. Simply put, were there any connection between restricted dispensing and the quality of counseling, FDA would require restricted dispensing for more than 0.08% of the drugs it regulates.

63. Dictating where a patient must be located when she is handed a pill that she may choose to take several days later, and which would not result in any rare serious adverse events until days later, is illogical and without medical basis.

The Prescriber Registration Requirement

64. Under the REMS, all clinicians who seek to prescribe Mifeprex must register with the drug distributor by completing a "prescriber agreement." A clinician cannot order and stock mifepristone for the first time without first completing, signing, and faxing this form to the distributor. In my expert opinion, this requirement treats Mifeprex differently than virtually all other drugs—which providers are permitted to prescribe within their clinical skills and competencies without notifying the drug manufacturer that they are competent to do so; is unnecessary for the safe provision of Mifeprex; and deters qualified clinicians from prescribing this medication.

65. The prescriber agreement requires the individual completing the form to certify that they meet certain qualifications for prescribing mifepristone. Specifically, they must certify that they are able to accurately assess the duration of

pregnancy, diagnose ectopic pregnancies, provide or make plans for a follow-up procedure in the event of incomplete abortion and/or heavy bleeding, 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 prescribing information for mifepristone.

66. By signing the form, the clinician also agrees to follow certain basic guidelines for Mifeprex use, which include: reviewing the Patient Agreement form with the patient, fully explaining the risks of the mifepristone-misoprostol treatment regimen, and answering any patient questions; signing and obtaining the patient's signature on the Patient Agreement; providing the patient with a copy of the Patient Agreement 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; 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.

67. This prescriber registration requirement does not enhance patient safety, and treats Mifeprex differently than virtually all other drugs with no medical basis. 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."[44] 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.

68. Thus, FDA rarely requires any provider certification for clinicians to dispense drugs; even drugs that carry "black box" warnings from FDA indicating that they present serious or life-threatening risks typically do not require special certification, because it is an integral part of the practice of medicine to assess the

[44] *Code of Professional Ethics of the American College of Obstetricians and Gynecologists*, Am. Coll. of Obstetricians and Gynecologists 2 (Dec. 2018), https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/acog-policies/code-of-professional-ethics-of-the-american-college-of-obstetricians-and-gynecologists.pdf.

proper treatment for a patient based on the patient's diagnosis and eligibility. All drugs require an accurate assessment of patient eligibility to ensure that they will be appropriate, safe, and effective for the patient, and all clinicians are trained in making these assessments within their skills and competencies; there is no medical basis for treating Mifeprex any differently. A requirement that physicians self-certify that they are qualified to prescribe mifepristone is a striking aberration from normal practice and does not enhance the preexisting protections that these ethical, legal, and clinical standards provide.

69. There is nothing about Mifeprex that justifies this differential treatment. Even if in 2000, when 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. Indeed, I am aware that clinicians can now obtain training in medication abortion care online. But more importantly, speaking from my extensive experience training residents in medication abortion, prescribing Mifeprex does not require any specialized clinical skills beyond those common to any sort of care for pregnant patients.

70. It is relatively easy for a clinician to determine an individual patient's eligibility for mifepristone. As with any medication, a clinician would review a pre-determined list of the medication's indications and contraindications against the patient's self-reported medical history. The prescriber must also 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 the patient's self-reported history or, in some cases, an ultrasound and/or blood work. These skills are threshold competencies well within the scope of practice of clinical providers who care for pregnant patients. It is my understanding from years of attending national meetings and conferences that all or virtually all clinicians who provide pregnancy-related care and issue prescriptions as part of their scope of practice are trained in the skills of diagnosing an intrauterine pregnancy and dating the pregnancy.

71. Notably, medication abortion and procedural abortion require the same diagnostic skills (diagnosing and dating an intrauterine pregnancy), but the treatment in a medication abortion simply involves prescribing medications. Thus, a clinician already trained in safely providing procedural abortion care can safely prescribe medication abortion after reading the mifepristone prescribing information and medication guide.

72. 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 pregnancy-related care. And, if for some reason a

clinician is not comfortable diagnosing, dating, and locating a pregnancy, they can easily obtain this information by ordering an ultrasound.

73. The fact that ectopic pregnancies (a pregnancy implanted outside the uterus, such as within a fallopian tube) are contraindicated for mifepristone does not justify prescriber registration. *First*, they are a topic in which all clinicians who provide pregnancy-related care would have training. *Second*, ectopic pregnancy is a rare condition—particularly among patients seeking abortion, who have been found to have generally even lower rates of ectopics than the general United States population.[45] *Third*, ectopic pregnancies are contraindicated for mifepristone not because the mifepristone-misoprostol regimen causes any complications in the context of an ectopic pregnancy, but because it typically does not have any *effect* on an ectopic pregnancy. In the extremely rare event that a patient with an ectopic pregnancy takes Mifeprex, they may eventually need some other effective treatment for this condition if it does not resolve on its own—and the need for further care would typically become clear based on self-reported symptoms that would be a red flag for any clinician who cares for pregnant people (such as asymmetric abdominal or pelvic pain). It is common and appropriate for clinicians to provide a certain course of treatment and then adjust as needed if the clinical picture changes. And

[45] *Medication Abortion Up to 70 Days Gestation*, *supra* note 16, at 3.

any clinician prescribing Mifeprex would have already counseled their patient about the risk of ectopic pregnancies and potential warning signs, in accordance with the prescribing information set out in the labeling.

74. The requirement that the prescriber certify their ability to ensure patient access to surgical intervention and blood transfusions and resuscitation if necessary also does not justify prescriber registration. Emergency departments regularly treat patients who present with heavy uterine bleeding due to miscarriage or childbirth, and thus nearly all emergency departments are equipped to manage such patients. And, of course, emergency departments also treat patients suffering significant blood loss for countless other reasons (such as a gunshot wound), and would be able to provide resuscitation and/or blood transfusion either directly or by facilitating a transfer.

75. As a general matter, ensuring patients know what to do in the event that a treatment is ineffective or they experience a complication is a standard part of medical counseling; presumably for this reason, FDA does not require a REMS for countless drugs more likely than Mifeprex to require routine or emergency follow-up care. There is nothing about Mifeprex that would justify this requirement, and it is notable that other drugs like warfarin that pose greater risks of severe bleeding than Mifeprex are not subject to these constraints. Because all clinicians are able to

direct patients to emergency care as needed, all clinicians can satisfy the REMS requirement that they have a plan for intervention under such circumstances.

76. It likewise serves no medical purpose to require Mifeprex prescribers to self-certify that they are qualified to read and understand the prescribing information for Mifeprex. Licensed clinicians with prescriptive authority are qualified to read and understand prescribing information for virtually any drug, and particularly a drug as safe, effective, and straightforward as Mifeprex.

77. Finally, requiring would-be Mifeprex prescribers 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. This results in redundant paper work without clinical value. Laws and ethical standards already require abortion providers, like all clinicians, to obtain informed consent from patients before providing treatment. On top of that, in my experience, most if not all medical institutions have mandatory protocols and standards in place to obtain patient informed consent. This requirement merely asks prescribers to certify that they will act in accordance with laws and norms that already govern their conduct.

78. This is not to say that special training or certification would never be appropriate for *any* medication. In exceptional cases—for instance, in the context of opioid medications, where there is overwhelming evidence of a pervasive and lethal

problem of patient misuse and abuse[46]—special training or certification may well be appropriate. But given Mifeprex's strong safety profile, and the basic nature of the qualifications set out in the prescriber agreement, there is no reason to single out Mifeprex as a drug requiring a unique prescriber certification. This medication simply does not fit the bill.

The Patient Agreement Form

79. Under the REMS, a patient cannot receive mifepristone before completing and signing a "Patient Agreement" form that duplicates information contained in the medication guide that comes with every Mifeprex prescription. FDA rarely requires patient agreement forms for prescription drugs, and does not require a patient agreement form for misoprostol—for good reason.

80. 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

[46] *See Opioid Medications*, U.S. Food & Drug Admin. (Mar. 29, 2021), https://www.fda.gov/drugs/information-drug-class/opioid-medications ("One of the highest priorities of FDA is advancing efforts to address the crisis of misuse and abuse of opioid drugs harming families. Opioids are claiming lives at a staggering rate, and overdoses from prescription opioids are reducing life expectancy in the United States.").

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. Indeed, the Patient Agreement undermines informed consent by creating confusion, and in some cases even trauma, for patients.

81. The Mifeprex Patient Agreement is based on the science that existed in 2016 and as a static document, it does not reflect current, evidence-based clinical practice. For instance, many years before the 2016 Mifeprex labeling change and REMS approval, the 600 mg dosage of Mifeprex that the FDA originally authorized in 2000 was found to be unnecessarily high. As I previously noted (*see* n.34), off-label use of a medication consistent with scientific evidence is widespread and permissible. 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 stating that they had read the medication guide, which instructed them to take a 600 mg dosage that in fact was no longer the standard of care. As another example, evidence has long confirmed that the mifepristone-misoprostol regimen is safe beyond 49 days of pregnancy, the time period stated in the Mifeprex labeling and Patient Agreement. In 2016, FDA finally updated the labeling to reflect such evidence—but for years beforehand, I and many other abortion providers provided

care to patients beyond 49 days of pregnancy, consistent with high-quality medical evidence. Nevertheless, we had to have all of our Mifeprex patients sign a form stating that they were less than 49 days pregnant, even when that was untrue, which understandably confused patients and raised some questions about whether to trust the medical judgment of their provider or of FDA.

82. 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.

83. The Patient Agreement form can be particularly distressing for patients using mifepristone for a non-abortion indication, including miscarriage management. As discussed above, the Mifeprex-misoprostol regimen has become the standard of care for miscarriage management: 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 taking Mifeprex in order to "end [their] pregnancy." The Patient Agreement form thus creates confusion and sometimes distress for such patients and fails to reflect innovations in safe and effective patient care.

The Mifeprex REMS Diminishes Patient Safety

84. Far from improving patient safety, 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 study analyzed medication abortion provision and the impact of the REMS based on a nationally representative survey of ACOG fellows (who are currently practicing, board-certified obstetrician/gynecologists). The researchers found that, among respondents who have patients seeking abortion care, fewer than one in five had provided medication abortion care in the past year—and that remarkably low figure even includes clinicians who prescribed something other than the mifepristone-misoprostol regimen (such as misoprostol alone). But the research found that if clinicians were permitted to write a prescription for mifepristone—i.e., if not for the REMS—the

proportion of medication abortion providers would *double*.[47] Notably, the number of respondents in the South and Midwest who said they would begin providing medication abortion if not for the REMS was higher than the number currently providing such care. And while the overwhelming majority of current abortion providers said they practice in urban areas, 40 percent of clinicians who would provide medication abortion care if they could write a prescription identified their practice as "suburban" or "midsize town, rural, or military." In short, FDA's restricted dispensing requirement reduces the pool of abortion providers in the areas most in need of access.

85. The prescriber registration requirement also deters qualified providers from providing medication abortion care, or from using the superior mifepristone-misoprostol regimen in the context of miscarriage management. Because of anti-abortion terrorism and harassment in the United States, many clinicians are concerned about filling out a form that may identify them as an abortion provider, fearing that doing so could expose them and their families to violence and/or harassment. I have heard these concerns from colleagues at professional conferences. I have also had many one-on-one conversations with physicians who

[47] Sara Daniel et al., *Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone*, Contraception, 5 (2021).

would like to implement mifepristone in their gynecological practices, but are concerned that completing the prescriber agreement might enable anti-abortion activists to access their information and target them for harassment or worse. And when I discuss mifepristone with my students, they regularly 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 trade-offs between offering mifepristone, which is part of safe and effective patient care, and fulfilling the prescriber registration requirement and potentially becoming the target of harassment and violence. As an expert in the medical management of early pregnancy loss, I personally have received many queries from clinicians around the country asking for advice on how to convince their hospital and practices to stock mifepristone for the benefit of patient care. The REMS has repeatedly been cited as a barrier to implementation.

86. By reducing the number of providers offering FDA-approved medication abortion regimen, the Mifeprex 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 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 a lengthier procedure involving an overnight stay in the area for patients who do not live near an abortion provider. The cost for a second-trimester abortion is about three times the cost of a medication abortion in my hospital, and we have one of the lowest cost bases for hospital-based second-trimester abortion care in the country.

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

CONCLUSION

88. The Mifeprex REMS provides no medical benefit. There is no valid scientific reason for FDA to single out this safe and effective medication for onerous restrictions that, far from improving patient safety, delay or block patients' access.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 14, 2021.

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

Schreiber Decl.

Exhibit A-1

UNIVERSITY OF PENNSYLVANIA - PERELMAN SCHOOL OF MEDICINE
Curriculum Vitae

Date: 02/23/2021

Courtney Anne Schreiber, MD, MPH

Address: Department of Obstetrics and Gynecology
3400 Spruce Street, 1000 Courtyard
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

Military Service:
[none]

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	Director, PEACE
2017-present	Division Chief, Family Planning, Department of Obstetrics and Gynecology, Penn Medicine

Other Appointments:

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

Specialty Certification:

2007	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	James E Constantine Award in Obstetrics and Gynecology, NYU School of Medicine
1999	Dr. Martin Gold Visionary Provider Award, Diana Foundation, NY, NY
2001	Resident Teaching Award, Hospital of the University of Pennsylvania
2004	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2005	Donald F. Richardson Memorial Prize Paper Award Nominee, American College of Obstetricians and Gynecologists
2005	Philip F. Williams Prize Award, American College of OB/GYN
2005	Wyeth New Leader's Award Fellowship, Association of Reproductive Health Professionals
2010	Women's Way Unsung Heroine Award: Turning Talk into Action
2011	Emily B. Hartshorne Mudd Award for Contributions to the Field of Family Health
2011	The Penn Medicine "Penn Pearls" Award for Excellence in Teaching
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

Memberships in Professional and Scientific Societies and Other Professional Activities:

International:

2017-present	Fellowship in Family Planning (Advisory Board (Chair, 2017-2019))

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
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 (Complex Family Planning Committee Chair 2019 Complex Family Planning Division Chair 2020-present)
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	The Accreditation Council for Graduate Medical Education, Complex Family Planning Task Force

2021-present American Gynecological and Obstetrical Society (AGOS)

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)

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-Present	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-Present	Member, Review Committee for the Department of Biostatistics, Epidemiology, and Informatics
2018-present	Department of Obstetrics and Gynecology Executive Committee

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	Director, Family Planning Fellowship Program
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
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"

Lectures by Invitation (Last 5 years):

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	"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
Nov, 2018	"Miscarriage Management: Updates and Innovations" 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, D.C.
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.
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.

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, California
Apr, 2017	Organizer and Panel Moderator, "Moving Forward: Protecting and Promoting Reproductive Health" University of Pennsylvania
May, 2019	Chairperson, Directors' Meeting, Fellowship in Family Planning Boston, Mass

Bibliography:

Research Publications, peer reviewed (print or other media):

1. Schreiber CA, Wan L, Sun Y, Krey L, Lee-Huang S: The antiviral agents MAP30 and GAP31 are not toxic to human spermatozoa and may be useful in preventing the sexual transmission of HIV-I. Fertil Steril 72:686-690, 1999.

2. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: Same day initiation of the transdermal hormonal delivery system (contraceptive patch) versus traditional initiation methods. Contraception 72(5):333-36, 2005.

3. Murthy AS, Creinin MD, Harwood BJ, Schreiber CA: A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation. Contraception 71(5):333-336, 2005.

4. Schreiber CA, Creinin MD, Harwood BJ, Murthy AS: A pilot study of mifepristone and misoprostol administered at the same time for abortion from 50-63 days gestation. Contraception 71(6):447-50, 2005.

5. Schreiber CA, Creinin MD, Reeves MF, Harwood BJ: Mifepristone and misoprostol for the treatment of early pregnancy failure: a pilot clinical trial. Contraception 74:458-462, 2006.

6. Schreiber CA, Harwood BJ, Switzer GE, Creinin MD, Reeves MF, Ness RB: Training and attitudes about contraceptive management across primary care specialties: a survey of graduating residents. Contraception 73:618-622, 2006.

7. Schreiber CA, Meyn, L, Creinin MD, Barnhart KT, Hillier SL: The effects of long-term use of nonoxynol-9 on vaginal flora. Obstet Gynecol 107:1-9, 2006.

8. Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA: Medical abortion at the same time (MAST) study trial group. Mifepristone and misoprostol administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial. Obstet Gynecol 109(4):885-894, 2007.

9. Schreiber CA, Sammel M, Barnhart KT, Hillier SL: A little bit pregnant: Modeling how the accurate detection of pregnancy can improve HIV prevention trials. Am J Epidemiol 169(4):515-521, 2009.

10. Schreiber CA, Ratcliffe SJ, Barnhart KT: A randomized controlled trial of the effect of advanced supply of emergency contraception in postpartum teens: a feasibility study. Contraception 81(5):435-40, 2010.

11. Schreiber CA, Sober S, Ratcliffe S, Creinin MD: Ovulation resumption after medical abortion with mifepristone and misoprostol. Contraception 84(3):230-3, 2011.

12. Schreiber CA, Whittington S, Cen L, Maslankowski, L: Good Intentions: Risk factors for unintended pregnancies in the U.S. cohort of a microbicide trial. Contraception 83(1):74-81, 2011.

13. Su IH, Schreiber CA, Fay C, Parry S, Elovitz MA, Zhang J, Shaunik A, Barnhart K: Mucosal integrity and inflammatory markers in the female lower genital tract as potential screening tools for vaginal microbicides. Contraception 84(5):525-32, 2011.

14. Chen SP, Massaro-Giordano G, Pistilli M, Schreiber CA, Bunya V: Tear osmolarity and dry eye symptoms in women using oral contraception and contact lenses. Cornea 32(4):423-8, 2013.

15. Kinariwala M, Quinley K, Datner E, Schreiber CA: Manual vacuum aspiration in the emergency department for management of early pregnancy failure. Am J Emerg Med 31(1):244-7, 2013.

16. Pentlicky S, Rosen M, Coffey P, Kilbourne-Brook M, Shaunik A, Schreiber CA, Barnhart K: An exploratory, randomized, crossover MRI study of microbicide delivery with the SILCS diaphragm compared to a vaginal applicator. Contraception 87(2):187-92, 2013.

17. Swica Y, Chong E, Middleton T, Prine L, Gold M, Schreiber CA, Winikoff B: Acceptability of home use of mifepristone for medical abortion. Contraception 88(1):122-7, 2013.

18. Colleselli V, Schreiber CA, D'Costa E, Mangesius S, Ludwig W, Seeber BE: Medical management of early pregnancy failure (EPF):a retrospective analysis of a combined protocol of mifepristone and misoprostol used in clinical practice. Arch Gynecol Obstet 289(6): 1341-45, Jun 2014.

19. Foster DG, Grossman D. Turok DK, Peipert JF, Prine L, Schreiber CA, Jackson A, Barar R, Schwarz EB: Interest in and experience with IUD self-removal. Contraception 90(1): 54-59, Jul 2014.

20. Wilson S, Tennant C, Sammel MD, Schreiber C: Immediate postpartum etonogestrel implant: a contraception option with long-term continuation. Contraception 90(3): 259-64, Sep 2014.

21. Quinley K, Ratcliffe S, Schreiber C: Psychological coping in the immediate post-abortion period. J Women's Health 23(1):44-50, 2014.

22. Schreiber CA, Traxler S: State of family planning. Clin Obstet Gynecol 58(2): 392-408, Jun 2015

23. Eisenberg DL, Schreiber CA, Turok DK, Teal SB, Westhoff CL, Creinin MD: Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. Contraception 92(1): 10-16, Jul 2015.

24. Quinley KE, Falk A, Kallan MJ, Datner EM, Carr BG, Schreiber CA: Validation of ICD-9 Codes for Stable Miscarriage in the Emergency Department. West J Emerg Med 16(4): 551-6, Jul 2015.

25. Schreiber CA, Ratcliffe SJ, Quinley KE, Miller C, Sammel MD: Serum biomarkers to predict successful misoprostol management of early pregnancy failure. Reprod Biol 15(2): 79-85, 2015.

26. Schreiber CA, Ratcliffe SJ, Sammel MD, Whittaker PG.: A self-assessment efficacy tool for spermicide contraceptive users. Am J Obstet Gynecol 214(2): 264.e1-7, Feb 2016.

27. Sober S, Shea J, Shaber A, Whittaker P, Schreiber C: Postpartum Adolescents' Contraceptive Counselling Preferences. Eur J Contracept Reprod Health Care 22(2): 83-87, April 2016.

28. Wilson SF, Degaiffier N, Ratcliffe SJ, Schreiber CA: Peer counselling for the promotion of long-acting, reversible contraception among teens: a randomised, controlled trial. Eur J Contracept Reprod Health Care 21(5): 380-7, Oct 2016.

29. Roe AH, Traxler SA, Hadjiliadis D, Sammel MD, Schreiber CA: Contraceptive choices and preferences in a cohort of women with cystic fibrosis. Respir Med 121: 1-3, Dec 2016.

30. Schreiber CA, Chavez V, Whittaker PG, Ratcliffe SJ, Easley E, Barg FK: Treatment Decisions at the Time of Miscarriage Diagnosis. Obstet Gynecol 128(6): 1347-1356, Dec 2016.

31. Frisse AC, Marrazzo JM, Tutlam NT, Schreiber CA, Teal SB, Turok DK, Peipert JF: Validity of Self-Reported History of Chlamydia trachomatis Infection. Am J Obstet Gynecol 216(4): e1-393, April 2017.

32. Akers AY, Steinway C, Sonalkar S, Perriera LK, Schreiber C, Harding J, Garcia-Espana JF: Reducing Pain During Intrauterine Device Insertion: A Randomized Controlled Trial in Adolescents and Young Women. Obstet Gynecol 130(4): 795-802, Oct 2017.

33. Sonalkar S, Gurney EP, McAllister A, Schreiber CA: A randomized pilot evaluation of individual-level abortion stigma resulting from Pennsylvania mandated abortion counseling. Contraception 96(4): 227-232, Oct 2017.

34. Colwill AC, Schreiber CA, Sammel MD, Sonalkar S: Six-week retention after postplacental copper intrauterine device placement. Contraception 97(3): 215-218, Mar 2018.

35. Schreiber CA, Teal SB, Blumenthal PD, Keder LM, Olariu AI, Creinin MD: Bleeding patterns for the Liletta levonorgestrel 52 mg intrauterine system. Eur J Contracept Reprod Health Care 23(2): 116-120, Apr 2018.

36. Akers AY, Harding J, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S: Satisfaction with the Intrauterine Device Insertion Procedure Among Adolescent and Young Adult Women. Obstet Gynecol 131(6): 1130-1136, Jun 2018.

37. Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT: Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 378(23): 2161-70, Jun 2018 Notes: selected as a CME activity for the New England Journal of Medicine.

38. Gurney EP, Sonalkar S, Mcallister A, Sammel MD, Schreiber CA: Six-month expulsion of postplacental copper intrauterine devices placed after vaginal delivery. Am J Obstet Gynecol 219(2): 183.e1-183.e9, Aug 2018.

39. Whittaker PG, Schreiber CA, Sammel MD: Gestational hormone trajectories and early pregnancy failure: a reassessment. Reprod Biol Endocrinol 16(1): 95, Oct 2018.

40. Sonalkar S, Hunter T, Gurney EP, McAllister A, Schreiber CA: A Decision Analysis Model of 1-Year Effectiveness of Intended Postplacental Compared with Intended Delayed Postpartum Intrauterine Device Insertion. Obstet Gynecol 132(5):1211-122, Nov 2018.

41. Clement EG, Horvath S, McAllister A, Koelper NC, Sammel MD, Schreiber CA: The Language of First-Trimester Nonviable Pregnancy: Patient-Reported Preferences and Clarity. Obstet Gynecol 133(1):149-154, Jan 2019.

42. Frarey A, Gurney EP, Sober S, Whittaker PG, Schreiber CA: Postpartum contraceptive counseling for first-time adolescent mothers: a randomized

controlled trial. Arch Gynecol Obstet 299(2):361-369, Feb 2019.

43. Frarey A, Schreiber C, McAllister A, Shaber A, Sonalkar S, Sammel MD, Long jA: Pathways to Abortion at a Tertiary Care Hospital: Examining Obesity and Delays. Perspect Sex Reprod Health 51(1):35-41, Mar 2019.

44. Sackeim MG, Gurney EP, Koelper N, Sammel MD, Schreiber CA: Effect of contraceptive choice on rapid repeat pregnancy. Contraception 99(3):184-186, Mar 2019.

45. Chen BA, Blithe DL, Muraguri GR, Lance AA, Carr BR, Jensen JT, Kimble TD, Murthy AS, Schreiber CA, Thomas MA, Walsh TL, Westhoff C, Burke AE: Acceptability of the Woman's Condom in a phase III multicenter open-label study. Contraception 99(6): 357-362, Jun 2019.

46. O'Flynn O'Brien KL, Akers AY, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S: Intrauterine Device Insertion Procedure Duration in Adolescent and Young Adult Women. J Pediatr Adolesc Gynecol 32(3):312-315, Jun 2019.

47. Deshpande NA, Labora A, Sammel MD, Schreiber CA, Sonalkar S: Relationship between body mass index and operative time in women receiving immediate postpartum tubal ligation. Contraception 100(2): 106-110, Aug 2019.

48. Traxler SA, Chavez V, Hadjiliadis D, Shea JA, Mollen C, Schreiber CA: Fertility considerations and attitudes about family planning among women with cystic fibrosis. Contraception 100(3):228-233, Sep 2019.

49. Miller CA, Roe AH, McAllister A, Meisel ZF, Koelper N, Schreiber CA: Patient Experiences with Miscarriage Management in the Emergency and Ambulatory Settings. Obstet Gynecol 134(6):1285-1292, Dec 2019.

50. Horvath S, Tsao P, Huang ZY, Zhao L, Du Y, Sammel MD, Luning Prak ET, Schreiber CA: The concentration of fetal red blood cells in first-trimester pregnant women undergoing uterine aspiration is below the calculated threshold for Rh sensitization. Contraception 102(1): 1-6, Jul 2020.

51. Albright BB, Shorter JM, Mastroyannis SA, Ko EM, Schreiber CA, Sonalkar S: Gestational Trophoblastic Neoplasia After Human Chorionic Gonadotropin Normalization Following Molar Pregnancy: A Systematic Review and Meta-analysis. Obstet Gynecol 135(1): 12-23, Jan 2020 Notes: [Epub ahead of print] Dec 2019.

52. Anand P, McAllister A, Hunter T, Schreiber C, Koelper N, Sonalkar S: A Simulated Patient Study to Assess Referrals to Abortion Care by Student Health Centers in Pennsylvania. Contraception 102(1): 23-29, Feb 2020.

53. Hunter TA, Sonalkar S, Schreiber CA, Perriera LK, Sammel MD, Akers AY: Anticipated Pain During Intrauterine Device Insertion. J Pediatr Adolesc Gyneco 33(1): 840-847, Feb 2020.

54. Nagendra D, Koelper, N, Loza-Avalos SE, Sonalkar S, Chen M, Atrio J, Schreiber CA*, Harvie HS* (co-senior authors): Cost-effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy. Secondary Analysis of a Randomized Clinical Trial. JAMA Network Open 3(3):e20159, Mar 2020.

55. Chen BA, Eisenberg DL, Schreiber CA, Turok DK, Olariu AI, Creinin MD: Bleeding changes after levonorgestrel 52mg intrauterine system insertion for contraception in women with self-reported heavy menstrual bleeding. Am J Obstet Gynecol 222(4S):S888.e1-S888.e6, Apr 2020.

56. Sonalkar S, Koelper N, Creinin MD, Atrio JM, Sammel MD, McAllister A, Schreiber CA: Management of early pregnancy loss with mifepristone and misoprostol: clinical predictors of success from a randomized trial. Am J Obstet Gynecol Apr 2020.

57. Turok DK, Nelson AL, Dart C, Schreiber CA, Peters K, Schreifels MJ, Katz B: Efficacy, Safety, and Tolerability of a New Low-Dose Copper and Nitinol Intrauterine Device: Phase 2 Data to 36 Months. Obstet Gynecol 135(4):840-847, Apr 2020.

58. Roe AH, McAllister A, Sammel MD, Schreiber CA: Pregnancy intentions and contraceptive uptake after miscarriage. Contraception 101(6): 427-431, Jun 2020.

59. Nagendra D, Sonalkar S, Schurr D, McAllister A, Roe AH, Shorter JM, Sammel MD, Schreiber CA.: Opioid prescription for pain after osmotic dilator placement in abortion care: A randomized controlled trial. Contraception 103: 13-18, Jan 2021.

60. Shorter JM, Koelper N, Sonalkar S, Oquendo MA, Sammel MD, Schreiber CA.: Racial Disparities in Mental Health Outcomes Among Women With Early Pregnancy Loss. Obstet Gynecol 137: 156-163, Jan 2021.

61. Hawkins L, Gertz AM, Badubi O, Sickboy O, Mussa A, Maotwe T, Whittaker PG, Schreiber CA, Ramagola-Masire D, Morroni C.: Integration of family planning services into health care for HIV-positive women in Botswana. Int J Gynaecol Obstet 152: 208-214, Feb 2021.

62. Flynn AN, Roe AH, Koelper N, McAllister A, Sammel MD, Schreiber CA.: Timing and efficacy of mifepristone pretreatment for medical management of early pregnancy loss. Contraception ontraception, 2021.

63. Sonalkar S, Maya E, Adanu R, Samba A, Mumuni K, McAllister A, Fishman J,

Schurr D, Schreiber CA, Kolev S, Doe R, Gaffield ME.: Pilot monitoring and evaluation of the WHO Postpartum Family Planning Compendium mobile application: an in-depth, qualitative study. Int J Gynaecol Obstet nt J Gynaecol Obstet, 2021.

Research Publications, peer-reviewed reviews:

1. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (Suppl):19-24, 2005.

2. Schreiber CA, Creinin MD: Mifepristone in abortion care. Semin Reprod Med 23(1):82-91, 2005.

3. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient (RA suppl):10-12, 2006.

4. Barnhart KT, Schreiber CA: Return to fertility following discontinuation of oral contraceptives. Fertil Steril 91(3):659-63, 2009.

5. Schreiber CA, Barnhart KT: Contraceptive Concerns: Return to Fertility. The Female Patient 34(12), 2009.

6. Gibson E, Schreiber CA: Controversies in Family Planning: When uterine leiomyomas complicate uterine evacuation. Contraception 82(6):486-8, 2010.

7. Vasquez P, Schreiber CA: Controversies in Family Planning: The missing IUD. Contraception 82(2):126-8, 2010.

8. Perron-Burdick M, Schreiber C, Gupta P: Ophthalmic migraines and combined hormonal contraceptives. Contraception 84(5):442-4, 2011.

9. Quinn SM, Schreiber C: Controversies in Family Planning: IUD use in HIV-positive women. Contraception 83(2):99-101, 2011.

10. Sober SP, Schreiber CA: Controversies in family planning: are all oral contraceptive formulations created equal? Contraception 83(5):394-6, 2011.

11. Lathrop E, Schreiber C: Controversies in family planning: management of second-trimester pregnancy terminations complicated by placenta accreta. Contraception 85(1):5-8, 2012.

12. Pentlicky S, Harken T, Schreiber CA: Controversies in family planning: first trimester uterine evacuation for the anticoagulated patient. Contraception 85(5):434-36, 2012.

13. Owen C, Sober S, Schreiber CA: Controversies in family planning: desired pregnancy, IUD in situ and no strings visible. Contraception 88(3):330-3, 2013.

14. Patel PR, Schreiber CA: Controversies in family planning: contraceptive counseling in the solid organ transplant recipient. Contraception 138-142, 2013.

15. Wilson S, Tan G, Baylson M, Schreiber CA: Controversies in family planning: how to manage a fractured IUD. Contraception 599-603, 2013.

16. Sober S, Schreiber CA: Postpartum contraception. Clin Obstet Gynecol 57(4): 763-76, Dec 2014.

17. Dzuba IG, Grossman D, Schreiber CA: Off-label indications for mifepristone in gynecology and obstetrics. Contraception 92(3): 203-5, Sep 2015.

18. Roe A, Traxler SA, Schreiber CA: Contraception in Women with Cystic Fibrosis: A Systematic Review of the Literature. Contraception 93(1): 3-10, Jan 2016.

19. Horvath S, Schreiber CA: Unintended Pregnancy, Induced Abortion, and Mental Health. Curr Psychiatry Rep 19(11): 77, Sep 2017.

20. Shorter Jm, Atrio JM, Schreiber CA: Management of early pregnancy loss, with a focus on patient-centered care. Seminars in Perinatology Dec 2018.

Contributions to peer-reviewed research publications, participation cited but not by authorship:

[none]

Research Publications, non-peer reviewed:

[none]

Abstracts (Last 3 years):

1. Hunter T, Gurney EP, Schreiber C, McAllister A, Sonalkar S: Probability of Pregnancy after Intended Postplacental versus Interval Intrauterine Device Placement. ACOG Annual Clinical and Scientific Meeting; Austin, TX. _ Apr 2018.

2. Eisenberg D, Schreiber C, Carr B, Turok D, Chen B, Creinin M: Change in Bleeding Patterns After Liletta Insertion for Women with Subjective Baseline Heavy Menstrual Bleeding. Poster Presentation, Forum on Family Planning, New Orleans, LA. _ Oct 2018 Notes: Winner, Translational Poster Award.

3. Flynn A, Sonalkar S, Schreiber C: Unintended Pregnancy and Contraception among Women with Resolved Pregnancy of Unknown Location. Poster presentation, Forum on Family Planning, New Orleans, LA. _ Oct 2018.

4. Horvath S, Luning Prak E, Schreiber C: Flow Cytometric Quantification of Feto-Maternal Maternal Hemorrhage Following Uterine Aspiration. Oral Poster Presentation, Forum on Family Planning, New Orleans, LA October 2018.

5. Lang B, McAllister A, Epperson CN, Schreiber C: Comparing Mood and Sexual Side Effects among Users of Hormonal and Non-hormonal Contraceptives. Poster Presentation, Forum on Family Planning, New Orleans, LA. _ Oct 2018.

6. Nagendra D, Harvie H, Koelper N, Sonalkar S, Loza-Avalos S, Courtney Schreiber CA: Cost Effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy. Oral presentation, ACOG Annual Clinical and Scientific Meeting _ May 2019.

Editorials, Reviews, Chapters, including participation in committee reports (print or other media):

1. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient 10-12, Jan, 2006 (RA Suppl).

2. Schreiber CA, Creinin MD: The health benefits of hormonal contraception. The Female Patient 19-24, Apr, 2005 (Suppl).

3. Schreiber CA, Rhoa MF, Holland L: Vaginal Discharge. Clinical Handbook of Pediatrics, 3rd Edition. Schwartz MW (eds.). Lippincott Williams and Wilkins, Baltimore, MD. Page: 747-753, 2003.

4. Schreiber CA, Rhoa MF, Holland L: Pelvic Pain. Clinical Handbook of Pediatrics, 3rd Edition. Schwartz MW (eds.). Lippincott Williams and Wilkins, Baltimore, MD, Page: 569-576, 2003.

5. Schreiber CA, Rhoa MF, Holland L: Vaginal Bleeding. Clinical Handbook of Pediatrics, 3rd Edition. Schwartz MW (eds.). Lippincott Williams and Wilkins, Baltimore, MD. Page: 739-746, 2003.

6. Schreiber CA: The Female Reproductive System. Concepts in Medical Physiology. Seifter J, Sloane D, Ratner A (eds.). Lippincott Williams & Wilkins, Philadelphia, PA, Page: 573-604, October 2005.

7. Barnhart K, Schreiber CA, Shaunik A: Contraception. www.endotext.org 2006.

8. Schreiber CA, Barnhart KT: Contraception. Yen & Jaffe's Reproductive Endocrinology. Drs. Strauss and Barbieri (eds.). 6th edition: 873, 2009.

9. Schreiber CA: Introduction to Controversies in Family Planning. Contraception 82:25, August 2010.

10. Tennant C, Schreiber CA: Time to trim the loose ends of the tailstring debate. Contraception 84(1): 108; author reply 108-9, Jul 2011.

11. Schreiber CA, Ratcliffe S, Barnhart KT: Finding the right face for advanced supply of

emergency contraception. Contraception 2011.

12. Schreiber CA, Barnhart KT: Contraception. Yen & Jaffe's Reproductive Endocrinology 7/e. Strauss/Barbieri (eds.). Chpt 36, October 2013.

13. Pentlicky S, Schreiber C: Vaginal Bleeding. Schwartz's Clinical Handbook of Pediatrics 5th edition. Zorc JJ, Alpern ER, Brown L, Clark BJ, Marino BS, Mollen CM, Eds (eds.). Lippincott Williams and Wilkins, Page: 833-840, 2013.

14. Pentlicky S, Schreiber C: Pelvic Pain. Schwartz's Clinical Handbook of Pediatrics 5th edition. Zorc JJ, Alpern ER, Brown L, Clark BJ, Marino BS, Mollen CM, Eds (eds.). Lippincott Williams and Wilkins, Page: 624-632, 2013.

15. Pentlicky S, Schreiber C: Vaginal Discharge. Schwartz's Clinical Handbook of Pediatrics 5th edition. Zorc JJ, Alpern ER, Brown L, Clark BJ, Marino BS, Mollen CM, Eds. (eds.). Lippincott Williams and Wilkins, Page: 841-848, 2013.

16. Warden M, Schreiber C, Steinauer J: Diagnostic criteria for nonviable pregnancy. New Engl J Med 370(1): 86, Jan 2014.

17. Sonalkar S, Schreiber CA, Barnhart KT: Contraception. http://www.ncbi.nlm.nih.gov/books/NBK279148/ De Groot LJ, Beck-Peccoz P, Chrousos G, Dungan K, Grossman A, Hershman JM, Koch C, McLachlan R, New M, Rebar R, Singer F, Vinik A, Weickert MO (eds.). MDTEXT.com South Dartmouth, MA, Nov 2014.

18. Sober S, Schreiber CA: Pregnancy Counseling Options. Contraception for Adolescent and Young Adult Women. Whittaker A, Gilliam M (eds.). Springer Science+Business Media, NY, Chpt 14, 2014.

19. Schreiber CA, Barnhart KT: Contraception. Yen and Jaffe's Reproductive Endocrinology. Strauss II JF, Barbieri RL (eds.). Elsevier, 2018.

20. Sonalkar SS, Schreiber CA: It is cost effective to improve the standard of care for women experiencing miscarriage. Lancet Glob Health 7(9): e1164-e1165, Sep 2019.

21. Schreiber CA, Madden T.: Complex family Planning: A newly accredited, landmark fellowship. Contraception 103: 1-2, Jan 2021.

Books:

[none]

Alternative Media:

[none]

Patents:

Courtney Schreiber: Medical Management of Nonviable Pregnancy. USA Patent Number 62/777,369, 2018.