ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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]

PLAINTIFFS' CONCISE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT; EXHIBITS A-L; CERTIFICATE OF SERVICE

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

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Exhibit L: *Risk Mitigation Review* for Korlym®

Mifeprex Regimen and Safety

1. There are two methods to end early pregnancy: a procedural (or "surgical") abortion performed in a clinical setting, or a medication abortion, using prescription drugs to induce a process similar to miscarriage. Decl. of Courtney Schreiber, M.D., M.P.H., attached as Ex. A, at ¶12.
2. Today, medication abortion accounts for 39% of abortions and 60% of abortions in the first ten weeks of pregnancy. Schreiber ¶13.
3. The FDA-approved medication abortion regimen involves: (1) *mifepristone* (Mifeprex®), which blocks the effect of a hormone necessary to sustain pregnancy, and (2) *misoprostol*, which causes contractions and bleeding that empty the uterus. Schreiber ¶¶15, 22.
4. Mifeprex is "important to the health of women," offering a "meaningful therapeutic benefit" over procedural abortion that may be "preferable and safer in [a patient's] particular situation." Administrative Record ("AR") 0226 (2000), 228 (2000), 0860 (2016);[1] Schreiber ¶14.
5. Since 2000, Mifeprex "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare." AR 0539 (2016).

[1] Direct quotes of FDA admissions appear as citations either to the AR or Joint Stipulations of Facts, Dkt. 140 ("Stips."), with the year of FDA's statement in parentheses. AR excerpts are attached as Ex. B.

6. Mifeprex had been used nearly 2 million times by 2012. Stips. Ex. H, at 0351.
7. Major adverse events among Mifeprex users are "exceedingly rare, generally far below 0.1% for any individual adverse event." AR 0574 (2016).
8. The serious adverse events listed in Mifeprex's labeling are "Serious and sometimes fatal infections or bleeding." Stips. ¶19.
9. FDA acknowledges that risks of serious infections and bleeding are not inherent to Mifeprex but exist whenever the pregnant uterus is emptied. *See* Stips. ¶19 & Ex. A, at 0383-84, 0387, 0398.
10. The risk of death associated with pregnancy and childbirth is approximately 14 times higher than with abortion. Schreiber ¶11; AR 0859 n.6.
11. "[T]he physiology of pregnancy may be a more plausible risk factor" than Mifeprex for rare serious infections following use. AR 0880-81 n.69 (2016).
12. Rare complications of heavy bleeding or infection would not occur until hours or days after taking Mifeprex. Stips. Ex. A, at 0385-86; Schreiber ¶¶61, 50, 20.
13. A small fraction of Mifeprex users have a follow-up procedure, typically for reasons FDA acknowledges are *not* serious adverse events, such as ongoing pregnancy. Schreiber ¶¶33-34; Stips. Ex. A, at 0395.
14. This follow-up procedure is identical to that used for procedural abortion or uterine evacuation during miscarriage. Schreiber ¶¶35-36.
15. FDA does not require any physical examination, testing, or in-person counseling

for Mifeprex: clinicians can and do assess eligibility through telemedicine and provide all counseling remotely. AR 0873; Stips. Ex. J, at 2; Schreiber ¶¶16-17; Decl. of Erin King, M.D., attached as Ex. C, at ¶¶6-7, 12; Decl. of Julie Amaon, M.D., attached as Ex. D, at ¶¶5, 12, 15.

16. Leading medical groups, including the American Medical Association, oppose the Mifeprex REMS. Schreiber ¶54.

17. FDA's April 2021 guidance temporarily authorizing patients to obtain Mifeprex by mail or through a supervised mail-order pharmacy relied on data showing no increase in serious safety risks under this model. Stips. Ex. J, at 1-2; Schreiber ¶¶26, 39.

Mifeprex Risk Evaluation and Mitigation Strategy ("REMS")

18. In 2015-2016, FDA claimed to "evaluate[] ... whether each Mifeprex REMS element remains necessary." Stips. Ex. I, at 0680.

19. FDA's 2016 REMS Review addressed no statutory benefit/risk factors except that Mifeprex is "well-understood after more than 15 years of marketing" and "[s]erious adverse events are rare." Stips. Ex. I, at 0681.

20. FDA's 2016 REMS Review included among "Materials Informing Our Review" the clinical review cited at *supra* ¶5 and *infra* ¶21, but *not* FDA's 2013 REMS Review. Stips. Ex. I, at 0701.

21. In 2016, FDA removed language directing patients to take Mifeprex at "[their]

provider's office," based on data showing "no significant difference in either efficacy or safety" when patients took mifepristone at home. AR 0566 (2016); Stips. ¶¶16, 30.

22. In 2016, FDA removed the REMS requirement that Mifeprex's sponsor report serious adverse events except death, since no new safety concerns have arisen since 2005 and "known serious risks occur rarely." AR 0535 (2016); Stips. Ex. C, at 0407; Stips. Ex. H, at 0354.

23. All drugs require accurate eligibility assessments for safe usage. Schreiber ¶68.

24. Numerous laws and ethical standards require clinicians to obtain informed consent and prescribe only medications they are qualified to provide. Schreiber ¶¶67, 77, 82; Decl. of Graham T. Chelius, M.D., attached as Ex. E, at ¶¶ 37, 40.

25. Ensuring patients know what to do if their treatment is ineffective or they experience a complication is standard medical counseling. Schreiber ¶¶67, 77, 82; Chelius ¶40.

26. Clinicians with state-licensed prescribing authority are qualified to understand any prescribing information sufficiently to discern whether they are qualified to prescribe or administer a particular drug. Schreiber ¶76; *accord* Dkt. 101, at 8, ¶20.

27. Virtually all clinicians who provide pregnancy-related care and issue prescriptions are trained to diagnose and date an intrauterine pregnancy, and

those who are not could obtain this information by ordering an ultrasound if needed. Schreiber ¶¶69-73; Stips. ¶67.

28. All clinicians can refer patients to the nearest Emergency Department, ensuring access to the uterine evacuation procedure used for abortion or miscarriage, blood transfusions, and resuscitation. Schreiber ¶¶74-75; AR 0875.

29. The Patient Agreement is "duplicative of information in [Mifeprex's] Medication Guide," "does not add to safe use conditions," and "is a burden for patients." Stips. ¶41 (2016); AR 0437 (2016).

30. Evidence-based "off-label" medication use is common and permissible. Schreiber ¶81.

31. The Patient Agreement can confuse patients because it is not tailored to their circumstances, and distress patients using Mifeprex for miscarriage care. Schreiber ¶¶80-83; Decl. of Jane Roe, M.D., attached as Ex. F, ¶¶23-24; AR 0437.

32. It is highly unusual for FDA's Commissioner to weigh in on a REMS decision, much less overrule scientific reviewers. Decl. of Peter R. Mathers, J.D., attached as Ex. G, at ¶¶17, 19.

Reduced Access

33. Abortion access is "very limited" in some areas of the United States. AR 0540 (2016), 0616; Decl. of Diana M. Pearce, Ph.D., attached as Ex. H, at ¶19.

34. Fewer than 20% of OB-GYNs provide medication abortion. Schreiber ¶84.

35. Nearly 40% of reproductive-aged women lack an in-county abortion provider. Pearce ¶19.

36. Twenty-seven major cities have no publicly advertised abortion provider within 100 miles. Pearce ¶19.

37. Abortion patients travel, on average, 68 miles round-trip for care. Pearce ¶19.

38. In a majority of states, at least 20% of reproductive-aged women live over 100 miles round-trip from the nearest abortion clinic. Pearce ¶19.

39. But for the REMS, many more clinicians would provide medication abortion. Schreiber ¶84; Chelius ¶¶8-9, 41; Decl. of Jared Garrison-Jakel, M.D., attached as Ex. I, at ¶¶9-10, 14; Decl. of Joey Banks, M.D., attached as Ex. J, at ¶¶10-13; Decl. of Charisse M. Loder, M.D., M.Sc., attached as Ex. K, at ¶¶7, 23; Roe ¶25; King ¶5; Amaon ¶21.

40. The number of OB-GYNs providing Mifeprex would likely double without the REMS. Schreiber ¶84.

41. In a nationally representative survey, the number of OBGYNs in the South and Midwest who would begin providing medication abortion absent the REMS was higher than the number currently providing medication abortion, and 40% of OBGYNs who said they would provide medication abortion absent the REMS practice outside of urban areas. Schreiber ¶84.

42. "[D]ifficulty obtaining supplies" is among the "greatest barriers to providing an abortion." Stips. Ex. H, at 0354 (2013).

43. Many clinicians who could write a prescription for Mifeprex find it difficult or impossible to dispense Mifeprex onsite. Schreiber ¶¶84-85; Chelius ¶¶8, 26-29, 32, 35-38; Garrison-Jakel ¶¶9-10, 14; Roe ¶¶4, 9-22, 25; Loder ¶15; Banks ¶¶7-13; King ¶5; Amaon ¶21.

44. Securing approval to stock Mifeprex, and developing protocols to store, dispense, and bill onsite, can require substantial time and jeopardize clinicians' professional reputations and relationships. Loder ¶¶7-23, 29-30; Roe ¶¶9-22; Chelius ¶¶8, 27-28, 38; Schreiber ¶85.

45. Plaintiff Dr. Chelius and California Academy of Family Physicians member Dr. Garrison-Jakel do not provide Mifeprex because colleagues object to stocking it onsite, but would be able to write a pharmacy prescription. Chelius ¶¶27-28, 38; Garrison-Jakel ¶10.

46. Because responsibilities for purchasing, storing, dispensing, and billing are often divided across staff, the REMS injects many more people into abortion care, posing confidentiality risks. Chelius ¶¶32-35; Roe ¶21.

47. Plaintiff Society of Family Planning ("SFP") members have spent up to five years navigating the approvals and protocols necessary to stock Mifeprex. Roe ¶¶9-22; Loder ¶¶2, 6-21, 29-30.

48. The Prescriber Registration deters Mifeprex provision because clinicians fear anti-abortion harassment or violence if their registrations became public. Schreiber ¶85; Banks ¶¶8, 12; Chelius ¶¶29-31; *Risk Mitigation Review* for Korlym, attached as Ex. L, at 0301.

49. The REMS requires patients who have obtained all evaluation and counseling via telemedicine to travel to a health center to pick up Mifeprex and sign the Patient Agreement. Stips. Ex. J, at 2 ("clinic visit solely for this purpose"); Schreiber ¶18; Amaon ¶¶5, 10, 15, 17-19; King ¶6, 10.

Patient Burdens

50. At minimum, 75% of abortion patients have incomes too low to afford basics like housing, food, and childcare, much less emergency expenses. Pearce ¶¶7-18.

51. Approximately 60% of abortion patients are people of color, and more than half are Black or Hispanic. Pearce ¶13.

52. Sixty percent of abortion patients have children. Pearce ¶11.

53. Abortion patients are disproportionately single mothers of color, a population that overwhelmingly lacks income sufficient to meet basic needs. Pearce ¶¶11-16.

54. When clinicians must refer low-income patients elsewhere for abortion, or patients must make unnecessary in-person visits, the costs and burdens, including transportation, childcare, lost wages, and meals, can substantially delay or block care. Pearce ¶¶21-45.

55. Few low-wage workers have paid time off. Pearce ¶31.

56. Childcare is particularly expensive outside regular hours. Pearce ¶36.

57. Traveling for an abortion may necessitate overnight lodging, *e.g.*, to accommodate transportation schedules and early appointments. Pearce ¶¶26-28.

58. For patients living on Kaua‘i, Hawai‘i, Lana‘i, Moloka‘i, or Ni‘ihau, obtaining an abortion typically means flying to O‘ahu. Chelius ¶¶11-18; Pearce ¶27.

59. To secure funds for travel, abortion patients often forgo essentials like groceries or rent, or borrow at high interest rates. Pearce ¶¶37-40.

60. These costs and arrangements compel some patients to disclose their pregnancy and abortion, *e.g.*, to an employer or abusive partner. Pearce ¶¶21-22, 32-33, 39.

61. These costs and arrangements can destabilize patients' families economically, jeopardize their employment, impinge their privacy, and increase risk of domestic violence. Pearce ¶¶7, 22-33, 36, 39, 41.

62. The burdens caused by the REMS disproportionally injure low-income and rural patients and people of color, as SFP's 2016 letter to FDA explained. Stips. Ex. F, at 1255; Pearce ¶¶11-14, 16-19, 22-29, 46; Amaon ¶¶5, 8, 16-19; King ¶¶6, 10; Chelius ¶¶11-18; Garrison-Jakel ¶¶6-8, 11; Roe ¶¶7-8, 12.

63. Extensive research demonstrates that increases in travel distance, even of as little as 10-12 miles, prevent abortions. Pearce ¶¶42-44.

64. A 2017 study found that when the distance to the nearest abortion facility

increased by 25-49 miles, abortions decreased 25.3%; when the change was 50-99 miles, abortions decreased 35.7%. Pearce ¶43.

65. Plaintiffs and their members have had patients carry unwanted pregnancies to term because the REMS prevented them from writing a Mifeprex prescription. Chelius ¶17; Garrison-Jakel ¶13; Roe ¶8.

66. When patients were temporarily permitted to obtain Mifeprex by mail, some were able to have an abortion they otherwise could not have obtained. Amaon ¶14; King ¶8.

67. Even for patients able to obtain an abortion, the REMS causes significant treatment delays by reducing the availability of Mifeprex and increasing costs and burdens of accessing care. Pearce ¶¶7, 22-24, 38, 41-46; Chelius ¶¶10-19, 41; Roe ¶¶8, 12; Loder ¶¶21-26; Garrison-Jakel ¶¶11-12; King ¶¶8, 10-11; Amaon ¶¶5, 19-20.

68. Delay means a patient must bear the risks and burdens of pregnancy longer. Schreiber ¶86; Chelius ¶13; Garrison-Jakel ¶12.

69. While abortion is very safe, the risks and costs increase as pregnancy advances. Schreiber ¶¶86-87.

70. Delays may mean medication abortion is no longer available; necessitate a two-day abortion procedure; and/or push patients past the limit for abortion care at their nearest provider, requiring even farther and more costly travel. Chelius

¶¶10, 13-18; Amaon ¶20; Pearce ¶45; Loder ¶25.

71. International research shows patients are more likely to be able to use medication abortion earlier in pregnancy absent dispensing restrictions like those imposed by FDA. Schreiber ¶60.

72. Other than "COVID-related risks," FDA has never addressed how the Mifeprex REMS burdens access or whether those burdens are undue. Stips. Ex. J, at 2 (2016); *see generally* Stips. Exs. H-I.

Disparate Treatment of Mifeprex

73. Numerous drugs posing greater risks than Mifeprex have no REMS. Schreiber ¶¶44-48.

74. Korlym®, mifepristone approved to treat Cushing's Syndrome, has no REMS and is sent to patients in bottles of up to 280 pills through a specialty mail-order pharmacy under a voluntary restricted distribution system. Stips. ¶¶62, 65 & Ex. L, at 0299; Schreiber ¶47.

75. FDA found "the rate of adverse events with Mifeprex is much lower" than for Korlym. AR 0537 (2016).

76. In evaluating Korlym, FDA stated: the "challenge of this application is because of the more controversial use of this active ingredient for medical termination of pregnancy." AR 0310 (2012).

77. FDA's Korlym REMS Review analyzed each of the statutory benefit/risk factors

before determining a REMS was not necessary. Ex. L, at 0296-0301.

78. FDA did not impose a REMS for Korlym in part because a REMS can "reduce[] access" and cause "treatment delays." Ex. L, at 0303-04.

79. FDA found it "unlikely that many pharmacies will keep Korlym stocked" but concluded that "[d]istribution through a central pharmacy" would "ensure[] timely access." AR 0328 (2012).

80. The Mifeprex-misoprostol regimen is safer and more effective than misoprostol alone and the superior regimen for abortion and miscarriage management. Schreiber ¶¶15-23, 49-53.

81. Misoprostol's labeling warns of "severe genital bleeding" and "fetal and maternal death." Schreiber ¶53.

82. Warfarin, an anticoagulant often taken long-term to treat common clotting conditions, does not have a REMS. Schreiber ¶48.

83. Warfarin's labeling carries a black-box warning of "major or fatal bleeding," with incidence of 0.6–4.6% for certain patients. Schreiber ¶48.

84. Of the 17 drugs FDA requires patients to *obtain* in a clinical setting, Mifeprex and its generic are the only ones for which FDA does not also regulate where the patient *takes* it; all others must be taken under clinical supervision because of the administration method (*e.g.*, intravenous) or because the drug can be safely administered only in certain settings (*e.g.*, with monitoring for immediate

reactions such as "life-threatening respiratory depression"). Schreiber ¶¶41-43; Stips. ¶61.

85. In FDA's words, opioids "claim[] lives at [such] a staggering rate" that they are "reducing life expectancy in the United States." Schreiber ¶78 n.46.

Dated: April 16, 2021

Respectfully submitted,

/s/ Julia Kaye
JULIA KAYE
RACHEL REEVES
LORIE CHAITEN
WHITNEY WHITE
RUTH HARLOW
American Civil Liberties Union Foundation

/s/ Jongwook "Wookie" Kim
JONGWOOK "WOOKIE" KIM
ACLU of Hawaii Foundation

JOHN FREEDMAN
Arnold & Porter Kaye Scholer LLP

Attorneys for Plaintiffs

CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the length limit of Local Rule 56.1(c) and the Court's order granting in part the parties' "Joint Motion for (1) Leave to Exceed the Page/Word Limits for Briefing on Cross-Motions for Summary Judgment; and (2) Summary Judgment Hearing on Proposed Dates and Continuance of Trial Date" (Dkt. 82) because, excluding the parts of the document exempted by Local Rule 7.4(d), it contains 2,500 words. In compliance with Local Rules 7.4(e) and 10.2(a), I further certify that this document has been prepared using Microsoft Word 2016 in 14-point Times New Roman font.

Dated: April 16, 2021

/s/ Jongwook "Wookie" Kim
JONGWOOK "WOOKIE" KIM
ACLU of Hawaii Foundation

Attorney for Plaintiffs

Exhibit A

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

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

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

Plaintiffs,

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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.

Exhibit B

Excerpts from Administrative Record

Exhibit B Index

Description	Date	Excerpted Bates Numbers
Mifeprex NDA Summary Review	September 28, 2000	0223, 0226, 0228
Korlym NDA Summary Review	February 17, 2012	0307-08, 310,
Mifeprex Supplemental NDA Summary Review	March 29, 2016	0412-13, 0437
Mifeprex Supplemental NDA Medical Review	March 29, 2016	0527-28, 0535, 0537, 0539-40, 0566, 0574, 0616
FDA Denial of August 20, 2002, Citizen Petition by American Association of Pro Life Obstetricians and Gynecologists, Christian Medical and Dental Associations, and Concerned Women for America	March 29, 2016	0856, 0859-60, 0873, 0875, 0880-81, 0887

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: September 28, 2000

FROM: [redacted] /S/ SEP 28 2000

SUBJECT: [redacted] Memo

TO: NDA 20-687 MIFEPREX (mifepristone) Population Council

This memo documents the approval action concerning the Population Council's NDA for mifepristone for the medical termination of intrauterine pregnancy through 49 days' pregnancy. The application was initially submitted to the Food and Drug Administration (FDA) on March 14, 1996. The Reproductive Health Drugs Advisory Committee met on July 19, 1996 and voted that benefits exceeded risk for this drug product with 6-yes, 0-no, and 2 abstentions. An approvable action letter was issued September 18, 1996 citing deficiencies in areas of Clinical (distribution system), Chemistry/Manufacturing and Controls, Biopharmaceutics, and Labeling. A complete response was received August 18, 1999. The last action by the Office was on February 18, 2000. That approvable action letter listed application deficiencies consisting of Chemistry/Manufacturing and Controls, Labeling, and the Distribution System issues. The Population Council submitted a complete response on March 30, 2000. After a brief summary of effectiveness and safety, this memo addresses those outstanding issues listed in the last action letter, Phase 4 commitments, and other issues.

Summary of Effectiveness and Safety

Effectiveness and safety data were derived from one U.S. clinical trial and two French trials. Effectiveness was defined as the complete expulsion of products of conception without the need for surgical intervention.

The U.S. trial consisted of 859 women providing safety data and 827 women providing effectiveness data for gestations of 49 days or less, dated from the last menstrual period. Demographic data showed racial composition of the U.S. trial was similar to the overall U.S. general population. Medical abortion was complete in 92.1% of 827 subjects. Surgical intervention was performed in 7.9% of subjects: 1.6% had medically indicated interventions (1.2% for heavy bleeding), 4.7% had incomplete abortions, 1.0% had ongoing pregnancies, and 0.6% had intervention at the patient's request. One of the 859 patients received a blood transfusion.

The two French trials enrolled a total of 1,681 women providing effectiveness outcomes and 1,800 women providing safety information. Medical abortion was complete in 95.5% of the 1681 subjects. Surgical intervention was performed in 4.5% of subjects: 0.3% for bleeding, 2.9% for incomplete abortions, and ~~1.3~~% for ongoing pregnancies. Of the 1,800 women, 2 patients received blood transfusions.

The Advisory Committee reviewed the French data in 1996 and voted 6-yes and 2-no for data supporting efficacy, 7-yes and 1-abstention for data supporting safety. As stated above, the overall vote for benefits exceeding risk was 6-yes, 0-no, and 2-abstentions. During the second review cycle in 1999, the committee received a copy of the U.S. study report, as they requested, to provide FDA with comments. None were received. The U.S. trial data confirms the effectiveness and safety of the product.

APPEARS THIS WAY
ON ORIGINAL

The labeling for Mifeprex states that it is used with misoprostol for termination of pregnancy of 49 days or less. Human data on mifepristone and misoprostol used in this timeframe is available. Safety Update Report #3 submitted on March 31, 2000 contains Exelgyn Laboratories Periodic Safety Update Report #9 for the period of September 1, 1998 to November 30, 1999. It lists 38 on-going pregnancies with mifepristone plus misoprostol. The Lancet published a letter in July 1998 from Exelgyn in which they mention that they had reviewed 71 cases of continuing pregnancies after failed early termination of pregnancy occurring from 1987 to 1998 and found no reported cases of malformation associated with use of mifepristone and misoprostol. There was one report of sirenomelia and cleft palate in a patient who had a therapeutic termination at week 7 gestation associated with mifepristone use alone. On July 6, 1999 the European Summary of Product Characteristics contains a statement for mifepristone that in humans, the reported cases do not allow a causality assessment for mifepristone alone or used with a prostaglandin. On August 21, 2000 the sponsor provided Exelgyn's 12/1/99 to 5/31/00 Periodic Safety Update on pregnancy outcomes following early pregnancy exposure. The current labeling has these new data on 82 pregnancies exposed to mifepristone only (40) and mifepristone used with misoprostol (42). FDA agrees that no conclusion can be made from the data at this time. Information on the possibility of a risk of malformation, including the above information as well as the anecdotal reports, is nevertheless included in the professional labeling, Medication Guide, and Patient Agreement. The Population Council has committed to continuing ongoing surveillance of human malformation risk.

Medication Guide

This product will be approved with a Medication Guide which dispensers must provide with the drug. It is important for patients to be fully informed about the drug, as well as the need for follow up, especially on Day 14 to confirm expulsion. A Medication Guide was determined to be necessary to patients' safe and effective use of the drug. The drug product is important to the health of women and the Medication Guide will encourage patient adherence to directions for use. Patient adherence to directions for use and visits is critical to the drug's effectiveness and safety.

Distribution System

Since 1996, FDA and the Population Council have agreed, as publicly discussed with the Reproductive Drug Products Advisory Committee, that once approved, the drug will be distributed directly to physicians. It will not be available from pharmacies. There were also discussions about the qualifications of the physicians receiving mifepristone for dispensing. The Committee also stated it was important that women have access to medical abortion as this new therapeutic option may offer women avoidance of a surgical procedure.

In January 2000, the Population Council provided its initial plan for drug distribution. This plan was resubmitted in its complete response of March 30, 2000. This plan had acceptably addressed the issue of physical security of the drug. The distribution system plan stated specific requirements imposed on and by distributors of the drug, including procedures for storage, dosage tracking, damaged product returns, and other matters. See Subpart H of this memo for more details. Other aspects of the distribution system are addressed below.

Physician Qualifications

Physician qualifications were discussed within CDER, the Agency, and with the Population Council. FDA also discussed physician qualifications with a special government employee with expertise in early pregnancy. The Population Council proposed that the drug be directly distributed to qualified physicians, as opposed to other types of health care professionals (midwives, physician's assistants, nurse practitioners, etc.). This restriction was supported by the discussions of the 1996 Advisory Committee. In fact, the clinical trial data was derived from the experience of physicians using this drug. Thus, physicians remain the initial population who will receive this drug for dispensing. This does not preclude another type of health care provider, acting under the supervision of a qualified physician, from

Subpart H

In the February 18, 2000 approvable letter, FDA stated that the eventual approval of this drug would be under Subpart H. (21 CFR 314.500-314.560). This subpart applies to certain new drugs that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments. FDA has determined that the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H. The meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure. Subpart H applies when FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, such as to certain physicians with special skills or experience. In the case of mifepristone, the Population Council proposed and FDA agreed that this drug will be directly distributed via an approved plan that ensures the physical security of the drug to physicians who meet specific qualifications. Under 21 CFR 314.520, distribution of mifepristone is restricted as described below.

- Mifepristone must be provided by or under the supervision of a physician who meets the following qualifications:
  - Ability to assess the duration of pregnancy accurately
  - Ability to diagnose ectopic pregnancies
  - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
  - Has read and understood the prescribing information of Mifeprex
  - Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well
  - Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSEAGE AND ADMINISTRATION in the event of an on-going pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure
  - Must report any hospitalization, transfusion or other serious events to the sponsor or its designate
  - Must record the Mifeprex package serial number in each patient's record

- With respect to the aspects of distribution other than physician qualifications described above, distribution of Mifeprex will be in accordance with the system described in the Population Council's submission of March 30, 2000, which includes the following:
  - Secure manufacturing, receiving, and holding areas for the drug
  - Secure shipping procedures, including tamper-proof seals
  - Controlled returns procedures
  - Tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality
  - Use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug
  - Provision of drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing

The Population Council agreed to approval under Subpart H in their letter of September 15, 2000.

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202107Orig1s000

SUMMARY REVIEW

Summary Review for Regulatory Action

Date	February 17, 2012
From	Mary H. Parks, M.D.
Subject	Division Director Summary Review
NDA/BLA # **Supplement #**	202107 (cross reference IND 76480)
Applicant Name	Corcept Therapeutics, Inc.
Date of Submission	April 18, 2011
PDUFA Goal Date	February 17, 2012
Proprietary Name / Established (USAN) Name	Korlym (mifepristone immediate-release tablet)
Dosage Forms / Strength	300-mg tablets
Proposed Indication(s)	To control hyperglycemia in adult patients with endogenous Cushing's syndrome with T2DM or glucose intolerance who have failed surgery or are not candidates for surgery
Action/Recommended Action for NME:	Approval

1. Introduction

Corcept Therapeutics has submitted this new drug application (NDA) under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA) for the use of Korlym® (mifepristone) in the treatment of patients with endogenous Cushing's syndrome who have failed surgery or are not candidates for surgery.

Cushing's syndrome is due to hypercortisolism and its clinical and metabolic consequences. It is broadly separated into exogenous and endogenous forms, the former due to exogenous glucocorticoid administration for varied medical conditions and the latter due to the body's over production of cortisol. Endogenous Cushing's syndrome is further divided into ACTH-dependent and ACTH-independent forms to distinguish between an extra-adrenal or intra-adrenal pathology.[1] As this application is only for the treatment of endogenous Cushing's syndrome, the remainder of this memo will refer to Cushing's syndrome with an understanding that it is specific to only the endogenous forms of this condition.

Approximately 80-85% of Cushing's syndrome are ACTH-dependent with 80% of these due to a pituitary tumor (Cushing's disease) and 20% due to ectopic ACTH secretion from a non-pituitary tumor with the most prevalent ones being bronchial carcinoid and small cell lung

[1] Pivonello R et al. Cushing's Syndrome. *Endocrinology and Metabolism Clinics of North America.* 2008; 37(1): 135-149.

attribution of effect and safety to drug. The mechanism of action of the drug presented another complexity as to the appropriate endpoint to evaluate effectiveness of Korlym. Just as the diagnosis of Cushing's syndrome requires evidence of elevated cortisol levels, the treatment of these patients relies on a demonstration of reduced cortisol levels as a measure of response and/or success. Since the drug's selective antagonism of the GR does not result in reduced cortisol levels, this biomarker was not of any utility for establishing efficacy and could not be employed as a measure for dose titration. Sections 6.0 and 7.0 of my memo delve further into the trial design and how the reviewers considered multiple lines of evidence to make a determination of safety and effectiveness.

The regulatory and legal challenge of this application is because of the more controversial use of this active ingredient for medical termination of pregnancy in the approved formulation, Mifeprex®. Given as one-time lower doses than proposed in Cushing's syndrome, mifepristone binds to the progesterone receptor (PR) to achieve pregnancy termination. Mifeprex, manufactured by Danco, was approved on September 28, 2000 under 21 CFR Subpart H and is available only through a restricted distribution program. With passage of the Food and Drug Administration Amendments Act (FDAAA) of 2007, a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU) was applied to Mifeprex on June 8, 2011. Mifeprex is not distributed to or dispensed through retail pharmacies but is limited to specialty clinics and prescribed by physicians who have enrolled in a certification program. (Please see DRISK review for a full description of the Mifeprex REMS with ETASU).

Prior to the submission of Korlym and throughout the NDA review, multiple internal meetings and discussions were held to determine if Korlym and its proposed indication met the regulatory requirements for a REMS with ETASU or if one would be necessary to maintain the integrity of Mifeprex's REMS with ETASU.

Dr. Dragos Roman in his cross-disclipine team leader (CDTL) memo has clearly outlined these discussions and the reader is also referred to memos written by DRISK reviewers, Drs. Robottom, LaCivita, and Karwoski, and meeting minutes prepared by Dr. Amy Egan for a meeting involving CDER Center Director and senior managers in OND, OSE, and ORP. On November 3, 2011, a CDER recommendation was made that given the rarity and seriousness of Cushing's syndrome and the unique situation in which it would be used, a REMS with ETASU was not warranted. However, the applicant has agreed to establish a voluntary limited distribution system and a drug utilization study will be required postmarketing. Please see Section 13.0 for further discussions of the PMR for this application.

3. CMC/Device

CMC has recommended approval without any additional testing or studies required. Please see reviews of Drs. Ysern and Al-Hakim dated January 12, 2012.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

020687Orig1s020

SUMMARY REVIEW

Summary Review for Regulatory Action

Date	March 29, 2016
Subject	Summary Review
NDA #/Supplement #	20687/S-020
Applicant name	Danco Laboratories, LLC
Date of submission	May 28, 2015
Date of submission receipt	May 29, 2015
PDUFA goal date	March 29, 2016
Proprietary name/established name	Mifeprex/mifepristone
Dosage form/strength	Oral tablet/200 mg
Dosage regimen	Mifeprex 200 mg tablet orally followed in 24-48 hours by 800 mcg buccal misoprostol
Proposed indication	Mifeprex is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation
Action	Approval

be reflected in labeling: 1) a more flexible time interval of 24 to 48 hours between Mifeprex and misoprostol administration, 2) the option of at home administration of misoprostol, 3) the option of repeat misoprostol dosing, if clinically indicated, 4) flexibility in the follow–up time frame of 7 to 14 days, and 5) permitting qualified healthcare providers other than physicians to prescribe Mifeprex.

The safety findings of the proposed dosing regimen were acceptable and were similar to those seen with the original dosing regimen approved in 2000.

After review of the REMS modifications proposed by the Sponsor, I concur with the clinical team and (b) (6) recommendations that:

1. The Medication Guide can be removed from the Mifeprex REMS program. The Medication Guide requirements under 21 CFR part 208 require the Medication Guide to be distributed to patients. Mifeprex will only be dispensed by a healthcare professional who will be knowledgeable and able to provide the patient instructions on appropriate use of the drug, including what potential side effects may occur or follow-up that may be required as appropriate, and who will answer any questions the patient may have. In that setting, the Medication Guide will already be a required available tool for counseling. Therefore, given the existing requirements under 21 CFR part 208, I concur that there is no reason for the Medication Guide to specifically be a part of the REMS.

2. The Prescriber Agreement Form (ETASU A) as revised reflects current FDA format and content to conform to current REMS programs and reflect the labeling changes that will be approved in this supplement. I concur that the changes are acceptable.

3. Revision of the Mifeprex REMS goals (ETASU C) will adequately mitigate the risk of serious complications by requiring certification of healthcare providers who prescribe and ensuring the Mifeprex is dispensed only in certain healthcare settings by or under the supervision of a certified prescriber.

4. Removal of the Patient Agreement Form (ETASU D): I concur with the clinical review team that the Patient Agreement Form, which requires a patient's signature, does not add to safe use conditions for the patient for this REMS and is a burden for patients. It is standard of care for patients undergoing pregnancy termination to undergo extensive counseling and informed consent. The Patient Agreement Form contains duplicative information already provided by each healthcare provider or clinic. I believe that it is much more critical for the healthcare provider who orders or prescribes Mifeprex to provide and discuss informed consent derived from their own practice so that care can be individualized for the patient.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

020687Orig1s020

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	SE-2 Efficacy Supplement
Application Number(s)	NDA 020687/S-020
Priority or Standard	Standard
Submit Date(s)	May 28, 2015
Received Date(s)	May 29, 2015
PDUFA Goal Date	March 29, 2016
Division / Office	(b) (6)
Reviewer Name(s)	(b) (6) and (b) (6)
Review Completion Date	March 29, 2016
Established Name	Mifepristone
(Proposed) Trade Name	Mifeprex
Therapeutic Class	Progestin antagonist
Applicant	Danco Laboratories, LLC
Formulation(s)	Oral Tablet
Dosing Regimen	For pregnancies through 70 days gestation: Mifeprex 200 mg tablet orally followed in 24-48 hours by 800 mcg buccal misoprostol.
Indication(s)	Mifeprex is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.
Intended Population(s)	Pregnant women who desire a medical termination through 70 days gestation.

- Removal of "under Federal law" from the Prescriber Agreement Form is acceptable (see discussion in Additional Submissions / Issues).
- The term "healthcare providers who prescribe" is preferable to the Applicant's proposed "(b) (4) (see discussion in Additional Submissions / Issues).
- It is appropriate to modify the current adverse event reporting requirements under the REMS, which are currently outlined in the Prescriber's Agreement to include "hospitalization, transfusion or other serious event." Under these requirements, healthcare providers report certain adverse events to the Applicant, which then is required to report the adverse events to FDA. FDA has received such reports for 15 years, and it has determined that the safety profile of Mifeprex is well-characterized, that no new safety concerns have arisen in recent years, and that the known serious risks occur rarely. For this reason, ongoing reporting by certified healthcare providers to the Applicant of all of the specified adverse events is no longer warranted. . It should be noted that the Applicant will still be required by law, as is every NDA holder, to report serious, unexpected adverse events as 15-day safety reports, and to submit non-expedited individual case safety reports, and periodic adverse drug experience reports.

(b) (6) concurs with the following modifications recommended by (b) (6)

- Removal of the Medication Guide (MG) from the REMS. The MG will remain a required part of labeling and will be required to be provided to patients consistent with the requirements in 21 CFR part 208. FDA has been maintaining MGs as labeling but removing them from REMS when, as here, inclusion in REMS is not necessary to ensure that the benefits of a drug outweigh the risks, such as when the MG is redundant and not providing additional use or information to the patient about the risk(s) the REMS is intended to mitigate. This is consistent with ongoing efforts to streamline REMS by allowing for updates to the MG without need for a REMS modification.
- Removal of the Patient Agreement form (ETASU D). This decision was based on the well-established safety profile of Mifeprex, as well as the fact that the small numbers of practitioners who provide abortion care in the US use informed consent practices that are duplicated of the current Patient Agreement and thus the Patient Agreement is no longer necessary to ensure that the benefits of the drug outweigh the risks.
- Revision of the Prescriber Agreement Form to reflect changes to labeling revisions pursuant to the proposed efficacy supplement, and to improve the flow of the document.
- Revision of the REMS goals to reflect the above changes

1.4 Recommendations for Postmarket Requirements and Commitments

There are no recommendations for postmarket requirements or commitments for this efficacy supplement.

2.3 Availability of Proposed Active Ingredient in the United States

Mifepristone: The only other FDA approval for mifepristone is the product Korlym, approved under NDA 202107 on February 17, 2012 for the control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

2.4 Important Safety Issues with Consideration to Related Drugs

Korlym (mifepristone) is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym is taken in oral doses of 300 mg to 1200 mg daily. It is contraindicated in pregnancy, patients taking simvastatin, lovastatin and CYP3A substrates with narrow therapeutic ranges, patients on corticosteroids for lifesaving purposes, and women with unexplained vaginal bleeding or endometrial hyperplasia with atypia or endometrial carcinoma. The label[2] provides warnings and precautions regarding adrenal insufficiency, hypokalemia, vaginal bleeding and endometrial changes, QT prolongation, exacerbation or deterioration of conditions treated with corticosteroids, use of strong CYP3A inhibitors, and opportunistic infections with *Pneumocystis jiroveci* pneumonia in patients with Cushing's. Adverse reactions noted in ≥20% of patients in clinical trials with Korlym included nausea, fatigue, headache, hypokalemia, arthralgia, vomiting, peripheral edema, hypertension, dizziness, decreased appetite and endometrial hypertrophy.

Reviewer comment:

Some of the adverse events noted with Korlym are also seen with Mifeprex, such as nausea and vomiting. However, Korlym is taken in higher doses, in a chronic, daily fashion unlike the single 200 mg dose of Mifeprex that is the subject of this supplement; the rate of adverse events with Mifeprex is much lower.

Ella (ulipristal acetate) is a progesterone agonist/antagonist emergency contraceptive indicated for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. The **ella** label[3] notes that in clinical trials, the most common adverse reactions (≥ 10%) in women receiving **ella** were headache (18% overall) and nausea (12% overall) and abdominal and upper abdominal pain (12% overall).

Due to **ella's** high affinity binding to the progesterone receptor, use of **ella** may reduce the contraceptive action of regular hormonal contraceptive methods. The label notes that after **ella** intake, menses sometimes occur earlier or later than expected by a few

[2] http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202107s000lbl.pdf

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf

- For use with prostaglandin analogues for termination of pregnancy for medical reasons beyond the first trimester
- Labour induction in foetal death in utero[5]

The estimated cumulative use of Mifeprex in the US since the 2000 approval is 2.5 million uses. Estimated global occurence of MAB and SAB combined was 43.8 million abortionsin 2008 (Guttmacher Institute data)[6]. MAB has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare.[7] Medical abortion comprises 16.5% of all abortions in the US, 25.2% of all abortions at or before 9 weeks of gestation[1], and based on data from 40 reporting areas sending data to the CDC, 30.8% of all abortions at or before 8 weeks gestation (2012 data).[8] In 2011, approximately 239,400 medical abortions were performed, which was a 20% increase from 2008 data.[9] Data show that in the most recently reported 12 months (September 29, 2014-September 28, 2015), (b) (4) Mifeprex tablets were distributed in the US (NDA 20687 SD # 650, Annual Report-15, submitted October 09, 2015). Further, the vast majority of practitioners in the US who provide medical abortion services use a regimen other than the FDA-approved one. In 2008, Wiegerinck et al published a survey of members of the National Abortion Federation which showed that only 4% of facilities were using the current FDA-approved regimen.[10]

It is noteworthy that ten years ago, the combination of mifepristone and misoprostol for medical abortion was included on the World Health Organization (WHO) Model list of Essential Medicines for termination of pregnancy where legal and acceptable, up to 9 weeks of gestation.[11] Several other national and international organizations have also endorsed the safe use of medical abortion up to 9 and 10 weeks of gestation. This topic will be discussed thoroughly in the Efficacy and Safety Sections.

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[5] Mifegyne Summary of Product Characteristics. Exelgyn Laboratories- June 2013. *https://www.medicines.org.**uk**/emc/medicine/617*

[6] Sedgh G et al., Induced abortion: incidence and trends worldwide from 1995 to 2008. Lancet, 2012;379:625-32.

[7] Cleland K, Smith N. Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data. Contraception 2015;92:179-81.

[8] Pazol K, Creanga AA, Zane SB, Burley KD, Jamieson DJ. Abortion surveillance--United States, Centers for Disease Control and Prevention (CDC). MMWR Surveill Summ 2012;61(SS-8):1–44 and Surveillance Summaries Nov 27, 2015; 64(SS10);1-40.

[9] Jones RK, Jerman J. Abortion incidence and service availability in the United States, 2011. Perspectives on Sexual and Reproductive Health 2014;46(1):3-14.doi10.1363/46e0414.

[10] Wiegerinck MMJ, Jones HE, O'Connell, K, Lichtenberg ES, Paul M, Westhoff CL. Medical abortion practices: a survey of National Abortion Federation members in the United States. Contraception 2008;78:486-491.

[11] World Health Organization April 2015 Model Lists of Essential Medicines Available online at http://www.who.int/medicines/publications/essentialmedicines/en/.

MAB is a choice that women have available in many areas, especially urban, in the US, although it should be noted that some geographical areas in the US have very limited availability of both the surgical and medical options or even one option for early pregnancy termination.

The primary advantages of having a MAB compared to a surgical abortion (SAB) are the following:

- Limited or no anesthesia
- Limited likelihood of any surgical intervention

Reviewer's Comment:

A very small number of physicians currently provide early medical terminations. In the most recent REMS update from the Applicant (stamp date June 3, 2015), the cumulative number of certified prescribers since 2000 is only (b) (4). Between May 1, 2012 and April 30, 2015, the number of new prescribers was (b) (4) and the number of prescribers ordering Mifeprex was (b) (4) during this 3-year period. The number of healthcare providers that are performing early SAB is not documented.

3 Ethics and Good Clinical Practices

3.1 Submission Quality and Integrity

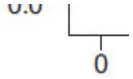
Because this submission did not rely on datasets from any of the clinical trials, no FDA inspections were performed at clinical sites. The authors of the numerous articles, however, have published widely in peer-reviewed medical journals.

3.2 Compliance with Good Clinical Practices

This submission relies on findings from the published medical literature. The majority of the publications included a statement that the study was conducted under institutional review board (IRB) or Ethical Review Committee approval and the women gave informed consent.

3.3 Financial Disclosures

None were submitted or required.



Many studies have recorded data on home use in the US and elsewhere and "demonstrated that 87-97% of women find home use of misoprostol acceptable. Home use of misoprostol is now standard in the US."[50] The 2009-10 Swica comparative study focused on the option to take both mifepristone and misoprostol at home after being counseled at the office/clinic. There was no significant difference in either efficacy or safety for the 139 women (46%) who took both medications at home compared to 161 women who took mifepristone in the office and misoprostol at home.

Table 8 that follows is a list of studies where data are available on home use of misoprostol and the specific efficacy findings.

[50] Swica Y, et al. Acceptability of home use of mifepristone for medical abortion. Contraception 2013;88:122-127.

6.1.14 Discussion of Persistence of Efficacy and/or Tolerance Effects

There is no evidence that repeated medical or surgical abortion is unsafe or that there is a tolerance effect. Return to fertility is well-documented: in the Patient Counseling Information section, the labeling states "inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses" and "inform the patient that contraception can be initiated as soon as pregnancy expulsion has been confirmed, or before she resumes sexual intercourse."

6.1.15 Additional Efficacy Issues/Analyses

The Applicant has requested that revised labeling provide only for the new proposed regimen and that the original approved regimen be deleted.

Reviewer Final Recommendation:

While there are no safety or efficacy reasons that would lead us to withdraw approval of the currently labeled dosing regimen, we concur that it may be deleted from labeling because very few providers currently use it, and inclusion of two options for dosing could be confusing. Of note, PPFA and NAF guidelines have used mifepristone 200 mg oral and misoprostol 800 mcg (initially given vaginally and now buccally) since 2001.

7 Review of Safety

Safety Summary

- Medical abortion with the new proposed regimen of Mifeprex 200 mg followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation is safe. Major adverse events including death, hospitalization, serious infection, bleeding requiring transfusion and ectopic pregnancy with the proposed regimen are reported rarely in the literature on over 30,000 patients. The rates, when noted, are exceedingly rare, generally far below 0.1% for any individual adverse event. The number of postmarketing deaths associated with Mifeprex pharmacovigilance is very low. Non-vaginal routes of administration of misoprostol have increased and since the *C. sordellii* deaths associated with vaginal misoprostol, there have been no *C. sordellii* deaths. Given that the numbers of these adverse events appear to be stable or decreased over time, it is likely that these serious adverse events will remain acceptably low.

- Common adverse events associated with medical abortion occur at varying but acceptable rates.

- There are scarce cases of uterine rupture associated with early medical abortion. Medical abortion using mifepristone with or without misoprostol in the first trimester is safe from this perspective.

- Medical abortion with Mifeprex is provided by a small group of organizations and their associated providers. Their documents and guidelines cover the safety information that is duplicated in the Patient Agreement.
- ETASUs A and C remain in place: The Prescriber's Agreement under ETASU A requires that providers "explain the procedure, follow-up, and risks to each patient and give her an opportunity to discuss them." The REMS will continue to require that Mifeprex be dispensed to patients only in certain healthcare settings, specifically, clinics, medical offices, and hospitals. This ensures that Mifeprex can only be dispensed under the supervision of a certified prescriber at the time the patient receives treatment with Mifeprex.
- Labeling mitigates risk: The Medication Guide, which will remain a part of labeling, contains the same risk information covered under the Patient Agreement.

APPEARS THIS WAY ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

MAR 29 2016

Donna Harrison, M.D.
Executive Director
American Association of Pro Life Obstetricians and Gynecologists
P.O. Box 395
Eau Claire, MI 49111

Gene Rudd, M.D.
Senior Vice President
Christian Medical and Dental Associations
P.O. Box 7500
Bristol, TN 37621

Penny Young Nance
CEO and President
Concerned Women for America
1015 Fifteenth St., NW
Suite 1100
Washington, DC 20005

Re: Docket No. FDA-2002-P-0364

Dear Drs. Harrison and Rudd and Ms. Nance:

This letter responds to your citizen petition submitted on August 20, 2002, to the Food and Drug Administration (FDA or Agency) on behalf of the American Association of Pro Life Obstetricians and Gynecologists (AAPLOG), the Christian Medical Association (CMA) (n/k/a the Christian Medical and Dental Associations), and Concerned Women for America (CWA) (Petition).[1] Your Petition requests that the Agency stay FDA's approval of Mifeprex (mifepristone, also known as RU-486), thereby halting the distribution and marketing of the drug pending final action on the Petition. The Petition also requests that the Agency revoke FDA's approval of Mifeprex and requests a full audit of the French and U.S. clinical trials submitted in support of the new drug application (NDA) for Mifeprex.

We have carefully considered the information submitted in your Petition, comments on your Petition submitted to the docket, other submissions to the docket, and other relevant data available to the Agency. Based on our review of these materials and for the reasons described below, your Petition is denied.

[1] The citizen petition was originally assigned docket number 2002P-0377/CP1. The number was changed to FDA-2002-P-0364 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008. This citizen petition was submitted by AAPLOG, CMA, and Sandy Rios, the then-President of CWA. We have addressed this response to CWA's current CEO and President, Penny Young Nance.

(Petition at 21-23). Thus, you assert that the approval of Mifeprex did not meet the requirements for product approval under subpart H (Petition at 23).

We disagree with your conclusion that we inappropriately approved Mifeprex under subpart H. As stated in section I above, the accelerated approval regulations apply to new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (§ 314.500). As FDA made clear in the preamble to the final rule for subpart H, the subpart H regulations are intended to apply to serious or life-threatening conditions, as well as to illnesses or diseases.[4] The Agency also made clear that a condition need not be serious or life-threatening in all populations or in all phases to fall within the scope of these regulations.[5] Unwanted pregnancy falls within the scope of subpart H under § 314.500 because unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances.

Pregnancy can be a serious medical condition in some women.[6] Pregnancy is the only condition associated with preeclampsia and eclampsia and causes an increased risk of thromboembolic complications, including deep vein thrombophlebitis and pulmonary embolus. Additionally, there is a significant risk of a major surgical procedure and anesthesia if a pregnancy is continued; for 2013 (the most recent data available), the Centers for Disease Control and Prevention reported an overall 32.7 percent rate of cesarean sections in the United States.[7] Other medical concerns associated with pregnancy include the following: disseminated intravascular coagulopathy (a rare but serious complication); amniotic fluid embolism; life-threatening hemorrhage associated with placenta previa, placenta accreta, placental abruption, labor and delivery, or surgical delivery; postpartum depression; and exacerbation or more difficult management of preexisting medical conditions (e.g., diabetes, lupus, cardiac disease, hypertension). In addition, approximately 50 percent of all pregnancies in the United States each year are unintended.[8] According to the

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[4] See, e.g., 57 FR 58942, 58946 (Dec. 11, 1992).

[5] Id.

[6] According to data from the Centers for Disease Control and Prevention (CDC), for 2012 (the most recent year for which data are available), the pregnancy-related mortality ratio in the United States was 15.9 maternal pregnancy-related deaths per 100,000 live births. See CDC, Pregnancy Mortality Surveillance System, available on the CDC Web page at http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html. A 2012 study by Raymond and Grimes provides a comparison for the mortality rate associated with legal abortion to live birth in the United States for the earlier period from 1998 through 2005. Investigators reported that over the study period, the pregnancy related mortality rate among women who delivered live neonates was 8.8 deaths per 100,000 live births. This lower rate excludes deaths from ectopic pregnancies, stillbirths, gestational trophoblastic disease, etc. During the same period, the rate of abortion related mortality was 0.6 per 100,000 abortions. The risk of childbirth related death was therefore approximately 14 times higher than the rate associated with legal abortion. Raymond, EG and DA Grimes, Feb. 2012, The Comparative Safety of Legal Induced Abortion and Childbirth in the United States, Obstet Gynecol, 119 (2, Part 1):215-219.

[7] See CDC, Nov. 5, 2014, Trends in Low-risk Cesarean Delivery in the United States, 1990-2013, National Vital Statistics Report, 63(6), available at http://www.cdc.gov/nchs/data/nvsr/nvsr63/nvsr63_06.pdf .

[8] Guttmacher Institute, Feb. 2015, Unintended Pregnancy in the United States, at 1, available at http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.pdf. See also Institute of Medicine, 2011,

Institute of Medicine, women experiencing an unintended pregnancy may experience depression, anxiety, or other conditions.[9]

Furthermore, consistent with § 314.500, medical abortion through the use of Mifeprex provides a meaningful therapeutic benefit to some patients over surgical abortion.[10] Although FDA provided several examples in the preamble to the final rule to illustrate how the term "meaningful therapeutic benefit" might be interpreted, the Agency did not suggest that the meaning of the term was limited to the examples provided.[11] In the Phase 3 clinical trial of Mifeprex conducted in the United States, medical termination of pregnancy avoided an invasive surgical procedure and anesthesia in 92 percent of the 827 women with an estimated gestational age (EGA) of 49 days or less.[12] Complications of general or local anesthesia, or of intravenous sedation ("twilight" anesthesia), can include a severe allergic reaction, a sudden drop in blood pressure with cardiorespiratory arrest, death, and a longer recovery time following the procedure. Medical (non-surgical) termination of pregnancy provides an alternative to surgical abortion; it is up to the patient and her provider to decide whether a medical or surgical abortion is preferable and safer in her particular situation.[13]

Clinical Preventive Services for Women: Closing the Gaps (Closing the Gaps), at 102-110, available at http://books.nap.edu/openbook.php?record_id=13181 (stating that "[u]nintended pregnancy is highly prevalent in the United States").

[9] See Closing the Gaps, supra note 8, at 103.

[10] For a discussion of how FDA interprets the phrase "meaningful therapeutic benefit to patients over existing treatments" in 21 CFR 314.500, see FDA guidance for industry, *Expedited Programs for Serious Conditions—Drugs and Biologics*, at 3-4, 16-17, available on the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[11] 57 FR 58942, 58947 (Dec. 11, 1992).

[12] FDA, 1999, Medical Officer's Review of Amendments 024 and 033: Final Reports for the U.S. Clinical Trials Inducing Abortion Up to 63 Day Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments (Medical Officer's Review), at 11 (Table 1) and 16, available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf and http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P2.pdf. Spitz, IM, et al., 1998, Early Pregnancy Termination With Mifepristone and Misoprostol in the US, NEJM, 338:1241-1243.

[13] CDC data indicate that for the 730,322 abortions reported in 2011, there were 2 deaths. The CDC's calculated case fatality rate over the period from 2008 to 2011 (the most recent year for which data are available), the case fatality rate was 0.73 legal induced abortion-related deaths per 100,000 reported legal abortions. http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6410a1.htm?s_cid=ss6410a1_e. Mortality rates identified by type of abortion (medical or surgical) were not available. However, the evidence suggests that the risk of mortality associated with medical abortion is quite low. Confirmation of the low risk of medical abortion is provided in a study by Trussell, et al., which recorded no deaths for 711,556 medical abortions performed by Planned Parenthood clinics under the buccal misoprostol administration protocol (Trussell J, D Nucatola, et al., Mar. 2014, Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion, Contraception, 89(3):193-6). We note that one study reported a comparatively high occurance of fatality (1 death in a study of 11,155 early medical abortions); however, this apparent high occurence of fatality is likely due to instability in the estimate as a result of the small sample size (Goldstone P, J Michelson, et al., Sept. 3, 2012, Early Medical Abortion Using Low-Dose Mifepristone Followed by

You maintain that the Mifeprex regimen is unsafe because it does not require ultrasound examination. Specifically, you maintain that the use of transvaginal ultrasound is necessary to accurately date pregnancies and to identify ectopic pregnancies, and you note both that Mifeprex was approved in 2000 only for women through 49 days' gestation and that it is contraindicated for women with a confirmed or suspected ectopic pregnancy (Petition at 57-61).

Although the protocol for the U.S. clinical trial required a transvaginal sonogram (TVS) for each patient at Visit 1 and stated that the test should be used "as indicated" at Visits 2 and 3, this does not mean that a TVS is essential to ensure the safe use of Mifeprex.[47] As stated in the Mifeprex Approval Memorandum, during the review process, the Agency carefully considered the role of ultrasound.[48] In the clinical trials, ultrasound was performed to ensure proper data collection on gestational age, but in clinical practice, pregnancies can also be (and frequently are) dated using other clinical methods. (As discussed in section II.F below, safeguards employed during clinical trials are not always essential for safe use of the approved drug product.) As part of the restricted distribution of Mifeprex put in place in 2000, each provider must have the ability to accurately assess the duration of pregnancy and to diagnose ectopic pregnancy. We determined that it was inappropriate for us to mandate how providers clinically assess women for duration of pregnancy and for ectopic pregnancy. These decisions should be left to the professional judgment of each provider, as no method (including TVS) provides complete accuracy. The approved labeling for Mifeprex recommended ultrasound evaluation as needed, leaving this decision to the judgment of the provider.

You claim that the only way to date a pregnancy accurately enough to exclude EGA > 49 days is by using TVS (Petition at 58). That is incorrect. As noted above, using TVS (or any other method) does not ensure complete accuracy in dating a pregnancy. In most cases, a provider can accurately make such a determination by performing a pelvic examination and obtaining a careful history, which would include the following: date of last menstrual period, regularity of menses, intercourse history, contraceptive history, and (if available) home pregnancy test results.[49] If in doubt, the provider can order an ultrasound and/or a blood test measuring the quantitative beta-human chorionic gonadotropin (hCG) to further assist in dating the gestational age.

Furthermore, use of a TVS does not guarantee that an existing ectopic pregnancy will be identified. As of April 30, 2015, there were 89 unduplicated reports in FDA's Adverse Event Reporting System (FAERS) database of ectopic pregnancy in women in the United States who had received mifepristone for termination of pregnancy since the approval of Mifeprex in the United States. In

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[47] We note that the French clinical trials did not require an ultrasound examination; rather, the decision as to whether an ultrasound was needed was left to the discretion of the investigator.

[48] Mifeprex Approval Memorandum, supra note 16, at 5.

[49] See, e.g., Fielding, SL, et al., 2002, Clinicians' Perception of Sonogram Indication for Mifepristone Abortion up to 63 Days, Contraception, 66:27-31 (discussing the results of a prospective study of 1,016 women in a medical abortion trial at 15 sites that concluded that "clinicians correctly assessed gestational age as no more than 63 days in 87% of women. In only 1% (14/1013) of their assessments did clinicians underestimate gestational age. We conclude that the clinicians felt confident in not using ultrasound in most cases").

necessary under § 314.520. In accordance with this determination, the Prescriber's Agreement for Mifeprex stated the following:[53]

> Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:
>
> - Ability to assess the duration of pregnancy accurately.
> - Ability to diagnose ectopic pregnancies.
> - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have [sic] made plans to provide such care through others, and are [sic] able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
> - Has read and understood the prescribing information of Mifeprex….

As noted in the Mifeprex Approval Memorandum, the requirement that a physician certify, by signing the Prescriber Agreement, that he or she has the qualifications described in that Agreement limited the physicians who would be eligible to receive Mifeprex from the sponsor to those who are familiar with managing early pregnancies.[54] Because only such qualified physicians would be using or would oversee the use of Mifeprex, we concluded that there was no need for special certification programs or additional restrictions. Additionally, as noted in the Mifeprex Approval Memorandum, in the U.S. clinical trial of Mifeprex, 11 out of roughly 850 patients needed surgical intervention to treat bleeding, and three of these patients were treated by non-principal investigators such as emergency room physicians and a non-study gynecologist.[55] These data suggested that patients would receive any needed surgical intervention from either their physician or another physician with the needed skills.[56] The Mifeprex Approval Memorandum also pointed out that the Mifeprex labeling and the Medication Guide approved at that time highlight that surgery may be needed and that patients must understand whether the provider will furnish any necessary medical intervention or whether they will be referred to another provider and/or facility.[57]

In addition, one of the Phase 4 commitments accompanying the approval of Mifeprex was a cohort-based study of safety outcomes when Mifeprex is prescribed by physicians with the skills for surgical intervention compared to physicians who refer patients for surgical intervention. In a February 2008 submission, the applicant stated that so few medical abortions are prescribed by physicians who do not have surgical intervention skills that it was not feasible to do a meaningful

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[53] Mifeprex labeling (June 8, 2011), Mifeprex (mifepristone) tablets, 200 mg, Prescriber's Agreement, available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020687s014lbl.pdf.

[54] Mifeprex Approval Memorandum, supra note 16, at 5.

[55] Id.

[56] Id.

[57] Id.

[With respect to ectopic pregnancy:]

> MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.
>
> Women who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

The Agency has regularly completed a cumulative summary of U.S. postmarketing adverse events reported for the use of mifepristone for medical termination of pregnancy. From the approval date of Mifeprex (September 28, 2000) through October 31, 2012, we received 2,740 reports of adverse events associated with the use of mifepristone in the United States to terminate pregnancy,[66] including 57 reports of severe infections[67] and 416 incidences of blood loss requiring transfusion. From November 1, 2012, through April 30, 2015, we received 984 reports of adverse events associated with the use of mifepristone in the United States to terminate pregnancy, including 9 reports of severe bacterial infections and 134 incidences of blood loss requiring transfusion.[68] As of April 30, 2015, 89 ectopic pregnancies associated with the use of mifepristone in the United States had been reported since the approval of Mifeprex. As of July 24, 2015, 17 U.S. deaths had been reported since the approval of Mifeprex. Deaths were associated with sepsis in 8 of the 17 reported fatalities (7 cases tested positive for *Clostridium sordellii*, and 1 case tested positive for *Clostridium perfringens*).[69] Seven of the eight fatal sepsis case reported vaginal misoprostol use;

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[66] This represents data from the FDA's previous adverse event reporting system, which was known as AERS.

[67] Severe infections generally involve death or hospitalization for at least 2-3 days, intravenous antibiotics for at least 24 hours and total antibiotic usage for at least 3 days, and any other physical or clinical findings, laboratory data or surgery that suggest a severe infection.

[68] This represents data from the current FDA Adverse Event Reporting System (FAERS), which was implemented in September 2012 and replaced AERS. FDA migrated all of the data from the previous reporting system (AERS) to FAERS. FDA validated and recoded product information as the reports from the AERS database were migrated to the FAERS database. In addition, the FAERS database features a new search functionality that is based on the date FDA initially received for the case; this facilitates more accurate follow-up for cases that have multiple reports and multiple receipt dates. For these reasons, there may be differences in the case counts between AERS and FAERS.

[69] We note your statements in your October 10, 2003, Response to Opposition Comments that the presence of retained products of conception can lead to the development of intrauterine or systemic infection and that Mifeprex might potentiate this possibility through negative effects on immune system function or normal protective mechanisms (Response to Opposition at 17). Regarding retained products of conception and the emergence of infections, based on autopsy and/or ultrasound reports, there were no retained products of conception in any of the eight deaths associated with infections (sepsis). With respect to your claim that Mifeprex might increase the likelihood of infection by adversely affecting immune system function, although

one case reported buccal misoprostol use. Seven of the nine remaining U.S. deaths involved two cases of ruptured ectopic pregnancy and one case each of the following: substance abuse/drug overdose; methadone overdose; suspected homicide; suicide; and a delayed onset of toxic shock-like syndrome. In the eighth case, the cause of death could not be established despite performance of an autopsy; tissue samples were negative for *C. sordellii*. In the ninth case, infection was ruled out and the final autopsy report listed pulmonary emphysema as the cause of death. [70]

We disagree with your assertion that adverse event reporting for Mifeprex is "spotty" and that, as a result, the database for post-approval adverse events for Mifeprex is incomplete (Response to Opposition at 18). You are correct that reporting to the Agency's MedWatch program is voluntary, and we acknowledge that there is always a possibility with any drug that some adverse events are not being reported. We believe, however, that the potential for underreporting of serious adverse events associated with the use of Mifeprex for medical abortion has been very low because of the restricted distribution of the product and because healthcare providers have agreed in writing to report any hospitalizations, transfusions, or other serious adverse events associated with the drug to the sponsor, which is required under FDA's regulations to report all adverse events, including serious adverse events, to the Agency (see 21 CFR 314.80, 314.81). As with all drugs, we will continue to closely monitor the postmarketing safety data on Mifeprex.

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published experimental data from animal models suggest that this is a theoretical possibility, the overall event rate of serious infections does not support this. If Mifeprex were adversely affecting immune system function, we would expect to see a much higher rate of serious infections from more common organisms, as well as a higher number of deaths in Europe (where mifepristone has been approved for over 24 years) and in the United States. Contrary to your statements, data from the medical literature and findings by the CDC suggest that the critical risk factor in the reported cases of sepsis is pregnancy itself (see Miech, RP, 2005, Pathophysiology of Mifepristone-Induced Septic Shock Due to *Clostridium sordellii*, Ann Pharmacother, 39:1483-1488). In May 2006, FDA, along with the CDC and the National Institute of Allergy and Infectious Diseases at the National Institutes of Health held a workshop on emerging clostridial disease. The issue of immunosuppression also was discussed at length during this public workshop. It was clear from the presentations at the workshop that *C. sordellii* causes rapid and serious clinical illness in settings other than medical abortion, including among pregnant women who have recently undergone spontaneous abortion or term delivery. The fact that cases of *C. sordellii* have been identified both in pregnant women who have undergone medical abortion and those who have not supports the idea that the physiology of pregnancy may be a more plausible risk factor for *C. sordellii* illness than having undergone a medical abortion with Mifeprex.

[70] FDA is aware of 11 additional deaths of women in foreign countries who used mifepristone for the termination of pregnancy. This included one death associated with sepsis (*Clostridium sordellii* identified in tissue samples) in a foreign clinical trial, and 10 deaths identified from post-marketing data. These 10 fatal cases were associated with the following: sepsis (Group A *Streptococcus pyogenes*); a ruptured gastric ulcer; severe hemorrhage; severe hemorrhage and possible sepsis; "multivisceral failure"; thrombotic thrombocytopenic purpura leading to intracranial hemorrhage; toxic shock syndrome (*Clostridium sordellii* was identified through uterine biopsy cultures); asthma attack with cardiac arrest; respiratory decompensation with secondary pulmonary infection 30 days after mifepristone in a patient on the lung transplant list with diabetes a jejunostomy feeding tube, and severe cystic fibrosis; *Clostridium septicum* sepsis (from a published literature report).

In addition, as noted in the Mifeprex Approval Memorandum (at 7), we agreed with the Population Council both that it would not be feasible to identify and enroll sufficient numbers of repeat users of the drug and that the pharmacology of mifepristone does not suggest any carryover effect after one-time administration. Accordingly, we did not include item 3 as a Phase 4 commitment in the September 28, 2000, approval letter. However, we note that data from many other studies reported in the medical literature using mifepristone for, e.g., fibroids, uterine myoma, meningioma, psychiatric illnesses, and Cushing's disease, in much higher daily and lower daily doses for chronic use (months) have not raised any major safety issues.[80]

III. REQUEST FOR STAY AND REVOCATION OF APPROVAL

You request that we immediately stay the approval of Mifeprex, thereby halting all distribution and marketing of the drug pending final action on your Petition (Petition at 2). You cite 21 CFR 10.35 as the basis for your request for a stay (Petition at 1). In addition, you urge us to revoke the approval of Mifeprex because of the purported legal violations and safety concerns set forth in your Petition (Petition at 2).

As described above, we are denying your Petition. Therefore, your request for a stay pending final action on your Petition is moot.

For the reasons set forth in section II of this response, we conclude that you have not presented any evidence that the applicable grounds in 21 CFR 314.530 have been met with respect to Mifeprex. Furthermore, you have not provided any evidence that any of the applicable grounds in section 505(e) of the FD&C Act have been met for Mifeprex.[81] Therefore, you have not provided any evidence that would serve as a basis for seeking to withdraw the approval of Mifeprex.

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[80] See, e.g., Tristan, M, et al., 2012, Mifepristone for Uterine Fibroids (Review), Cochrane Library, 8:1-47; Esteve, JL, et al, 2013, Mifepristone Versus Placebo To Treat Uterine Myoma: A Double-Blind, Randomized Clinical Trial, Int J Womens Health, 5:361; Spitz, IM, et al., 2005, Management of Patients Receiving Long-Term Treatment With Mifepristone, Fertil Steril, 84:1719; Blasey, CM, TS Block, JK Belanoff, and RL Roe, 2011, Efficacy and Safety of Mifepristone for the Treatment of Psychotic Depression, J Clin Psychopharmacol, 31:436; Fleseriu, M, et al., 2012, Mifepristone, a Glucocorticoid Receptor Antagonist, Produces Clinical and Metabolic Benefits in Patients with Cushing's Syndrome, J Clin Endocrinol Metab, 97:2039.

[81] You have not presented any clinical data or other information demonstrating that Mifeprex is unsafe for use under its approved conditions for use, either on the basis of evidence available to the Agency at the time of approval or when also considering evidence obtained subsequent to approval. In addition, you have not provided any new evidence that, when evaluated with the evidence available at the time of Mifeprex's approval, shows that there is a lack of substantial evidence that the drug will have its intended effect.

Exhibit C

Declaration of Erin King, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 ERIN KING, M.D., 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

Erin King, M.D. 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.

2. I am a board-certified Obstetrician Gynecologist ("Ob-Gyn") licensed to practice in Illinois and Missouri. I treat patients principally at a general Ob-Gyn practice in St. Louis, Missouri, and at the Hope Clinic for Women ("Hope Clinic") in Granite City, Illinois, where I also serve as the Executive Director. I provide patients with the full scope of obstetric and gynecological care, including abortion care.

3. I am a member of the American College of Obstetricians and Gynecologists, the National Abortion Federation, and the Society of Family Planning ("SFP"). I understand that SFP is a plaintiff in this litigation challenging the Risk Evaluation and Mitigation Strategy ("REMS") that the Food and Drug Administration ("FDA") imposes for mifepristone (brand name Mifeprex®). I write this declaration in support of Plaintiffs' Motion for Summary Judgment, on my own behalf, and not on behalf of Hope Clinic or any other institution.

4. I am a certified prescriber under FDA's mifepristone REMS. I prescribe mifepristone as part of a medication abortion regimen and for patients seeking medical management of miscarriage. I also provide training in medication abortion and other abortion and reproductive health care.

5. I am aware of clinicians who would prescribe mifepristone for medication abortion and miscarriage care for their patients if they could send in a prescription to a local or mail-order pharmacy as they do with nearly all other medication. However, the mifepristone REMS—which requires clinicians to register as certified prescribers and to stock and dispense mifepristone in their offices—has prevented them from using mifepristone in their patient care. Physicians I have trained have often told me that they are unable to find employment with practices that are willing to stock mifepristone and, as a result, were not able to provide medication abortion or miscarriage care using mifepristone to their patients, though they would have been able to provide this care if they could simply write a prescription.

6. The mifepristone REMS also imposes significant burdens on my patients. Because of the REMS, my patients whom I can evaluate and counsel via telemedicine have had to travel unnecessarily to my clinic for their medication. They have had to find and pay for transportation and child care and take time away from jobs that pay by the hour or day. This is particularly burdensome for my many patients who live with low incomes and have to travel long distances, from rural parts of southern Illinois, to get to my clinic. In addition, during the COVID-19 pandemic, the REMS has put them and their families at needless risk for contracting a deadly virus as they travel in person to pick up medication that they

could otherwise safely receive by mail at home.

7. Last year, a federal district court in Maryland issued an injunction suspending the mifepristone REMS in-person requirements for medication abortion for the duration of the COVID-19 federal Public Health Emergency ("PHE").[1] The injunction permitted me to contract with a mail-order pharmacy to ship mifepristone to my eligible patients. That meant that, for my medication abortion patients who did not require in-person assessment, I could provide all counseling and assessment in a telehealth visit and then have the medication delivered directly to them from the mail-order pharmacy.

8. On the day we began offering patients the option to receive their prescription through the mail-order pharmacy, I treated a patient who had had an appointment to come to the clinic for a medication abortion but had had to cancel because she could not get time away from work and could not find anyone to stay with her children. She told me that she would have had to forgo an abortion altogether if we had not been able to offer her a telemedicine visit and delivery of her medication, because she did not think she would ever be able to make the arrangements necessary to get to the clinic in person. But, because the REMS in-person requirements were enjoined, she was able to have a safe abortion from the

[1] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D.Md. 2020); *ACOG v. FDA*, Civ. No. TDA-20-1320, 2020 WL 8167535 (D.Md., Aug. 19, 2020).

safety and privacy of her own home.

9. Unfortunately, however, the U.S. Supreme Court entered a stay of the injunction, reinstating the in-person requirements.[2] As a result, for the past three months I have again been forced to require patients seeking medication abortion care to travel to the clinic to pick up their medication.

10. This requirement imposes substantial burdens on my patients. Since the Supreme Court reinstated the REMS in-person requirements, I have seen numerous patients who needed no in-person assessment but nevertheless had to travel multiple hours, each way, to come to my clinic to pick up their medication. These patients have had to bear the costs and burdens of arranging travel, time away from work, and child care, when they could just as safely have obtained their prescription by mail and avoided all of these burdens.

11. Needing to make these arrangements and raise funds for this travel has often delayed my patients' care—sometimes beyond the point when they can have a medication abortion. I recently saw a patient who wanted a medication abortion but was 13 weeks pregnant and therefore had to have an in-clinic procedure. She was very upset, explaining that she had rescheduled her appointment numerous times because she could not arrange for travel or find someone to take care of her children—and during the pandemic, she could not

[2] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

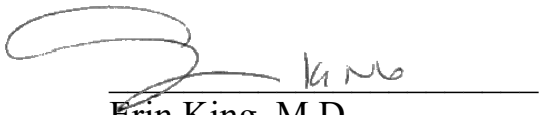
bring her children with her to our clinic, because we do not allow anyone other than the patient to enter in order to mitigate viral spread. But for the mifepristone REMS, I could have treated this patient in a telemedicine visit and had her medication delivered to her at home while she was still eligible for a medication abortion. This patient is not alone; I see patients every week with one variation or another of this story.

12. I am able to provide care entirely by telehealth for a wide array of other medical needs. For instance, I regularly use telehealth to diagnose, treat, and counsel patients regarding urinary tract infections, vaginitis, rashes, and contraception needs. In my practice, we also conduct prenatal and post-partum visits remotely. We can even examine a patient's sutures and evaluate how well the patient is healing after surgery in a telehealth visit. I can just as safely and effectively evaluate and comprehensively counsel eligible medication abortion patients in a telehealth visit. However, because of the REMS, my patients who require mifepristone have had to suffer needless burdens and risks that my patients who can obtain care entirely by telehealth are able to avoid.

13. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. I am very pleased that my patients receiving care by telehealth can now have their medication delivered directly to them from a mail-order pharmacy without the

costs, risks, and burdens of a needless in-person trip. However, when the PHE ends and this non-enforcement policy expires, the REMS in-person requirements will again impose substantial burdens on my patients.

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.



Erin King, M.D.

Exhibit D

Declaration of Julie Amaon, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 JULIE AMAON, M.D., 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

Julie Amaon, M.D., 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.

2. I am a board-certified family physician, licensed to practice in Minnesota, Texas, and Montana. I am trained to provide the full scope of family medicine with a focus on reproductive health care, including abortion.

3. Since July 1, 2020, I have been the Medical Director of Just The Pill, an organization founded in April of 2020 to improve access to sexual and reproductive health care for patients in rural Minnesota. To my knowledge, Just the Pill is the only mobile health center offering abortion care in the United States.

4. As a part of my practice, I prescribe mifepristone (brand name Mifeprex®) to patients seeking medication abortion. Because of restrictions imposed under the Food and Drug Administration ("FDA") Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, I cannot simply write a prescription for mifepristone for my patients to fill at a local or mail-order pharmacy, as they would for any other medication.

5. I can and do provide all counseling and assessment for eligible medication abortion patients in a telehealth visit, which FDA permits. FDA also permits my patients to take the medication at a location of their choice. But under the REMS, my patients have to travel in person to pick up their medication—a trip

that, for patients in rural Minnesota, can mean hours of travel each way and time away from family, and jobs. The challenge of arranging for lengthy travel and time away is often hugely burdensome for my patients, and, for some, means a delay of care beyond the point at which medication abortion is available to them or denial of access to abortion care altogether. In addition to these burdens, during the COVID-19 pandemic, the mifepristone REMS has subjected my patients and their families to needless risk of exposure to a deadly virus as they travel to pick up their medication.

6. I submit this declaration in support of the Plaintiffs' Motion for Summary Judgement in my individual capacity and not on behalf of Just The Pill or any other institution.

Limited Access to Abortion in Rural Minnesota

7. Minnesota's bricks-and-mortar abortion clinics are all located in three urban population centers: the Twin Cities, Duluth, and Rochester. According to the Guttmacher Institute in 2017, 61% of Minnesota women lived in a county lacking an abortion clinic.[1] Indeed, nearly half of the rural counties in Minnesota have no sexual or reproductive health clinics at all.[2]

[1] Jones RK, Witwer E and Jerman J, "Abortion Incidence and Service Availability in the United States, 2017," https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017.
[2] 2019 Minnesota Adolescent Sexual Health Report https://kstp.com/kstpImages/repository/cs/files/2019_ashr_final.pdf.

8. As a result, patients who reside in rural areas often must drive 3 or 4 hours *each* way to access abortion care, and sometimes longer in inclement weather during Minnesota's long winters. This travel requires patients to pay and arrange for transportation, time away from work, and child care, all of which can be costly and difficult. The expenses necessitated by this travel creates particularly weighty burdens for patients living with low incomes, which is the case for 75% of abortion patients.[3] As described below, for some patients the challenges they face in raising funds and arranging for travel and time away results in significant delays in their ability to access care and can prevent them from obtaining the abortion they seek.

COVID-19 and the Expansion of Telehealth Services

9. Just The Pill was established in the Spring of 2020, as the SARS-CoV-2 virus that causes COVID-19 spread through the United States, and access to abortion care in Minnesota became increasingly limited because of pandemic-related clinic closures and drastically reduced in-person care. At that time, the provision of health care in the United States was changing dramatically. Federal and state governments urged health care providers to use telemedicine to provide

[3] Guttmacher Institute, "Induced Abortion in the United States," September, 2019, https://www.guttmacher.org/fact-sheet/induced-abortion-united-states#.

care whenever possible to maximize patient access to health care while minimizing the risk of viral transmission associated with travel to health care facilities during the pandemic.

10. At that time, I was working in a family medicine clinic, and like other physicians throughout the country, my practice transformed from an almost entirely in-person practice to one in which a broad range of primary care was offered by telehealth. However, because of the REMS, medication abortion patients were still required to travel in person to a health care facility to pick up their mifepristone. For patients in rural Minnesota, this meant continuing to travel long distances to access care. Just The Pill was created with the goal of helping such patients reduce the burdens and risks of travel by offering care from a mobile health clinic that could bring services closer to the patients.

11. In the summer of 2020, as Just The Pill was raising the funds to pay for its mobile health clinic, a federal district court in Maryland entered an injunction suspending the mifepristone REMS in-person requirements for the duration of the COVID-19 Public Health Emergency ("PHE").[4] This meant that mifepristone prescribers could mail or deliver mifepristone to patients or arrange to have the medication sent from a mail-order pharmacy.[5] As a result, Just The Pill

[4] *Am. Coll. of Obstetricians & Gynecologists v. FDA* [hereinafter "*ACOG v. FDA*"], 472 F.Supp.3d 183 (D.Md. 2020).
[5] *Id.*; *ACOG v. FDA,* 2020 WL 8167535 (D.Md., Aug. 19, 2020).

pivoted from its plan to treat patients from a mobile health clinic and, in October of 2020, began offering medication abortion care via telehealth to eligible patients throughout Minnesota and delivering their medication directly to them through a mail-order pharmacy. However, in January of this year, the U.S. Supreme Court issued a stay of the injunction, reinstating the mifepristone REMS in-person requirements.[6]

12. From October of 2020 until the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill provided medication abortion by telemedicine with delivery from a mail-order pharmacy to nearly 100 patients in Minnesota. During this period, patients would schedule a telehealth appointment with me, where we would discuss the patient's medical history and symptoms to permit me to assess whether they were eligible for a fully remote medication abortion. If their medical history and symptoms were consistent with a fully remote medication abortion, I would provide comprehensive counseling, just as I would at an in-person visit. This included discussing the medication abortion process and the risks, benefits and alternatives to a medication abortion; reviewing FDA's Patient Agreement for mifepristone; informing the patient about our 24-hour-a-day phone line in the event that they had any questions after the appointment; reading the Minnesota state-mandated information about abortion;

[6] *ACOG v. FDA*, 141 S. Ct. 578 (2021).

and answering any questions they might have, ensuring that they had all the information they needed to make an informed decision about their care. After answering any additional questions, I would ask if they consented to a medication abortion, and if so, document that consent in their medical record. I would then *again* review the instructions for how and when to take their medication, what the follow-up process was, and what they should do if they experienced any of the (very rare) complications associated with mifepristone.

13. Following the telehealth visit, I would direct the mail-order pharmacy with which I have a contract for shipping and dispensing mifepristone to send the patient a package containing the medications (mifepristone, misoprostol, and, if requested, anti-nausea medication and ibuprofen for their comfort), written instructions, the mifepristone medication guide, and our 24-hour telephone number. We tracked shipments and confirmed delivery to patients from the mail-order pharmacy; the process was efficient and effective. As with the medication abortion itself, the medical follow-up for the vast majority of patients was also completed remotely, using telephone or audio-video communications and an at-home pregnancy test. None of the nearly 100 patients we treated through this process experienced a serious complication.

14. Being able to obtain their abortion medications from a mail-order pharmacy, without an unnecessary in-person trip to a health clinic, was a huge

relief for my patients. It enabled them to end their pregnancies earlier and more safely, without the need to travel long distances, arrange for child care, and take time away and lose pay from much needed jobs—and without the risk of viral exposure that jeopardized their health and lives and that of their families for no medical purpose. In a survey during part of this time in which 45 patients participated, 16 told us that, without the ability to have a telehealth visit and have their medication delivered directly to them, they would have had to delay care for "significantly more than 2 weeks," and 2 already knew they would not have been able to access abortion care at all and would have been forced to carry their unwanted pregnancies to term.

Burdens and Risk for Patients Following Supreme Court Stay

15. After the Supreme Court reinstated the mifepristone REMS in-person requirements, Just The Pill began providing care from a mobile health clinic at locations throughout the State to help patients access care. We did all evaluation and counseling with our patients via telemedicine, but we could no longer have their medication shipped to them; instead, they had to travel to where our mobile clinic was located on a given day.

16. We attempted to drive our mobile health clinic to locations that would be most helpful for our patients. These are largely places with communities facing the greatest barriers to traveling for care—such as communities with high

concentrations of migrant farm workers; areas with high poverty rates; and communities hardest hit by the COVID-19 pandemic, including those with large concentrations of Black, Indigenous, and people of color, and one particular community with a widespread outbreak of COVID-19 among workers at a meat-processing plant. However, we are a small operation, able to travel only a few days a week to a few different places in a very large state. Even with our atypical (and highly labor intensive) care delivery model, our patients continued to suffer significant burdens and risks as a result of the travel necessitated by the REMS.

17. For example, I recently treated a patient who lived in far northern Minnesota—on the Canadian border. Based on her medical history and symptoms, she was eligible for a fully remote medication abortion. I had conducted a telehealth visit with her, but, because of the REMS, she had to travel in person to pick up her medication. She scheduled her appointment on a day when we would be driving the mobile health clinic to our farthest north destination—approximately 4 hours northwest of Minneapolis. Even so, this meant that the patient had to travel 2 hours each way to us. She did not have a car and the only way for her to get to us was by cab, which cost approximately $300. When she arrived, she quickly got out of the cab, ran to the mobile clinic, and then immediately turned around to go home with her medication. Fortunately, we were able to raise private funds for this patient to get the care she needed. She told me that had assistance not been

available to pay for her to take a cab to our mobile clinic (or had Just The Pill's mobile clinic not been available), there is no way she could have afforded to get to clinic and she would have had to carry her pregnancy to term. But for the REMS, this patient could have received her medication without ever leaving her home.

18. We recently treated a patient who had 3 children, no car, and would have had to travel 3 hours round-trip to get to the nearest bricks-and-mortar clinic offering abortion care. We were able to treat her by telemedicine, but she had no one to care for her children and was unable to arrange for transportation to pick up her medication even from our mobile health center. In order to help this patient, we drove the mobile health clinic and parked it a block from her home so that she could walk to our mobile clinic. This was an extremely unusual situation; we simply could not do that for every patient. However, if we had not done so for this patient, she would not have been able to have the abortion she sought. But for the REMS in-person requirement, we could have had the medication sent directly to her following her telehealth visit.

19. Another patient with 4 or 5 children at home was trying to arrange to travel to our mobile health clinic to pick up her medication. This patient lived a 5-hour round-trip car ride from the nearest bricks-and-mortar clinic offering abortion care. She had a car, but it was not reliable, even for the 1-hour drive to our mobile clinic. We offered financial assistance for a cab, but this patient could not take

advantage of it, because she could not fit all of her children in the cab. Her spouse was a long-distance truck driver who was on the road most of the time, and, since the patient was new to the area, she did not have anyone she could turn to for child care assistance. To help this patient, we were able to drive the mobile health clinic to her town; however, this meant a delay of more than a week before she could obtain care. But for the REMS, we could have had her medication delivered directly to her home without such delay.

20. I have had numerous patients who have had to cancel appointments at the last minute because they can't get time off work, find child care, or forgo other obligations with which this travel interferes, or because their travel arrangements have fallen through. For some of these patients, when they tried to reschedule, we had to tell them that they were no longer eligible for a medication abortion because they were beyond 10 weeks in pregnancy. When that happens, we refer them to other abortion providers who offer in-clinic procedures, but, since there are so few abortion clinics in the state, this generally means even lengthier and more costly travel, and therefore more delay. Given the challenges that prevent such patients from accessing even our mobile clinic, I feel certain that some were never able to make the journey to a brick-and-mortar clinic in one of Minnesota's urban centers and therefore were forced to continue their pregnancies and have a child. But for

the REMS, these patients could obtain care without delay by telemedicine and home delivery of medication.

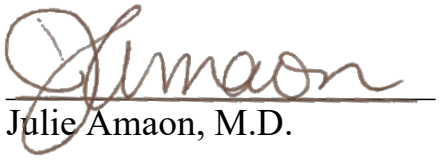
Barriers to Prescribing Mifepristone

21. Even though medication abortion could be safely provided in primary care and other health care settings throughout the state, the REMS requires health care providers to register as certified prescribers with the REMS program and stock mifepristone onsite for in-person dispensing. I have seen how these requirements prevent would-be mifepristone prescribers from providing this essential care to their patients. I know clinicians who would have prescribed mifepristone but were prevented from stocking and dispensing it onsite by others at the facilities in which they practice. For example, the family medicine clinic where I did my residency training was not permitted to stock mifepristone onsite because of opposition from someone at the institution. If it were not for the REMS, however, clinicians would have been able to send in mifepristone prescriptions to a pharmacy, as they do for virtually all other medications. Instead, because of the REMS, clinicians who practiced at the clinic could not provide mifepristone to their patients. The mifepristone REMS creates unnecessary barriers to the provision of care.

22. Earlier this week, FDA announced that it would suspend enforcement of the REMS in-person requirements during the COVID-19 PHE. This is

extremely good news for my patients, who now again have the opportunity to receive care by telehealth and have their medication delivered directly to them from a mail-order pharmacy. However, this non-enforcement policy is limited to the PHE: when the PHE ends, the REMS in-person requirements will again harm my patients as they have in the past.

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.



Julie Amaon, M.D.

Exhibit E

Declaration of Graham T. Chelius, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 GRAHAM T. CHELIUS, M.D., 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

Graham T. Chelius, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge and if called to testify I could and would do so competently as follows.

2. I am a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I provide this declaration in support of that litigation. I do so in my individual capacity, and not on behalf of any entity with which I am associated or where I practice, including my employer, Hawaii Health Systems Corporation.

3. I am a board-certified Family Medicine physician based on the island of Kaua'i in Hawai'i. I practice medicine at Kauai Veterans Memorial Hospital ("Kauai Veterans") and its associated clinics, West Kauai Clinics. Kauai Veterans is located on the western side of the island in the town of Waimea, Kaua'i. Kauai Veterans currently employs about 275 people.

4. I am currently the Chief of Staff at Kauai Veterans, a position I have held since February 2018. Immediately before that, and after serving for several years as a board member, I served as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region (which, in addition to Kauai Veterans, included Samuel Mahelona Memorial Hospital, on the eastern side of the

island in Kapa‘a, Kaua‘i), but resigned from that position in December 2017 in favor of this new opportunity as Chief of Staff. In my role as Chief Medical Officer, I was primarily responsible for managing the relationship between Hawaii Health Systems Corporation and the physicians who serve the Kaua‘i region, including participating in contract negotiations, overseeing physician staffing assignments, and responding to any complaints brought against physicians by both patients and staff. As Chief of Staff, I have very similar responsibilities, but rather than acting as a representative of the administration I am an elected representative of the physicians who form the medical staff. Both my current and former positions require that I be involved in resolving most conflicts that arise among the small clinical team at Kauai Veterans.

5. I received my medical degree from the University of Wisconsin in 2001, and completed my residency in Family Medicine at North Colorado Medical Center. Since January 2009, I have been practicing medicine in Hawai‘i at Kauai Veterans.

6. In my current role as Chief of Staff, I continue to treat patients. Within my specialty of Family Medicine, I focus in particular on women’s health, including obstetrics, and on chemical dependency treatment.

7. During the twelve years that I have been practicing medicine in Hawai‘i, I would estimate that I have cared for more than 2,750 pregnant patients

and delivered over 1,100 babies on the island of Kaua‘i. While many of my patients have much-wanted pregnancies, a substantial percentage choose to end their pregnancies, and come to me seeking abortion care. Most of these patients are medically eligible for the FDA-approved medication abortion regimen: Mifeprex followed by the drug misoprostol.

8. However, I am unable to prescribe Mifeprex to patients who need this medication because, as detailed below, complying with the requirements in the REMS that I procure, stock, and dispense Mifeprex at my health care facility—rather than issuing a prescription, from the privacy of my office, for my patient to fill at a pharmacy—would damage my professional standing locally, disrupt the workplace dynamics I am responsible for maintaining, interfere with my ability to continue to serve the many patients I now serve, and jeopardize my patients' confidentiality. The Mifeprex REMS deters clinicians and harms patients by imposing unique, unnecessary, and onerous requirements on their care. Put plainly, the REMS impedes my and other clinicians' ability to safely and appropriately care for our abortion and miscarriage patients as we would patients seeking any other service.

9. The distribution restriction substantially interferes with my ability to practice medicine in accordance with my professional judgment. Because of the Mifeprex REMS, I am unable to provide medication abortions to my patients, even

in situations when my best medical judgment would strongly counsel in favor of providing this care.

10. There is only a narrow window in which a patient can take the Mifeprex-misoprostol regimen for early pregnancy termination: this method has been approved by FDA only for the first ten weeks of pregnancy, and that is the period during which clinicians generally prescribe it. But patients cannot know they are pregnant until four weeks, and many patients do not realize they are pregnant until their sixth to eighth week. By the time a patient sees me, they typically have only a few weeks—indeed, often only a few days—in which to take the medications. If they cannot access Mifeprex within the window of availability, the only option is a surgical abortion. Nevertheless, because of the REMS, I am unable to provide medication abortion care in these time-sensitive situations.

11. There are no abortion providers on Kaua‘i, a federally designated "medically underserved area." The closest provider of abortion services is on O‘ahu, which can be reached only by airplane. I have seen the anxiety and confusion in my patients' eyes when I tell them that they have to fly to O‘ahu to obtain an abortion. I have heard them describe their frustration, anger, and heartbreak. For some patients—many of whom are already experiencing significant anxiety as a result of the unwanted pregnancy, and some of whom are also struggling with the challenges and trauma of poverty, drug addiction,

joblessness, and/or domestic violence—this news is simply devastating.

12. Traveling to O'ahu for a surgical abortion costs my patients money and time, and causes them stress. Many are forced to make significant personal and financial sacrifices in order to get the health care they need. They must find the money to pay, or if possible make arrangements for insurance to pay, for the costs of transportation to and from the airports on both islands, and for the flights themselves. They must arrange to take time off from work or school, and arrange for child care if they have children, which most do. If a loved one is accompanying them to O'ahu for support, that person must bear these costs as well. This travel and related logistics also impose significant psychological and emotional strain on many of my patients, and in my experience can be especially hard on young women, women struggling with substance abuse, women for whom English is not their first language, and women who are homeless.

13. Raising the money and making arrangements to travel is often time-consuming. Given the circumstances of my patients' lives, it is not uncommon for it to take several weeks, a month, or longer. Indeed, even for those of my patients fortunate enough to have insurance coverage for the abortion procedure and the travel to obtain it (though, of course, still not for child care, missed work, or food away from home), it typically takes one to two weeks just for the paperwork to be approved. As previously noted, delays often mean that patients are no longer

eligible for medication abortion at all, and instead must have a surgical procedure. Moreover, while abortion is very safe, the risks increase as pregnancy advances. And, on top of that, patients whose abortions are delayed also face health risks associated with continuing a pregnancy for additional days, weeks, or months. For such patients, delaying their abortion means they are sicker, longer.

14. I recall one patient whose experience powerfully illustrates many of the harms caused and burdens created by the REMS. She is a woman whom I had been treating for substance use disorder and who had previously seen us for obstetrical care for her first child. She came to my office seeking an abortion prior to 10 weeks of pregnancy. After evaluating her, I concurred that a medication abortion was an appropriate treatment, that she could utilize the Mifeprex-misoprostol regimen, and that she should do so without delay. I wanted to—and would have—provided her with the medication abortion she desired if I could have written a prescription for Mifeprex for her to fill at a pharmacy. But, because of the REMS, I could not provide that care to my patient. Instead, she was forced to travel to O‘ahu.

15. Because of the complications in this woman’s life, by the time she was finally able to make the journey to O‘ahu, more than six weeks had passed. At that point, she had to have a two-day dilation and evacuation (“D&E”) abortion instead of the medication abortion she had wanted. Not only is D&E a significantly

more complex and invasive procedure, but it also required her to bear the costs of staying on O'ahu—in a hotel, away from her home and her family—overnight. This was utterly unaffordable for her. Indeed, I understand that she called her sister on the day of her first appointment to tell her that she was on O'ahu for an abortion and had only $20 in her pocket. Her sister jumped on the plane to help my patient find lodging and provide her with emotional support during the procedure—which of course meant that my patient's sister also had to bear the costs of a round-trip flight, hotel, and food during her stay. Fortunately, her sister managed to drop everything and come to her aid, but otherwise I don't know how she would have managed to get to and from her appointments or where she would have stayed overnight.

16. I still feel frustrated and upset that my patient and her family had to bear the emotional trauma, financial burdens, and medical risks of this experience. And she is far from the only patient I have had who was eligible for medication abortion at the time I saw her, but ultimately had to not only fly to O'ahu to get the care they needed, but by the time they did so were too late for a medication abortion and had to have a procedure instead. Again, none of this would be necessary if I could have simply written this patient, and other patients like her, a prescription for Mifeprex when she was in my office early in her pregnancy.

17. While that patient *was* ultimately able to get an abortion—not all of my patients are. In some cases, the travel burdens created by the Mifeprex REMS are simply untenable, and my patients end up carrying pregnancies to term and having children against their will. For instance, one patient who struggles with chemical dependency never was able to get to O‘ahu, despite her expressed desire for an abortion and despite extensive assistance with the travel arrangements. As a result, she was forced to carry the pregnancy to term (and her child was exposed to drugs throughout the entire pregnancy). I have continued to care for such patients through the course of their pregnancies and beyond, and have seen firsthand the emotional, physical, and financial burdens that an unwanted pregnancy can cause.

18. Sadly, the situation is even worse for women who live on Ni‘ihau, which is a sparsely populated island just west of Kaua‘i. There are no paved roads, and no cell coverage—let alone health care—on Ni‘ihau. Because of the lack of access to reproductive health care on-island, women on Ni‘ihau have to schedule transportation by boat to Kaua‘i just to see a doctor. My hospital delivers virtually all the babies for pregnant women on Ni‘ihau. If a woman on Ni‘ihau wants to terminate her pregnancy, the obstacles are even greater for her than for a woman on Kaua‘i. But if the REMS did not exist, she could simply go to Kaua‘i to obtain Mifeprex the same day, instead of going to Kaua‘i only to then get referred to an O‘ahu-based abortion provider and facing all the associated obstacles. I mention

Ni‘ihau just to show how burdens can aggregate and compound into an entirely insurmountable barrier to accessing safe abortion care.

19. I became a doctor to make my patients' lives easier, less painful, and more fulfilling. But, because of the REMS, I must watch them suffer medical, emotional, and financial burdens when I cannot provide them with the abortion care that they desire. In addition, as a physician, I am concerned about continuity of care—yet the restrictions imposed by the Mifeprex REMS mean that I must needlessly hand off my patients to someone else for care, breaking that continuity for absolutely no medical reason. While I am confident that the providers to whom I refer my patients in O‘ahu provide high-quality care, it pains me to have to turn my patients away and send them off island to get care they need and that I am perfectly competent to provide. The Mifeprex REMS thus prevents me from providing uninterrupted, comprehensive primary health care to my patients, as I strive to do whenever possible. It violates my fundamental beliefs as a health care provider to have to deny a patient's request for time-sensitive, medically indicated care only because of medically unjustified restrictions like the Mifeprex REMS.

20. For the past several years, some of my patients have been able to avoid most of these burdens by participating in the Telemedicine Abortion Study ("TelAbortion"), which is run through the University of Hawai‘i. This study—which I understand operates as a temporary waiver of the REMS—allows certain

qualifying patients to receive Mifeprex by overnight mail from the study's principal investigators on O'ahu without having to fly to that island for care. Recognizing how difficult the journey to O'ahu is for many of my patients, wherever possible, I have assisted them in participating in the study. I believe this model of care delivery – mailing Mifeprex following a telemedicine visit – is safe and effective and a valuable option for my patients.

21. But the TelAbortion study's process carries its own burdens and complexities, and therefore excludes the most vulnerable, highest-risk patients. The cost of participation in TelAbortion presents the first hurdle. While the State of Hawai'i generally covers the cost of abortion services through its Medicaid program, it does not cover the cost of Mifeprex obtained through the TelAbortion study. Thus, Medicaid enrollees must pay out-of-pocket for Mifeprex provided through the study. This effectively excludes or deters many lower-income patients from participating.

22. The logistics are another hurdle. In most cases, the study protocols require that a participating patient first have a blood test and ultrasound performed, and then mail, fax, or email the results to a physician at the University of Hawai'i. Then, that physician must connect with the patient by secure videoconference at a set appointment time. Some of my patients—including some who are homeless, poor, or live in extremely remote parts of Kaua'i—do not have reliable internet or

cell phone service, access to technology with secure videoconferencing capability, or the ability to use this technology in a private space where they can speak confidentially. In such cases, I often have to step in to help them. On several occasions, I have stayed late at my office to let a patient use my computer to participate in the study, but this is not always possible: my patients' schedule, my schedule, and the schedule of the physicians on O'ahu do not always align, and certainly do not always align before the patient's window for a medication abortion closes. Helping my patients participate in the TelAbortion study has taken, and continues to take, many hours of my time—and even so, some of my patients still cannot successfully use it.

23. A third hurdle is that participating patients must have a physical address to which a package can be securely and confidentially mailed. But my patients who are homeless do not have such a safe address. So the study also cannot provide relief to such patients.

24. For all patients, even if they can gather the resources to participate in TelAbortion, the processes and requirements of participating in a research study delay care. I have on numerous occasions seen patients who were still within the window for a medication abortion, but did not have enough time to access it through the study.

25. Critically, I understand that the TelAbortion study is only temporary. When it ends, it will no longer exist as an option for me and my patients.

26. The harms and burdens I have described that both my patients and I are experiencing flow directly from my inability to issue a prescription for Mifeprex to be filled at a pharmacy or by mail order as I can do with countless other equally or less safe drugs. Most of these harms and burdens would be entirely eliminated, or substantially reduced, if the REMS were eliminated.

27. In addition, the REMS imposes a broader set of harms by deterring and blocking qualified clinicians from becoming medication abortion providers through its unique and unnecessary barriers. First, in order to comply with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my medical facility, I would have to risk serious damage to my professional standing in my workplace and to my respected role in the local community. Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff. It would also jeopardize my ability to continue in that elected position, threaten initiatives I am undertaking to improve care within our hospital system, and reduce the time I have

to treat patients. I cannot afford these personal and professional risks.

28. To be clear, many of my colleagues and staff already know that I provide abortion referrals. I know that some staff oppose even this; some have directly expressed such views to me. But if I were to comply with the Mifeprex REMS, I would be doing more than just supporting access to abortion in my *individual* professional capacity—I would also have to involve, and win the approval of, multiple colleagues and staff members in the process of procuring, stocking, dispensing, and billing for Mifeprex within our health care facility. Asking or demanding that my colleagues who have deeply held views against abortion participate or assist in providing abortions would cause significant conflict among my staff—conflict that, as Chief of Staff, I would also be required to manage, if possible. The negative consequences for my professional standing and for carefully nurtured workplace dynamics, which benefit all of our patients, deter me from attempting to comply with the Mifeprex REMS.

29. Relatedly, I also have had serious personal safety concerns about the requirement in the REMS that I register with the drug manufacturer and drug distribution company as an abortion provider. I understand that they must keep confidential the list of clinicians registered to prescribe Mifeprex. But particularly in light of the many recent health care hacking incidents, I have been concerned about being inadvertently or maliciously exposed as an abortion provider, and the

resulting likelihood of public backlash to me and my family.

30. Of course, my name is now public in the context of this litigation, and my experience since filing this lawsuit has validated my earlier concerns. Since the lawsuit was filed, I have received numerous phone calls and letters from strangers relating to this litigation. Many of those communications were positive and supportive. But a few were negative and concerning. Based on security consultations, I now carefully examine envelopes for toxic material, and have tried to remember to only open packages that I have been expecting. We also installed a security system at our house. In a country where abortion clinic shootings are commonplace and abortion providers have been assassinated, I have feared risking my and my family's safety by following through with what the Mifeprex REMS requires.

31. I ultimately made the difficult choice to publicize my desire to provide abortion care through this lawsuit, because I believe this case has the potential to expand access to medication abortion for patients all across the country. My family and I felt that this goal was worth the risk to our safety and privacy. But we did not make that choice lightly, and I expect that I am not the only physician who has found the REMS requirement that I add my name to a list of all medication abortion providers in the country a serious deterrent to providing this care.

32. I am also concerned that compliance with the Mifeprex REMS would jeopardize my patients' privacy. By requiring that my facility be responsible for the purchasing, stocking, dispensing, and billing of Mifeprex—discrete responsibilities held by discrete members of our staff—the REMS injects many more people into the abortion care process. This raises real confidentiality concerns in the small town community in which I practice. Everybody knows you and you know everybody in Waimea, a town of fewer than 2,000 people on an island of just over 65,000. In fact, it is not uncommon for members of my staff to bump into my patients at the grocery store, gym, or on the street. For myself, going to either of the two grocery stores in Waimea is a social event due to the fact that I will certainly know someone either working or shopping at the store.

33. Additionally, many members of the community have a family member, friend, or neighbor employed at Kauai Veterans, and, as a result, members of our community are sometimes nervous about seeking intimate medical care from us out of fear for their confidentiality. Certain elements of a person's medical history (history of abortion, sexually transmitted diseases such as HIV or gonorrhea, a history of rape, struggles with substance use disorder) are closely guarded by patients due to real or perceived stigma from those in the general population and medical providers.

34. For instance, I have a patient who, while pregnant, asked that a specific doctor not be involved in her care because she was afraid that the provider might divulge her medical history to family members of the doctor whom the patient also knew. Fortunately, I was able to sufficiently reassure this patient that I trust this physician to respect her confidentiality, which resulted in this patient continuing to receive care from us. But there is no doubt that, in our community, patients struggle with the decision of whether to get adequate medical care due to concerns about their confidentiality. And, indeed, it would be entirely reasonable for a patient to fear for the privacy of her abortion decision if she happens to know, for instance, some of the numerous people who may be involved with the billing, ordering, recording, and physical dispensing of medication at our facility (which, again, is a perfectly plausible scenario in our small town).

35. By contrast, if the Mifeprex REMS did not exist, I would be able to write a prescription for Mifeprex for my patient without needing to let anyone else know about the prescription except, at most, the patient's nurse, a medical records clerk, and the patient's trusted pharmacist (or a pharmacy on the other side of the island, or a mail-order pharmacy, if that is the patient's preference). The risk to my patients' confidentiality is thus substantially higher under the Mifeprex REMS.

36. The Mifeprex REMS also presents significant logistical hurdles. In order to stock and dispense Mifeprex onsite, I would need to first get a policy created for storing and dispensing the drug in the clinic, and then secure approval from the Pharmacy and Therapeutics committee at Kauai Veterans. I would also need to complete and submit all of the paperwork associated with becoming a certified prescriber under the Mifeprex REMS and setting up an account with the drug distribution company—a process that would take even more time and effort because the purchasing agreement would need to go through our contracting office, which has to follow burdensome state contracting guidelines and rules.

37. Of course, I am not now a certified prescriber (though I could easily satisfy the stated criteria for prescribing clinicians), because the certification requires me to provide a billing address and a shipping address where the Mifeprex can be sent to and then dispensed from—which, for the reasons I have stated, I am unable to do. And regardless of any certification requirement, I now provide and will always provide only medical care within the scope of practice for which I'm qualified. That is a well-recognized, basic standard of the medical profession.

38. As I have already noted, this approval process would be extremely challenging in the tense political climate surrounding abortion at my hospital, and it would almost certainly be subject to interference by colleagues and others who vehemently oppose abortion and therefore would object to a decision to stock

Mifeprex in our hospital system. As Chief of Staff tasked with maintaining good working relationships in my hospital, I find these risks unacceptable. They would not only interfere with my supervisory role, and the long-term positive changes for overall patient care that I am attempting to accomplish in that role, but also take valuable time away from my own practice.

39. In addition, I understand that the Mifeprex REMS would also require me to provide my patients with, and discuss and sign, a "Patient Agreement Form" describing the proper usage of, and risks associated with, Mifeprex as of March 2016. This special form requirement is unnecessary and singles out abortion in a manner that other medications, even much less safe medications, are not.

40. Informed consent counseling is a bedrock of medical care, taught as a core skill in medical school and reinforced by the American Medical Association's Code of Medical Ethics. I do not need any special requirement or form to ensure that I provide every patient with informed consent counseling, including discussion of proper usage and risks and what to do in the event that they need follow-up or emergency care. In fact, much less safe medications that I use in my chemical dependency practice, such as Sublocade®, which are controlled substances and are very high risk for patients, do not require any such "patient agreement form." Nor do the many other medications that I prescribe, that patients fill at a pharmacy, and that they take at home.

41. The bottom line is that, because of the REMS, I have been unable to provide my patients with essential health care that they need and that I am fully capable of providing. The REMS delays care, and forces patients to jump through hoops that are unnecessary, stigmatizing, and confusing. For some patients, the Mifeprex REMS makes abortion beyond reach. I greatly hope that Plaintiffs' motion for summary judgment once and for all lifts the unjustified REMS requirements from this safe, important drug, so that many other clinicians and I can provide it via prescription to our patients who need it.

42. I learned on April 13, 2021, that FDA has suspended the in-person dispensing requirement and authorized use of a mail-order pharmacy for providing patients with Mifeprex during the COVID-19 Public Health Emergency. I am exploring whether it will be possible for me to prescribe through a mail-order pharmacy under the special "supervision" requirement still imposed by FDA, and what kinds of contracts and/or billing practices may be necessary under FDA's non-enforcement guidance (which, of course, continues to treat Mifeprex differently than virtually all other drugs). I understand further that, even if I am able to take advantage of this in the short-term, this temporary allowance expires when the public health emergency ends. In short, there is an urgent need for

permanent relief through this litigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on 4/14, 2021

Graham T. Chelius, M.D.

Exhibit F

Declaration of Jane Roe, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 [redacted], M.D., 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

[redacted], M.D., a/k/a/ Jane Roe, M.D., 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.

2. I am a Family Medicine doctor trained in abortion care. I live and practice in a rural area in the western United States, approximately 100 miles away from the nearest abortion clinic. I am seeking to proceed pseudonymously out of fear of being exposed—nationally and in my small, rural town—as an abortion provider. In light of the extreme harassment and violence, including murder, that has been perpetrated against abortion providers in the United States, I attempt to keep my provision of abortion care as private as possible; I am painfully aware that my primary practice does not have the safeguards in place that exist at the abortion clinics (several hours away) where I work part-time—bulletproof glass, violent intruder protocols, alarm button, separate entrance for providers, and so on. Moreover, given the significant abortion stigma in my community, I expect that I would lose many of my non-abortion patients at my primary practice if the fact of my abortion provision were widely known.

3. I am a member of Plaintiff Society of Family Planning, and I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and not on behalf of any institution with which I am affiliated.

4. Attempting to comply with the Mifeprex REMS has been time-consuming, stressful, and professionally compromising. Because of the REMS, my ability to care for my patients in accordance with their needs and with my medical judgment has been conditioned on my seeking (and gaining) approval and assistance from countless individuals and committees within my health care institution. If not for the REMS, I could have simply written a prescription for Mifeprex for my patients to fill at a local or mail-order pharmacy, rather than having to mount a workplace lobbying campaign, and jeopardize my professional standing, in order to provide this safe medication onsite to my patients who need it.

5. I am a full-spectrum Family Medicine physician. In addition to my three years of residency, I completed a Family Medicine fellowship in obstetrics. I often care for three or four generations within a family—delivering a baby one day and caring for her grandmother the next. I perform a range of obstetric and gynecological services, such as cesarean sections, tubal ligations, leeps (which entails removing pre-cancerous lesions from the cervix), endometrial biopsies, and insertion and removal of intrauterine contraceptive devices.

6. I also provide miscarriage management, including by prescribing medications to evacuate the contents of a patient's uterus. When using medications to manage a miscarriage, it is the standard of care to use both Mifeprex and misoprostol, the same two drugs used in the FDA-approved medication abortion

regimen. Thus, as discussed further below, the restrictions on Mifeprex impact my ability to provide both abortion and miscarriage care.

7. I work at a hospital and affiliated clinic within a large health care system that includes multiple hospitals, each of which has one or more affiliated clinics. Many of my patients are low-income; virtually all are rural; and many travel to us from medically underserved areas in our state. Indeed, some of my patients live in areas where there are no roads—only snowmobile access in the winters.

8. Over the years, my colleagues and I have had multiple patients ask if we could provide a medication abortion, but—because we could not write them a prescription for Mifeprex to fill at a pharmacy—we had to refer all of these patients elsewhere for care. The nearest abortion clinic is a 200-mile round-trip, and some of these patients never made the journey, instead returning later for prenatal care. I recall one adolescent patient who told my colleague that she had repeatedly scheduled appointments at the abortion clinic, only to have to cancel multiple times because she simply could not make it there.

9. So, in February 2017, along with a few colleagues, I began the process of trying to get Mifeprex added to our hospital's formulary. The formulary is the list of medications approved for use by the pharmacy committees for our hospital and for our health care system, and then made available at our hospital for

dispensing or administering to patients. Based on conversations I had with colleagues about attitudes towards abortion at our institution, I concluded that there was a greater likelihood of my gaining approval to add Mifeprex to our formulary and dispense it in my office, rather than gaining approval to perform surgical abortion services in our operating room. That is because the latter would require the involvement of many clinicians, including nursing staff, certified scrub technicians, and anesthesia providers, and would thus require (at a minimum) approval from the CEO of the hospital and the departments overseeing each of those categories of clinicians, as well as the development of opt-out procedures for the supporting clinical staff.

10. Attempting to add Mifeprex to our formulary was a major undertaking. First, we had to obtain approval from the pharmacy committee at our hospital. Once that committee agreed to move forward with the process, we could elevate the request to the pharmacy committee for the entire health care system.

11. Over the next six months, we were delayed time and again in trying to get a decision from that system-level pharmacy committee—including being advised by a representative of the committee to delay raising the issue of Mifeprex until our request could undergo further "informal vetting," and then being bumped from the agenda for the committee's once-a-month meeting at least three times. In addition, the pharmacy committee representative insisted that *we* complete the

"new drug review" analysis for Mifeprex—a time-consuming assignment that, to my knowledge, is always completed by the system-level pharmacy committee, not by the hospital-level pharmacy committee or the individual physicians or pharmacists making the request. I believe this was demanded of us only because of the controversy and stigma surrounding abortion in our community, as in many places in this country.

12. Throughout the six months that we were slogging through this process—which would not have been necessary if not for the REMS—I was forced to turn away patients who needed my care. I know with certainty that, as a result, at least one of my patients was delayed past the point in pregnancy when she could obtain a medication abortion at all—which is available only up to 10 weeks of pregnancy—and had to travel 200 miles round-trip to have a surgical abortion instead. While abortion is one of the safest procedures in modern American medicine, and far safer for a woman than remaining pregnant and carrying to term, the risks associated with abortion increase as pregnancy advances. Thus, delaying a woman's abortion care increases the risks she faces.

13. It is inconsistent with both my medical judgment and my deeply held values to deny a patient's urgent request for time-sensitive medical care that I am qualified to provide—but that is exactly what the REMS required of me.

14. In September 2017, I was contacted by the Chief Medical Officer of

our health care system, who had apparently been informed of my request. To my knowledge, it is very unusual for the CMO to be involved in a formulary request, and I assume that my request was only elevated to this very high level because of the controversy surrounding abortion. He proposed a possible strategy to enable me to provide Mifeprex to my patients while avoiding the conflict that he expected would result from a system-wide debate on this question: namely, that I would prescribe and dispense Mifeprex as a "non-formulary drug," which the policy defines as "[a]n agent, which has not been reviewed by the [pharmacy committee] or has been reviewed and denied admission to the formulary."

15. This was a highly unusual application of our policy on non-formulary drugs, which to my knowledge is typically invoked in situations where patients admitted to our hospital need to continue a pre-established medication regimen for the short period of time that they are admitted. The policy on non-formulary drugs also expressly provides that usage of such medications will be "tracked and routinely reviewed . . . to evaluate appropriateness" by the system-level pharmacy committee—the very same committee that this strategy was designed to avoid, given the expectation of conflict over the abortion issue. Classifying Mifeprex as a non-formulary drug to be "tracked and routinely reviewed" meant that I had to continue to expend time, and put my professional reputation on the line, having discussions with leadership at my institution regarding my Mifeprex use. And, of

course, this designation meant that I could suddenly lose the ability to provide this care to my patients.

16. After gaining this temporary, precarious approval to stock and dispense Mifeprex on-site as a non-formulary drug, I next had to sign up with Danco (the manufacturer of Mifeprex) as a certified prescriber and set up an account with the drug distribution company. This was a significant ordeal in and of itself, further delaying my ability to care for my patients by approximately two months. I completed as much of the paperwork myself as I could, but setting up an account requires information (including on billing and shipping) that, as a doctor within a large health care institution, I do not have. This meant that I had to involve yet another colleague in the process—my Practice Administrator, who oversees finances, staffing, and other significant matters in our practice—and then repeatedly bother that person, who I know to be personally opposed to abortion, until it got done. If not for the REMS, I would not have had to compromise this important professional relationship in this manner.

17. I believe that the REMS has harmed my reputation among some of my colleagues by necessitating that I engage in an internal lobbying campaign to try to make Mifeprex available onsite, and necessitating the involvement of additional members of our staff in this care. For instance, I was informed about a senior leadership meeting at which a colleague raised as a "concern" that I was working

to make Mifeprex available at our facility (mentioning me by name).

18. *None* of this would have been necessary if I could simply write a prescription for Mifeprex for my patient to fill at a retail pharmacy, as I can do for virtually every other prescription drug. My colleagues do not have to expend such time and resources, or jeopardize their professional reputations, in order to prescribe other medications that are equally or less safe than Mifeprex.

19. Earlier in 2019, our health care system finally approved Mifeprex as a formulary drug. But this was no quick fix: ordering, stocking, and dispensing the medication remains a complicated, multi-stage process involving numerous staff members across our health care system. To begin, one provider from each individual clinic or hospital wishing to prescribe Mifeprex must register with the "buyer" for our health care system's central pharmacy. This entails attesting that they will oversee the prescription and dispensing of Mifeprex at their clinic or hospital site; completing the necessary materials for Danco; determining how many doses to order; and all of the correspondence and paperwork this necessitates. The central pharmacy then orders the medication to be stocked at the specific clinic or hospital.

20. In the Family Medicine clinic where I work, Mifeprex is stored under lock in our medication stock room, where we keep vaccines and other medications administered in the clinic (typically drugs administered by injection, or basic

painkillers like ibuprofen). When one of the medical assistants who works in my clinic sees that I have entered an order for Mifeprex, she goes into the medication stock room to obtain the pill and complete the special Mifeprex log, noting the serial number of the package (as required by the REMS) as well as the two-part patient ID (typically, the patient's medical records number and date of birth).

21. Having to comply with the REMS thus dramatically increases the number of people in our health care system who must be involved in the provision of Mifeprex. In addition to posing logistical complications, this heightens the risk of a violation of patient confidentiality—and perpetually threatens that a single individual who opposes abortion could delay or derail the process. By contrast, if not for the REMS, I could just electronically submit the prescription order to a pharmacy of my patient's choice and no one else would have to be involved.

22. Notably, formulary drugs are still subject to "annual" review by the system-level pharmacy committee (as compared to the "routine" review for non-formulary drugs)—which means that availability at our hospital is still subject to debate every year by a committee, the members of which change on a regular basis. My ability to include Mifeprex within my practice, and my patients' access to this vital care, remains precarious.

23. The Mifeprex REMS also requires me to provide my patients with and discuss, and for us each to sign, a "Patient Agreement Form" containing medical

information about Mifeprex dated to March 2016. This is not merely unnecessary from an informed consent perspective—it actively *undermines* my informed consent process by forcing me to discuss with my patients information that is inconsistent with my clinical approach and increasingly out-of-step with the research on Mifeprex as science moves forward. For instance, the form requires the patient's signature that, "[i]f my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy." However, I (like many clinicians) treat the small percentage of patients whose pregnancies continue following use of the Mifeprex and misoprostol regimen with additional medication doses in the first instance, not surgery. This is well within the standard of care, yet not reflected in the form—to the contrary, the form suggests to patients that surgery is the *only* option in such a case. Moreover, the statement that "the treatment will not work . . . . in about 2 to 7 out of 100 women" is misleading and not how I counsel my patients about the expected efficacy of the treatment: while in some small number of cases, the regimen listed on the label will not fully complete the abortion, the treatment may very well still work – after, for instance, an additional dosage of misoprostol.

24. The Form is particularly ill-suited for my patients to whom I am prescribing Mifeprex as part of miscarriage management, as has become the standard of care. The Form does not describe the clinical circumstances of patients

experiencing pregnancy loss, and can be confusing and distressing for them. Nevertheless, because of the REMS, I still must have these patients sign the Form before I can prescribe them Mifeprex. For all of these reasons, the Patient Agreement Form interferes with my ability to practice my profession in accordance with my medical judgment.

25. I hope that more clinicians within our health care system will begin providing Mifeprex at their own hospitals and clinics as well, and thus continue to expand access to this safe and effective medication. I have had numerous conversations with like-minded colleagues to that end, including giving them advice about navigating the multi-step, time-consuming process I described above to register with both our health care system and with Danco as a prescriber and then to actually get the medication onsite. Unfortunately, these logistical hurdles caused by the REMS have proven to be a significant deterrent, and there are still only a handful of us in the health care system who prescribe Mifeprex, either for abortion care or for miscarriage management.

I declare under penalty of perjury that the foregoing is true and correct.

Executed in [redacted], on [redacted], 2021.

[redacted]

[redacted], M.D., a/k/a Jane Roe, M.D.

Exhibit G

Declaration of Peter R. Mathers, J.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 PETER R. MATHERS, J.D., 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

Peter R. Mathers, J.D., 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.

2. I am a Senior Partner at the Washington, D.C., law firm of Kleinfeld, Kaplan & Becker, LLP. The firm was founded over 65 years ago with a concentrated practice in the area of FDA regulation of foods, drugs, cosmetics and other regulated medical and consumer products. I have worked in this field of law for my entire professional career—over 40 years. Since 2013, I have been recognized in the field of Food and Drugs Law in *The Best Lawyers in America* and the *Super Lawyers* lists. I have helped countless clients navigate the FDA's approval processes and the ongoing regulatory requirements applicable to products after they are approved.

3. The approval process for drugs and biological products (the "drug approval process") includes both the FDA's review and approval of the products for commercial sale as well as the FDA's assessment of whether particular approved products require what is now called a Risk Evaluation and Mitigation Strategy ("REMS"). I have advised drug product sponsors on both the potential imposition of REMS as well as the actual imposition of several of the FDA's approved REMS (including the Opioid Analgesic REMS, which applies to roughly 375 individual drugs). A copy of my curriculum vitae is attached at Exhibit G-1.

4. I submit this affidavit in my individual capacity and do not speak on

behalf of my law firm.

The FDA Approval Process

5. The FDA drug approval process takes many years. After a new drug or product candidate ("drug") is discovered, there is generally substantial testing on animals and then human subjects before an application seeking approval is submitted to the FDA. Throughout the course of human testing and before submission of a New Drug Application ("NDA"), a sponsor may meet with the FDA multiple times to discuss its plans, progress, findings, and the adequacy of data that it plans to submit in support of approval. Ultimately, the drug sponsor formally asks the FDA to approve the drug for marketing in the United States by submitting an NDA, which includes all the pertinent animal and clinical studies of the drug, as well as information about how the drug behaves in the body and how it is manufactured.

6. NDAs are reviewed by individuals within the Division that has been assigned responsibility for review of drugs that target the relevant therapeutic/disease area. These reviewing Divisions are part of the Office of New Drugs ("OND") within FDA's Center for Drug Evaluation and Research ("CDER").[1]

[1] For completeness, I note that FDA began reorganization of parts of the Agency, including CDER and OND, in April 2019. The reorganization was generally completed in 2020. *See Reorganization of the Office of New Drugs with Corresponding Changes to the Office of Translational Sciences and the Office of*

7. After an NDA is submitted, the FDA typically has 60 days to decide whether to formally "file" the NDA for review.[2]

8. If the FDA files the NDA, an FDA Review Team is assigned to the drug. The Review Team is composed of individuals within the reviewing Division responsible for the relevant therapeutic area and other experts within CDER's OND—a project manager, physicians, statisticians, chemists, pharmacologists, and other scientists and experts.[3] It is responsible for evaluating all aspects of the NDA, including the sponsor's research on the drug's safety and effectiveness, and

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Pharmaceutical Quality, U.S. Food and Drug Admin. (last modified May 21, 2020) [hereinafter "Reorganization of OND Webpage"], https://www.fda.gov/drugs/regulatory-science-research-and-education/reorganization-office-new-drugs-corresponding-changes-office-translational-sciences-and-office. However, the drug approval process remains substantively unchanged as a result of the reorganization. Further, any changes effected as a result of the reorganization (for example, relating to the structure, name, or number of the offices and divisions within OND that are responsible for carrying out the new drug review functions) are not pertinent to the historical organization, delegations and practices discussed here. According to the Reorganization of OND Webpage, the Agency may make "administrative updates" to guidance documents, webpages, and official policies and procedures as a result of the reorganization "to reflect updated organizational titles and processes." *Id.* Where an FDA source that was issued prior to the reorganization has been updated, I will so note. Otherwise, materials published by FDA that are dated prior to the reorganization are still in effect and have not been updated.

[2] *See* 21 C.F.R. § 314.101(a)(1) (2019).

[3] *See* Ctr. for Drug Evaluation and Res., *Review Team Responsibilities*, U.S. Food and Drug Admin. (last modified Sept. 1, 2015), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/review-team-responsibilities.

assessing the NDA to ensure that the drug's safety and efficacy have been thoroughly evaluated and established; that the health benefits it offers outweigh its known risks; and that the drug product will meet appropriate manufacturing and quality standards. The Review Team may also, at its discretion, seek input from one or more of the independent advisory panels established by FDA with members having expertise in the relevant areas.

9. If the Review Team's scientific and medical review ultimately establishes that the drug meets all of the applicable statutory standards, a recommendation for approval of the NDA is submitted to one of the CDER officials with authority to approve an NDA.[4]

10. In 2016, when the Mifeprex REMS review was underway, approval authority for new chemical entities was typically exercised by the Directors or Deputy Directors of the Offices of Drug Evaluation ("ODE") within the OND.[5] At

[4] *See* U.S. Food and Drug Admin., SMG 1410.104, Approval of New Drug Applications and Their Supplements § 1.A (June 12, 2012), https://www.fda.gov/media/84863/download.

[5] *See Office of New Drug Review Divisions*, U.S. Food and Drug Admin., https://www.accessdata.fda.gov/cder/sb-navigate/topic2/topic2/da_01_02_0040.htm (last visited April 6, 2021). The reorganization changed the structure of the OND, creating six cross-functional support offices and eight clinical offices as opposed to the six review offices previously in place. While FDA no longer identifies the offices as "ODEs," the concept remains the same: each office is responsible for different categories of drug

that time, there were six ODEs, each responsible for different categories of drug products. The ODEs were offices within the OND, which itself was an office within CDER. Put differently, the authority to approve an NDA was typically exercised by the appropriate Director or Deputy Director of a sub-office within CDER.

11. In situations involving a Supplemental NDA ("sNDA"), as was the case in the FDA's 2016 review of Mifeprex, the approval authority was delegated even further down on the organization chart.[6] Specifically, the approval authority for a supplemental NDA was delegated to and typically exercised by the Director or Deputy Director of the review Division within one of the ODEs with responsibility for products in the relevant therapeutic area—meaning, the approval authority rested with a Division within the relevant ODE, which as noted earlier was itself a sub-office of the OND, which was itself a sub-office of CDER.[7]

12. As part of the review process for both an NDA and an sNDA, the FDA must also approve the drug's "labeling." For prescription drugs, this must include "a summary of the essential scientific information needed for the safe and effective use

products, but the offices have been refined to align interrelated disease areas and house divisions with more focused areas of expertise.

[6] *See* SMG 1410.104, *supra* note 4, § 1.C.

[7] Notwithstanding the OND's reorganization, these delegations of authority for approval of both NDAs and Supplemental NDAs remain substantively unchanged. *See* Reorganization of OND Webpage, *supra* note 1.

of the drug," as well as, *inter alia*, the drug's purpose and proven benefits ("indications and usage"); how the drug is administered ("dosage form"); warnings; potential adverse reactions; and use in specific populations.[8]

13. On rare occasions, the Review Team may determine that a drug's expected benefits will outweigh its risks only if additional measures beyond the warnings and precautions and other directions described in the drug's labeling are taken.[9] Since the enactment of Food and Drug Administration Amendments Act of 2007,[10] the primary authority for such restrictions has been through a REMS, which imposes risk mitigation strategies beyond the FDA-approved labeling to ensure that the benefits of the drug outweigh the risks. A REMS may include one or more of the following:

- Medication Guide that outlines the risks in plain language for the patient;
- Communication Plan for healthcare providers to proactively inform them about risks of the drug; and
- Elements to Assure Safe Use ("ETASU"), which limit the conditions under which the drug may be prescribed or dispensed.[11]

[8] 21 C.F.R. §§ 201.56–57 (2019).

[9] 21 U.S.C. § 355-1(e).

[10] Pub. L. No. 110-85, 121 Stat. 823 (amending the Federal Food, Drug, and Cosmetic Act).

[11] 21 U.S.C. § 355-1(e), (f).

14. ETASU are the most restrictive kinds of REMS requirements. They may require, for instance, that clinicians be specially certified before prescribing the medication; that pharmacies be specially certified before dispensing the medication; that the drug be dispensed to patients only in certain health care settings or only once the patient has received certain laboratory test results; or that patients using the drug be subject to certain monitoring.[12]

15. The same individuals and offices within CDER who are responsible for approving NDAs also typically exercise authority over REMS approvals.[13] However, the process for REMS approval involves extensive consultation with various Offices within CDER, beyond just the OND.[14] These additional internal consultations are important in light of the extraordinary costs and burdens a REMS can impose on patients, prescribers, and other parts of the healthcare system.[15]

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[12] 21 U.S.C. § 355-1(f)(3).

[13] *See* Off. of Surveillance and Epidemiology, U.S. Food and Drug Admin., MAPP 6701.3 Rev.1, Development of a Single, Shared System (SSS) Risk Evaluation and Mitigation Strategy (REMS) or a Separate REMS with Elements to Assure Safe Use (ETASU): Responsibilities and Procedures § 6 (Oct. 28, 2020), https://www.fda.gov/media/123900/download. Although FDA updated this document following its reorganization, the delegation levels and structure for individuals with responsibility over NDA approvals and REMS approvals remains substantively unchanged.

[14] *Id.* at §§ 1–7.

[15] *See* Ctr. for Biologics Evaluation and Res., U.S. Food and Drug Admin., REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary, at 9–10 (Apr. 2019), https://www.fda.gov/media/100307/download (FDA considers

Changes to a REMS, including requests by the drug sponsor to amend or eliminate a REMS, are governed by these same procedures and chains of command.[16]

16. In my experience, both before and after the reorganization of CDER, the final decision as to whether to approve a new drug, whether to impose a REMS, and what a REMS should entail, rests exclusively within CDER. This is because the relevant offices within CDER have both the regulatory authority and responsibility for conducting the underlying reviews, as well as the scientific expertise and qualifications to assess the need for and proper scope of a REMS strategy and to assure the REMS authority is used appropriately and consistently. Delegating REMS authority to career scientific staff rather than to political appointees is also consistent with the FDA's Scientific Integrity Policy, which includes "[m]aintaining a firm commitment to science-based, data-driven decision-making" and "[s]hielding the

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potential "burden[s] on patient access and the health care delivery system" imposed by REMS in order "to ensure that REMS are designed to minimize delays or interruptions in drug therapy that may have untoward clinical impact," including for "patients . . . in rural or medically underserved areas").

[16] *See* Off. of New Drugs, U.S. Food and Drug Admin., MAPP 4191.1, Risk Evaluation and Mitigation Strategies Modifications and Revisions §§ 1–6 (June 29, 2020), https://www.fda.gov/media/128782/download. Although FDA updated this document following its reorganization, the procedures involved for changing a REMS remains substantively unchanged. The prior version effective as of July 10, 2019 is available at https://wayback.archive-it.org/7993/20191216012938/https:/www.fda.gov/media/128782/download.

agency's science and its scientific staff from political influence."[17] Both before and after the reorganization of CDER, this principle was and remains a core tenet of FDA's mission.

17. In my experience, both before and after the reorganization of CDER, it is very atypical for the FDA Commissioner, a political appointee, or anyone within the Office of the Commissioner, to be involved in the drug approval process in any way (outside of the internal dispute-resolution processes that apply either when a drug sponsor disagrees with a scientific determination or where there is an internal dispute among agency scientists).[18]

The Mifeprex Approval Process

18. I understand from Plaintiffs' attorneys that:

- The FDA originally approved Mifeprex in 2000 under its "Subpart H" regulations (21 C.F.R. §§ 314.500–560) subject to a restricted distribution scheme.

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[17] *See* U.S. Food and Drug Admin., SMG 9001.1, Scientific Integrity at FDA 2 (Feb. 3, 2012), https://www.fda.gov/media/82932/download; *see also Scientific Integrity at FDA*, U.S. Food and Drug Admin. (last modified Sept. 17, 2018), https://www.fda.gov/science-research/about-science-research-fda/scientific-integrity-fda.

[18] *See* Ctr. for Biologics Evaluation and Res., U.S. Food and Drug Admin., Formal Dispute Resolution: Sponsor Appeals Above the Division Level (Nov. 2017), https://www.fda.gov/media/126910/download; U.S. Food and Drug Admin., SMG 9010.1, Scientific Dispute Resolution at FDA (Jan. 13, 2009, updated June 19, 2019), https://www.fda.gov/media/79659/download.

- In 2007, pursuant to Section 909(b)(1) of the newly enacted Food and Drug Administration Amendments Act of 2007, Mifeprex was "deemed to have in effect an approved risk evaluation and mitigation strategy" (*i.e.*, REMS) because the FDA previously had imposed a restricted distribution scheme for Mifeprex under its "Subpart H" regulations.
- In 2011, the FDA affirmatively approved Mifeprex's REMS, maintaining the same requirements initially imposed in 2000 and subsequently deemed a REMS in 2007.
- In 2015, the sponsor, Danco, submitted an sNDA seeking approval to alter the Mifeprex indication, labeling, and REMS.
- The FDA reviewed both the Mifeprex labeling and REMS in 2015–2016.
- Dr. Robert M. Califf, then Commissioner of Food and Drugs ("Commissioner"), was briefed about the Mifeprex sNDA, including CDER's conclusion that a REMS remained necessary to ensure that the benefits of Mifeprex outweigh its risks, but that the REMS should be modified, including by removing one component of the REMS, the Patient Agreement Form.
- Subsequent to being briefed, the Commissioner requested that the Patient Agreement Form remain a component of the Mifeprex REMS.

- In a March 28, 2016, memorandum documenting the Commissioner's request and related action, Dr. Janet Woodcock, Director of CDER wrote: "The currently approved REMS for Mifeprex contains a Patient Agreement Form required to be signed by both the patient and the prescriber. During the review of the REMS in connection with [the sNDA submitted by Danco], [**redacted**] found that the information contained in the Patient Agreement Form is generally duplicative of information in the Medication Guide and of information and counseling provided to patients under standard informed consent practices for medical care and under professional practice guidelines. For the reasons further described in their reviews, the reviewers recommended that the Patient Agreement Form be removed from the REMS. After being briefed on the planned changes to the NDA that the Center [CDER] was considering, the Commissioner concluded that continuing the REMS requirement for a signed Patient Agreement Form would not interfere with access and would provide additional assurance that the patient is aware of the nature of the procedure, its risks, and the need for appropriate follow-up care. He requested that the Patient Agreement Form be retained as an element of the REMS. Therefore, I have asked [**redacted**] and [**redacted**] to continue to include a Patient Agreement

Form in the REMS for Mifeprex."

19. Not only is it highly unorthodox for the Commissioner to be involved in the approval process, but it is virtually unheard of for the Commissioner to overrule CDER's decision regarding an approval. There is only one other situation I am aware of where an individual at the Commissioner's level or higher intervened to overrule the Review Team's analysis: levonorgestrel, an emergency contraception pill commonly known as "Plan B."[19] There, FDA decided that the drug product could be made available over-the-counter but the Agency's decision was overruled by then-HHS Secretary Kathleen Sebelius in an action that was not supported by a scientific justification and that a federal court determined was politically motivated.[20] The court found that the HHS Secretary's "unprecedented" intervention

[19] Short of overruling a Review Team's analysis, the only other example I am aware of where political interference appears to have impacted FDA's empirical drug approval process involved FDA's issuance of an Emergency Use Authorization ("EUA") for chloroquine and hydroxychloroquine on March 28, 2020, without any reliable clinical trial data in support, after the Trump Administration's express support for the off-label use of these two products to treat COVID-19. *See* U.S. Gov't Accountability Off., GAO-21-207, COVID-19, Federal Efforts Accelerate Vaccine and Therapeutic Development, but More Transparency Needed on Emergency Use Authorizations 26 (Nov. 2020), https://www.gao.gov/assets/gao-21-207.pdf. Roughly two months following issuance, FDA revoked the EUA, stating that the products were "unlikely to be effective in treating COVID-19 and that the known and potential benefits no longer outweighed the known and potential risks for the authorized use." *Id.* at 22.

[20] *See Tummino v. Hamburg*, 936 F. Supp. 2d 162, 170–71 (Apr. 5, 2013).

was a "significant departure from agency practice" and that "this kind of political interference call[s] into serious question the legitimacy of the FDA's decision."[21] The court described the Secretary's actions as "an election-year decision" and found that the Secretary's reasoning was "so unpersuasive as to call into question her good faith."[22]

20. Notably, the FDA's treatment of Mifeprex has been atypical since the beginning. In addition to the Commissioner's interference in the 2016 approval, it was also highly unusual in the first place for the FDA, when it originally approved Mifeprex for sale in the United States in 2000, to regulate the medication under Subpart H. The FDA approved approximately 1,000 NDAs in the 15 years preceding the enactment of the REMS statute, and subjected only 7, including Mifeprex, to a restricted distribution scheme under Subpart H.[23]

21. Further, Mifeprex has been treated differently during the COVID-19 public health emergency than other closely regulated medications. For example,

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[21] *Id.* at 170.

[22] *Id.* at 170–71.

[23] *See* U.S. Gov't Accountability Off., GAO-08-751, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex 27 (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf; U.S. Gov't Accountability Off., GAO-07-49, New Drug Development: Science, Business, Regulatory, and Intellectual Property Issues Cited as Hampering Drug Development Efforts 20 (Nov. 2006), https://www.gao.gov/assets/gao-07-49.pdf.

FDA quickly issued non-enforcement guidance in March 2020 stating that, for the duration of the COVID-19 public health emergency, it would not take enforcement action against sponsors and others who did not comply with REMS in-person laboratory testing and imaging requirements.[24] But it is my understanding that the FDA refused for over a year to even respond to requests submitted in March and April 2020 from leading professional medical organizations and health care providers to similarly waive the in-person-dispensing REMS requirement for Mifeprex, before finally issuing non-enforcement guidance in April 2021. Although the in-person dispensing requirements were enjoined by the courts during part of this time, this delay left Mifeprex patients and providers uniquely mandated to risk exposure to COVID-19 infection to access medication that they are permitted to take at home without clinical supervision. Notably, in the April 12, 2021 letter announcing the non-enforcement guidance,[25] FDA provided no explanation of why in-person dispensing of Mifeprex would be warranted even outside the context of the pandemic, and in fact acknowledged that there was no evidence of an increase in adverse events or serious safety concerns during the period in which the in-person dispensing requirements were enjoined.

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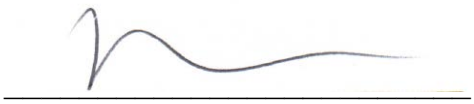
[24] U.S. Food and Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency, Guidance for Industry and Health Care Professionals (March 2020), https://www.fda.gov/media/136317/download.

[25] 2021 FDA Non-Enforcement Guidance, Joint Stipulation of Facts Ex. J, ECF No. 140.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed in Washington, D.C., on 13 April, 2021.



Peter R. Mathers, J.D.

Mathers Decl.

Exhibit G-1

Kleinfeld Kaplan Becker
1850 M Street NW, Suite 800
Washington, DC 20036

202.223.5120 › kkblaw.com

Peter R. Mathers
Partner
pmathers@kkblaw.com

Mr. Mathers joined Kleinfeld, Kaplan and Becker, LLP in October 1979, after graduating from Yale Law School. Since that time, Mr. Mathers has concentrated his legal practice primarily in the area of drug and medical device regulation under laws administered by the United States Food and Drug Administration and the United States Drug Enforcement Administration, and related federal and state laws. Mr. Mathers has counseled and represented a large number of drug development and manufacturing clients ranging from small start-up companies to major multinational firms, concerning pioneer/brand-name as well as generic drug products. He has assisted both pioneer and generic firms in developing and obtaining FDA approvals for their products, and has provided extensive assistance in ongoing compliance with manufacturing, promotion, and distribution requirements relating to approved drug products. He has also defended firms in judicial and administrative proceedings relating to the enforcement of drug manufacturing and promotion standards, integrity audits, and the potential withdrawal of existing product approvals.

Mr. Mathers has been involved in litigation with FDA over the development of generic drug approval procedures even before the 1984 Hatch-Waxman Amendments, and was involved in the drafting of those Amendments. He has continued to be engaged in the ongoing interpretation, application, negotiation, and litigation of critical issues arising under those Amendments and the subsequent legislation that has modified and expanded those provisions.

Mr. Mathers has also represented clients in connection with all aspects of the regulation of controlled substances and listed chemicals, including matters involving scheduling, approval, registration, manufacturing, quotas, import/export, labeling, distribution, security, records, investigations and penalties.

Kleinfeld Kaplan Becker

Education

Yale Law School, J.D., 1979
Member, Thomas Swan Barristers Union

Rensselaer Polytechnic Institute, B.S., *cum laude*, 1976
Omicron Delta Epsilon, Economics honor society

Professional Affiliations

The District of Columbia Bar
Food and Drug Law Institute

Practice Credentials

District of Columbia Court of Appeals
U.S. District Court for the District of Columbia
U. S. Court of Appeals, D.C. Circuit and other Federal Circuits
United States Supreme Court

Recognition

Best Lawyers in America®, FDA Law, 2013-2021

Exhibit H

Declaration of Diana M. Pearce, Ph.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 DIANA M. PEARCE, PH.D., 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

Diana M. Pearce, Ph.D., declares and states as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I provide the following facts and opinions as an expert in the field of Sociology, specifically specializing in poverty, women's welfare, and women studies in the United States. I hold an M.S.W. and a joint Ph.D. in Social Work and Social Science (Sociology) from the University of Michigan. I am currently the Scholar in Residence at the Center for Women's Welfare at the School of Social Work at the University of Washington, after serving as the Founder and Director of the Center for 18 years. For more than two decades, I have been on the faculty of the School of Social Work as a Senior Lecturer (now Senior Lecturer Emerita), as well as an affiliate of the Gender, Women and Sexuality Studies department and the West Coast Poverty Center, all at the University of Washington. For over 40 years, I have conducted research and published on the topics of poverty and women's welfare in peer-reviewed sociology and poverty journals. Most famously, I coined the term "the feminization of poverty,"[1] which became one of the ten themes of the Beijing Conference on Women in 1995, as well as the subject of countless articles and books.

[1] Diana M. Pearce, *The Feminization of Poverty: Women, Work and Welfare*, 11 Urb. & Soc. Change Rev. 28 (1978).

I have also authored numerous reports, including for the U.S. Department of Labor and the U.S. Civil Rights Commission.

3. Since 1996, I have been the creator and principal investigator of the Self-Sufficiency Standard (the "Standard"), which measures the amount of income necessary for different family types to meet basic needs without public subsidies or private/informal assistance. Since then the Standard has been calculated for 41 states.[2]

4. I have presented my research on poverty at numerous professional conferences and governmental briefings, including presentations to the U.S. Department of Health and Human Services and the U.S. House of Representatives. I also testified twelve times before the U.S. Congress. I have received various awards for my work and research, including:

- National Association of Social Workers, Presidential Award for Leadership in Research (presented at NASW Conference, The Feminization of Poverty Revisited) (2013)
- Wider Opportunities for Women, Setting the Standard (Lifetime Achievement) Award (2003)
- Workforce Development Council of Seattle-King County, for Visionary Research on Family Self-Sufficiency (2003)
- Society for Applied Sociology, Sociological Practice Award (2003)

[2] For all data and reports relating to and a general explanation of the Standard, see generally Self-Sufficiency Standard, http://www.selfsufficiencystandard.org/ (last visited Apr. 7, 2021).

5. A true and correct copy of my curriculum vitae is attached as Exhibit H-1 to this declaration.

II. THE IMPACT OF THE RISK EVALUATION AND MITIGATION STRATEGY (REMS) FOR MIFEPREX ON WOMEN SEEKING ABORTION CARE

6. I have been asked to evaluate the impact of the Mifeprex REMS on women in the United States seeking abortion care.[3] I understand that under the Mifeprex REMS, a patient cannot obtain the medication by prescription at a retail pharmacy or by mail; they must receive it at a clinic, medical office, or hospital from a clinician who has prearranged to stock and dispense Mifeprex. I understand that these requirements deter or prevent a significant number of health care providers, such as Dr. Graham Chelius on Kaua‘i, from prescribing medication abortion, and, as a result, some patients have to travel further distances or make an entirely unnecessary trip in order to access time-sensitive abortion care. I understand further that the REMS prevents medication abortion patients who have been evaluated and counseled via telemedicine from picking up their prescription at their local pharmacy or obtaining their mifepristone prescription by mail without even having to leave home, forcing such patients instead to make a trip to a REMS-certified provider just to pick up the pill and sign a form.

[3] I use “women” here as a shorthand for patients who need abortion care, but note that patients who are gender non-binary or transgender also utilize these services.

7. Data demonstrate that the overwhelming majority of abortion patients are low-income and struggle to make ends meet. As an expert in poverty and women's welfare who has studied the barriers that affect low-income women's access to health care, I know that low-income people find it extremely difficult just to afford their basic household needs, let alone unplanned emergency expenses like abortion. In my expert opinion, by requiring patients to make additional and/or lengthier trips to get a medication abortion, the Mifeprex REMS increases the costs and logistical burdens of accessing care—including missed work, transportation and child care costs—to such a degree that they significantly delay or entirely prevent women from accessing abortion care. Even for those who are ultimately able to access care, the resources and other hurdles that the REMS force women to navigate often require significant sacrifices for patients and their families that threaten patients' privacy and economic stability, including by jeopardizing their employment or housing, forcing patients to forgo other necessary expenses like food or other medical care, and increasing the risk of domestic violence.

A. Many Abortion Patients Cannot Afford to Meet Their Basic Needs.

8. The vast majority of women seeking abortion care have low incomes. In 2014, the most recent year for which data are available, half (49%) of women seeking abortions in the United States had incomes at or below the U.S. Official Poverty Measure (OPM), which for 2014 was $11,670 annually for a single person

or $19,790 for a family of three (in the contiguous U.S.).[4] Another quarter (26%) of U.S. abortion patients had incomes between 100 and 200% of the OPM in 2014.[5] In other words, based on the OPM, three out of four abortion patients are poor or very low-income.[6]

9. But it is likely that this statistic actually undercounts the percentage of abortion patients with inadequate income to meet their basic needs, because the OPM is based on a flawed and outdated methodology and set of assumptions. The OPM was developed decades ago and assumes that a family's total budget is three times what they spend on food—reflecting average American family expenditure patterns of the mid-1950s. However, household expenditure patterns have changed significantly since then. For instance, the cost of food has increased much less over

[4] Jenna Jerman, Rachel K. Jones & Tsuyoshi Onda, Guttmacher Inst., Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008 1, 7 (2016), https://www.guttmacher.org/report/characteristics-us-abortion-patients-2014; *Prior HHS Poverty Guidelines and Federal Register References*, U.S. Dep't of Health & Hum. Servs., https://aspe.hhs.gov/prior-hhs-poverty-guidelines-and-federal-register-references (last visited April 7, 2021). For 2021, the amounts are $12,880 for a single person and $21,960 for a family of three. *2021 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 26, 2021), https://aspe.hhs.gov/2021-poverty-guidelines.

[5] Jerman, Jones & Onda, *supra* note 4, at 1, 7.

[6] *Id.* Because these statistics are drawn from surveys of patients who received an abortion, they do not account for poor or low-income patients who wanted to have an abortion but were prevented from accessing one because of financial or other barriers to access. *Cf., e.g.*, Sarah C.M. Roberts et al., *Out-of-Pocket Costs and Insurance Coverage for Abortion in the United States*, 24 Women's Health Issues e211, e215 (2014), https://www.sciencedirect.com/science/article/abs/pii/S1049386714000048 (in longitudinal study of abortion patients at 30 facilities across the country, more than half reported that the need to raise money delayed access to care).

the past decades than almost all other basic expenses, while other costs have increased substantially (housing, health care, taxes). Moreover, the OPM does not account for geographic variation in costs or for variations in family type (such as by children's ages), and it does not explicitly reflect basic needs like child care, taxes, health care, and transportation.[7]

10. A more accurate measure of income inadequacy is the Self-Sufficiency Standard, which my colleagues and I first developed two decades ago to address gaps and deficiencies in the federal poverty measures. The Self-Sufficiency Standard describes the minimally adequate income that a family of a certain composition in a given place needs to meet their basic needs, without public or private assistance. It is tailored to reflect the minimum actual costs of housing, child care, food, transportation, health care, miscellaneous expenses, taxes, and tax credits for 719 family types in every county in a given state. The Standard additionally reflects cost

[7] Increasing recognition of the OPM's shortcomings led Congress in the 1990s to direct the National Academies of Sciences, Engineering and Medicine to undertake a wide-ranging study of the measure. *See* Nat'l Rsch. Council, Measuring Poverty: A New Approach xv, 2–3 (Constance F. Citro & Robert T. Michael, eds. 1995), https://www.nap.edu/download/4759#. The study and resulting report spurred a number of experimental measures piloted by the U.S. Census Bureau, and, in 2010, the Bureau adopted the Supplemental Poverty Measure (SPM). *See* Liana Fox, U.S. Census Bureau, The Supplemental Poverty Measure: 2019 (2020), https://www.census.gov/library/publications/2020/demo/p60-272.html. Although the SPM addresses some of the problems with the OPM, such as varying housing costs by Census region, it does not consider the substantial variation in housing costs within the four Census regions, and it either fails to or inadequately addresses the other flaws discussed above. In particular, the SPM methodology does not address the most serious shortcoming of the OPM— that it seriously underestimates the total cost of basic needs—and thus like the OPM, the SPM is likewise much too low, everywhere and for every family type.

differentials due to the age of children; thus, families with children below school age requiring full-time child care will have a higher Standard than those with older or no children. Whenever possible, the amount for a given need is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses).[8]

11. We have found that a substantial percentage of people across the country—and far more than are captured by the OPM—do not have incomes sufficient to meet their basic needs.[9] (This is true even though the vast majority of households with incomes below the Standard have at least one worker in them.[10]) The Standard is higher than the OPM in every jurisdiction for which we have

[8] For housing, the Standard uses the U.S. Department of Housing and Urban Development Fair Market Rents, which set the maximum rent allowed for Section 8 voucher (housing assistance) recipients; for child care costs, the Standard uses the maximum amount set by the state for reimbursement for those receiving child care assistance (minus child care copayments); and for food costs, the Standard uses the U.S. Department of Agriculture's "Low-Cost" Food Plan, which only covers the cost of basic groceries, with no allowance for any take-out or restaurant food. L. Manzer & A. Kucklick, Ctr. for Women's Welfare, Technical Brief: The Self-Sufficiency Standard 2021 Update (2021) (available upon request from the Center for Women's Welfare, University of Washington School of Social Work, www.selfsufficiencystandard.org).

[9] When calculating income inadequacy compared to the Standard, we consider all cash resources available to a household, including cash assistance, such as Temporary Assistance for Needy Families (TANF) or Supplemental Security Income (SSI). It should be noted, however, that the income limits for means-tested cash assistance are very low (often near or even below the OPM), and thus are never sufficient to bring a family up to their Self-Sufficiency Standard.

[10] *See, e.g.*, Diana M. Pearce, Ctr. for Women's Welfare, Overlooked and Undercounted 2018: Struggling to Make Ends Meet in Colorado, at vi (2018), http://www.selfsufficiencystandard.org/sites/default/files/selfsuff/docs/CO18_Demo_Web.pdf.

calculated it—sometimes significantly higher.[11] This is especially true for families—which is notable here since, nationwide, about 60% of women seeking an abortion have at least one child.[12]

12. In fact, the Self-Sufficiency Standard for a family consisting of one adult and one infant exceeds *200% of the OPM* in 92% of counties in the 31 states for which we have current Standard data and in every single county in 20 states. And the gaps are similarly stark for other family types.[13] In other words, given that the Standard is a bare-bones budget, it is clear that in the vast majority of counties in most states, abortion patients with incomes living up to 200% of OPM still lack the minimum income necessary to afford even their basic household needs.

13. My research in numerous states to determine the characteristics of households most likely to have income below the Self-Sufficiency Standard further reinforces the existing data showing that most abortion patients struggle to make ends meet. As noted, a majority of abortion patients are mothers,[14] and

[11] The states with current Standard data included in this analysis are: AL, AZ, CA, CO, CT, FL, GA, HI, IL, IN, KS, MA, MD, MI, MN, MO, NC, NJ, NV, NY, OK, OR, PA, SC, TN, TX, UT, VA, WA, WI, and WY. Data on file with the author.

[12] *Abortion Surveillance — United States, 2018*, Ctrs. for Disease Control & Prevention, at Table 7 [hereinafter "*CDC Abortion Surveillance*"], https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T7_down (last updated Nov. 7, 2020).

[13] For a family of one adult and one preschooler, the Standard exceeds 200% of the OPM in 88% of counties; for a family with one adult, one preschooler, and one school-aged child, in 83% of counties; and, for a family with two adults, one preschooler, and one school-aged child, in 84% of counties.

[14] *CDC Abortion Surveillance*, *supra* note 12, Table 7.

approximately 85% are unmarried.[15] Moreover, 60% identify as people of color, including 53% identifying as Black or Hispanic.[16] My colleagues and I have uniformly found that these are the very populations that are statistically more likely than other demographic groups to live below the Standard.

14. For example, the percentage of Black households with incomes below the Standard is on average double the percentage of white households with incomes below the Standard; the percentage of Latinx households is 2.5 times the percentage of white households; and the percentage of single-mother families with incomes below the Standard is 2.2 times that of married couples with children.[17] This is particularly true for single mothers of color: on average, almost three out of four (74%) Black single mothers, and almost four out of five (79%) Latina single mothers, have incomes below the Standard.[18]

[15] *Id.* at Table 6, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T6_down.

[16] *Id.* at Table 5, https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm#T5_down; *see also* Jerman, Jones & Onda, *supra* note 4, at 1, 5.

[17] Based on an analysis of Standard data and demographic reports for California (2019), Colorado (2016), Connecticut (2017), Maryland (2015), New York City (2019), New York State (2019), Pennsylvania (2017), Washington (2013), and Wyoming (2010–2014). Data on file with the author and/or available on the Standard website, in individual reports. *See Self-Sufficiency Standard by State*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/self-sufficiency-standard-state (last visited Apr. 8, 2021); *Research and Resources: Demographic Reports*, Self Sufficiency Standard, http://www.selfsufficiencystandard.org/node/30 (last visited Apr. 8, 2021).

[18] In every state for which we have performed these demographic analyses, at least 65% of Black single mothers and 74% of Latina single mothers had incomes below the Standard, compared to an average of 52% of white single mothers. See resources listed above, *supra* note 17.

15. To further illustrate this concept, consider Kaua'i. On that island, where Dr. Chelius's patients live, the 2020 Self-Sufficiency Standard—the *minimum* income necessary for basic subsistence, based largely on government reimbursement rates—for a single adult caring for one school-aged child and one preschooler was nearly 1.75 times the median household income for single-mother households in Kaua'i, and more than triple the 2020 OPM for a family of three.[19] For a single adult caring for one infant, the Standard was 1.8 times higher than the median income for single mothers in Kaua'i, and more than four times the 2020 OPM for a family of two.[20] Thus, many single-mother households in Kaua'i that would not be classified as poor or low-income according to the OPM are in fact struggling to afford basic household needs.

16. Kaua'i is not an outlier. I analyzed the monthly basic needs budget for families with one adult and one preschooler in the least expensive county, median county, and county with the largest city in eight representative states across the

[19] *Compare Hawaii Self-Sufficiency Standard Table, 2020*, at By County tab, Table 3, cell L71 (2020) [hereinafter "*Hawaii Standard 2020*"], http://www.selfsufficiencystandard.org/node/50 (Self-Sufficiency Standard of $69,224), *with* U.S. Census Bureau, *Table S1903: Median Income in the Last 12 Months*, https://data.census.gov/cedsci/table?q=S1903&tid=ACSST1Y2019.S1903 (filter by "Browse Filters: Geography," "Geography: County," "Within (State): Hawaii," and select "Kauai County, Hawaii) (last visited April 7, 2021) (median income of $39,422 for "Female householder, no spouse present" and "With own children under 18 years"), *and 2020 Poverty Guidelines*, U.S. Dep't of Health & Hum. Servs.: ASPE (last updated Jan. 21, 2020), https://aspe.hhs.gov/2020-poverty-guidelines (2020 OPM of $21,720).

[20] *Compare Hawaii Standard 2020*, *supra* note 19, at By County tab, Table 3, cell C71 (Self-Sufficiency Standard of $70,788), *with* U.S. Census Bureau, *Table S1903*, *supra* note 19 (median income of $39,422), *and 2020 Poverty Guidelines*, *supra* note 19 (2020 OPM of $17,240).

country, all of which have statewide poverty rates (according to the OPM) similar to either the national average or the average for their geographic region.[21] In every county in every state considered in this analysis, a full-time minimum wage worker[22] is unable to afford the minimum needs for their family. In all eight states, one adult with a preschool-aged child in the least expensive county in the state (*i.e.*, the county with the *lowest* Standard) needs at least 36% more than a full-time minimum wage income (Santa Cruz County, AZ) and as much as two or more times the minimum wage (Uvalde County, TX, and Person County, NC), just to afford their family's basic needs. For those living in the largest city in each of these states, the deficit is even more substantial: in Chicago (Cook County, IL), a single mother with a preschooler needs to earn almost twice the minimum wage, while in Charlotte, NC (Mecklenburg County), she needs to earn at least 3.6 times the minimum wage, just to meet her basic needs. These families are already forced to make sacrifices or economic trade-offs just to scrape by; *any* added expense, no matter how small, can be destabilizing, potentially forcing them to forgo basic needs like food, rent, or

[21] States used in this analysis are those (a) with statewide poverty rates closest to the national rate or to the average rate for states in their Census region, based on data from the U.S. Census Bureau, and (b) for which current Self-Sufficiency Standard data (2021) was available. *See* Exhibit H-2 (summarizing Standard data for all 8 states).

[22] The Standard assumes full-time work (40 hours per week). Thus, I am evaluating whether full-time work at the state (or local) minimum wage will be enough to meet the cost of basic needs in the Standard for this family type in each place.

medical care.[23]

17. Key economic trends indicate that American families may be facing even more challenges in the future. For example, in every state in which my colleagues and I have tracked the Standard over the last two decades, the cost of basic needs has been rising faster than income, even during the Great Recession and the subsequent Recovery.[24] In addition, the economic precarity of many working families across the country has only been amplified by the current economic recession relating to the COVID pandemic. While the data showing the full extent of the economic impact of the pandemic is not yet available, and uncertainty remains due to new surges in COVID cases, the widespread job losses and staggeringly high rates of unemployment experienced so far already have taken their toll, with large

[23] For many families, public assistance will be inadequate to fill these gaps. For example, as its name suggests, the Temporary Assistance for Needy Families Program (TANF) is not designed to be an ongoing source of income for working families; although work is required to maintain eligibility, even working part-time is likely to result in an income too high to maintain eligibility for TANF. And while in-kind benefits such as SNAP (food stamps), child care assistance, and housing assistance are meant to help low-wage workers, only a minority of eligible families actually receive those benefits. *See, e.g.*, Gov't Accountability Office, Child Care: Subsidy Eligibility and Receipt, and Wait Lists – Briefing to Senate Comm. on Health, Educ., Labor & Pensions and House Comm. on Educ. & Labor, GAO-21-245R, at 12 (2020), https://www.gao.gov/assets/gao-21-245r.pdf (only 14% of children eligible for child care assistance under federal standards, and only 22% of those eligible under state rules, actually receive such assistance in an average month); G.T. Kingsley, Urban Institute, Trends in Housing Problems and Federal Housing Assistance3 (2017), https://www.urban.org/sites/default/files/publication/94146/trends-in-housing-problems-and-federal-housing-assistance.pdf (only about one in five low-income renters with housing needs received assistance in 2015).

[24] For example, see Standard Reports for Colorado, Connecticut, Indiana, Maryland, Michigan, New York, New York City, North Carolina, Ohio, Oregon, South Carolina, Washington, Wisconsin, and Wyoming, all available at *Self-Sufficiency Standard by State*, *supra* note 17.

numbers of families citing serious economic impacts and concerns for the future.[25] These losses have disproportionately affected single mothers, particularly women of color, and other households that had inadequate income to meet their basic needs even before the recession.[26]

18. In sum, in considering the impact of the Mifeprex REMS on access to abortion nationwide, it is important to recognize that the vast majority of abortion patients—likely even *more* than the 75% of patients with incomes at or below 200% OPM—are already unable to afford their and their families' basic needs. For these patients, the unexpected, emergency expenses associated with traveling for abortion care—whether to another county, city, or state, or even to a second local health care facility—presents a serious hardship or is entirely impossible.

B. The Mifeprex REMS Imposes Significant Costs and Burdens on Medication Abortion Patients.

19. Abortion access is very limited in the United States. Approximately 90

[25] J. Horowitz et al., *A Year Into the Pandemic, Long-Term Financial Impact Weighs Heavily on Many Americans*, Pew Rsch. (Mar. 5, 2021), https://www.pewresearch.org/social-trends/2021/03/05/a-year-into-the-pandemic-long-term-financial-impact-weighs-heavily-on-many-americans/ (finding that 40% of adults say they or someone in their household lost a job or wages during the pandemic, and half of those who did so are still earning less than before the pandemic).

[26] *See id.* (finding that, during the pandemic, Black and low-income workers are more likely to have incurred debt or put off paying household bills due to lost income); A. Barroso & R. Kochhar, *In the pandemic, the share of unpartnered moms at work fell more sharply than among other parents*, Pew Rsch. (Nov. 4, 2020), https://www.pewresearch.org/fact-tank/2020/11/24/in-the-pandemic-the-share-of-unpartnered-moms-at-work-fell-more-sharply-than-among-other-parents/ (finding steepest declines among Black and Hispanic single mothers and single mothers with young children).

percent of U.S. counties lack an abortion clinic, and, nationwide, 38% of women of reproductive age live in those counties.[27] A survey of a nationally representative sample of more than 8,000 abortion patients found that the average distance traveled to reach the clinic was 68 miles round-trip.[28] In a majority of states, at least one in five women of reproductive age lives more than 50 miles from the nearest clinic.[29] While rural women are most likely to face significant travel distances,[30] women in many cities must also travel significant distances to obtain abortion care: for instance, a 2018 study characterized 27 major U.S. cities as "abortion deserts" because they did not have a publicly advertised facility that provides abortions within 100 miles.[31]

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[27] Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States*, *2014*, 49 Persp. on Sexual & Reprod. Health 17, 20 (2017), https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12015. Today, 95% of abortions are performed in clinics (rather than doctors' offices or hospitals). *Id.* at 17.

[28] Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623, 1625 (2019), https://pubmed.ncbi.nlm.nih.gov/31282804/.

[29] Jonathan M. Bearak et al., *Disparities and Change Over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, Lancet Pub. Health e493, e495–96 (2017), https://www.thelancet.come/action/showPDF?pii=S2468-2667%2817%2930158-5 (in six states, a majority live more than 50 miles away, including two where a majority live more than 150 miles from the nearest provider).

[30] *See, e.g.*, Nicole E. Johns et al., *Distance Traveled for Medicaid-Covered Abortion Care in California*, 17 BMC Health Serv. Res. 287, 294 (2017), https://doi.org/10.1186/s12913-017-2241-0 (more than half of rural women in California traveled more than 50 miles to obtain an abortion); Bearak et al., *supra* note 29, at e497 (identifying swath of rural counties in the middle of the United States with travel distances of more than 180 miles to nearest abortion clinic).

[31] Alice Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. 7 (2018), https://www.jmir.org/2018/5/e186/.

20. I understand that the Mifeprex REMS increases the distance that many women must travel to obtain a medication abortion, both by diminishing the number of medication abortion providers across the country (thus increasing the distance or number of trips patients must make to access care), and by preventing medication abortion providers from delivering mifepristone care to their eligible patients using telemedicine and mail (*i.e.*, but for the REMS, those patients would not have to travel at all to get the care they need).

21. As detailed below, the costs and burdens associated with increased travel and/or multiple trips to obtain an abortion typically include transportation, child care, and missed work, and may also include lodging, increased food costs (while traveling), and other unexpected expenses. There are also nonfinancial costs, as the logistics and time associated with travel, and the need to raise money for travel and associated costs, will often require the patient to share the fact of her abortion with people, such as household members and employers, whom she otherwise would not wish to tell—which may put her at risk for domestic violence or jeopardize her employment.

22. In my expert opinion, the overwhelming majority of people seeking abortions nationwide who have incomes too low to meet their basic needs—at *minimum*, three out of four abortion patients—suffer significant harm as a result of these added costs and burdens. Many are delayed in accessing this time-sensitive

care while they raise funds and make travel and logistical arrangements; some are blocked from obtaining an abortion at all because they cannot afford and navigate these costs and complications, or because they cannot safely share their abortion decision with household members or employers. Even those who are able to obtain an abortion despite these hurdles will have to make harmful trade-offs to do so—such as forgoing groceries or other medical care for themselves or their families, failing to pay bills including those for heat or rent, which puts the family at risk of losing their utilities or housing, or otherwise incurring debts that could have long-term consequences for household stability—or be forced to compromise their privacy and safety to access care.

Travel and Transportation

23. The additional travel costs necessitated by the REMS in order to access a medication abortion impose substantial burdens for low-income women. Even local trips of relatively short distances can present significant financial and logistical challenges for low-income women, who—as discussed above—are typically already struggling to afford basic household needs. And those costs and burdens are compounded for patients who live a considerable distance from the nearest medication abortion provider and who may have to incur significant financial costs for transportation, time off from work, child care, and potentially meals away from home, and lodging in order to access care.

24. For people with incomes below the minimum basic needs budget for their area, *any* added expenses—like refilling a gas tank, or taking a relatively short taxi ride—can stretch already strained and overextended budgets. The logistical burdens of arranging a trip to a REMS-certified provider can be especially challenging for those living in the majority of places in the United States with limited or essentially no public transportation options, particularly given that 9% of all households in the U.S. and 24% of households with incomes below the OPM do not have a vehicle, or have access to a vehicle.[32] Even if a low-income woman has access to a car, it may be shared among multiple people, which can limit access in practice, thus delaying care or forcing patients to disclose their abortion to others.

25. These burdens are compounded for those women who live farther from a REMS-certified provider and who may have to travel outside their county or state to access care. Cars owned by low-income households are older on average[33] and therefore less dependable for long journeys. And, for those without access to a

[32] *See* N. McGuckin & A. Fucci, U.S. Dept. of Transp., Summary of Travel Trends 2017 National Household Travel Survey 60, at Table 17, (2018) [hereinafter "NHTS 2017 Summary"], https://nhts.ornl.gov/assets/2017_nhts_summary_travel_trends.pdf; U.S. Dep't of Transp., Fed. Highway Admin., FHWA NHTS BRIEF 2014: Mobility Challenges for Households in Poverty 2. (2014), https://nhts.ornl.gov/briefs/PovertyBrief.pdf.

[33] NHTS 2017 Summary, *supra* note 32, at 8, 20; *see also* Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences For Patients Traveling for Services: Qualitative Findings from Two States*, 49 Perspectives on Sexual & Reprod. Health 95, 98 (2017) (in qualitative study of abortion patients in New Mexico and Michigan who crossed state lines or traveled long distances, factors including "limited access to safe and reliable transportation, or the need to use multiple means of transport[] significantly increased the time it took women to travel even relatively short distances" to access abortion care).

private car, bus or other transportation options between cities may be limited or inaccessible. For example, for a patient in Phillipston, MA,[34] there are abortion providers approximately 30 miles away in Worcester, MA,[35] and Keene, NH. But given limited public transportation options, traveling to Worcester would take at minimum 4 hours and three bus transfers, at an estimated round-trip cost of $42.50[36]; traveling to Keene, NH, would require five transfers and more than a day of travel.[37] For a patient in Cullowhee (Jackson County), NC, there are no public transportation options available to the nearest provider approximately 50 miles away in Asheville;

[34] With the exception of Kaua'i, Hawai'i, all other locations used to provide examples of travel distances, routes, and costs in this section are drawn from the same subset of counties in states with poverty rates similar to regional and national averages listed in Exhibit H-2.

[35] All distances to nearest providers are based on a search of publicly listed abortion clinics via Planned Parenthood, https://www.plannedparenthood.org/ (last visited Apr. 8, 2021), and *Find a Provider*, National Abortion Fed'n, https://prochoice.org/patients/find-a-provider/ (last visited Apr. 8, 2021). Driving distances in this section are estimated using Google Maps, assuming uncongested travel times. Bus, train, and flight fares assumed travel within two weeks of search.

[36] *See MART Trip Planner*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/trip-planner (search start: "Phillipston, MA," and finish: "Worcester, MA"). The Athol Link bus service departs Phillipston approximately every 90 minutes between 5:45 a.m. and 6:00 p.m., Monday through Friday. Patients would need to transfer at the Gardner City Hall stop to the Wachusett Shuttle line, which, at the time of search, was operating on a limited schedule of only four departures per day (6:05 a.m., 8:20 a.m., 1:05 p.m., and 6:05 p.m.). Patients would then need to transfer again at the MART Intermodal Transportation Center to the Clinton-Worcester Commuter Shuttle (commuter line, only running in morning hours) or the Worcester Shuttle (only three departures per day) for service to downtown Worcester. For full route schedules and fares, see *Routes and Schedules*, Montachusetts Reg'l Trans. Auth., http://www.mrta.us/routes-schedules (last visited Apr. 9, 2021), and *Fares and Passes*, Montachusetts Reg'l Trans. Auth, http://www.mrta.us/farespasses (last visited Apr. 9, 2021). Patients would also need to arrange transportation from home to the departure station and from the arrival station to the clinic.

[37] *See MART Trip Planner*, *supra* note 36. Although my search identified other clinics within 50 miles of Phillipston, travel by public transportation was similarly complicated for all options, involving multiple transfers and multiple-hour trips.

she would have to take a taxi all the way to the outskirts of the city to reach the closest bus stop, at a cost of $140–170.[38] For the families living below the Self-Sufficiency Standards for those states, these added expenses and lengthy travel time—not to mention the time and effort necessary to navigate multiple bus schedules and transfers in potentially unfamiliar locations—may be insurmountable.

26. Furthermore, routes and departure times are often very limited—even more so now, as some services reduced routes during the pandemic and have not yet resumed full service. If available arrival times do not align with available appointment times, even trips of only moderate distance may turn into more expensive cab rides,[39] or require overnight stays, requiring lodging and increasing child care costs and time away from work.

27. The burdens continue to increase for the sizeable percentage of women traveling especially long distances of 100 miles or more each way to access abortion care,[40] such as those in Quartzsite, AZ (La Paz County), who must travel

[38] *See* Rome2Rio, https://www.rome2rio.com/map/Asheville/Cullowhee (last visited Apr. 9, 2021).

[39] For example, a taxi between Phillipston and Worcester could cost approximately $110 one way, or $220 round-trip. *See* Taxi Fare Finder, https://www.taxifarefinder.com/ (last visited Apr. 12, 2021) (searching for "Phillipston, Massachusetts," to "Worcester, Massachusetts," and selecting "Cheapest" filter).

[40] *See, e.g.*, Bearak et al., *supra* note 29 (majority of women of reproductive age in North Dakota and Wyoming and one in five women in Alaska, Idaho, Kansas, Missouri, Montana, New Mexico, and South Dakota lived more than 100 miles from the nearest provider).

approximately 125 miles each way to reach a provider in Phoenix, AZ,[41] or Dalhart (Dallam County), TX, who must travel 200 miles each way to Lubbock, TX.[42] In extreme cases, such as for patients living in Hawai‘i or in other states with island populations (such as Alaska, Maine, North Carolina, and Florida), air travel may be required to access in-person abortion care. For example, in Hawai‘i, I understand that there are no clinics offering abortion care on the islands of Kaua‘i, Hawai‘i, Lana‘i, Moloka‘i, and Ni‘ihau, necessitating inter-island travel to O‘ahu to reach the nearest abortion provider. Since these arrangements are often made within a short timeframe, the costs tend to be higher than for long-planned travel. For example, the lowest round-trip ticket to O‘ahu (bought for travel within two weeks of purchase) was $178 for Kona, Lihu’e, or Hilo, according to Kayak.com.[43] On top of flight costs, abortion patients would also need to pay for ground transportation to and from the airport and/or overnight parking. For those living on Hawai‘i, the price of a taxi to or from the Hilo airport can run from $12 for people living in Hilo to $104 for

[41] Approximately 2 hours by car or bus ($56–62 round-trip, depending on how many days in advance of travel reservation is made, with only 4:00 a.m. departures and 10:30 p.m. returns available). *See Book A Trip*, Greyhound, https://www.greyhound.com/en (last visited Apr. 11, 2021). Clinics in El Centro, CA, and Coachella, CA, are similar distances by car, but options by bus take much longer and are more expensive.

[42] Approximately 3 hours by car. There is no bus service directly from Dalhart. Patients would have to arrange transportation to Dumas, TX (approximately 35 miles away), for bus service to Lubbock (at least 3.5–5 hours, depending on schedule), at a total round-trip cost of $200–280, including a taxi from Dalhart to Dumas. *See* Greyhound, *supra* note 41; Rome2Rio, https://www.rome2rio.com/map/Dalhart/Lubbock (last visited Apr. 11, 2021).

[43] Kayak.com, http://www.kayak.com (last visited April 7, 2021).

people living in Honoka‘a.[44] Additionally, the cost of public transportation once on O‘ahu is $5.50 per day. Thus, for a woman from Honoka‘a traveling to Honolulu for abortion care, the cost of ground transportation alone (in both places) can exceed $219.[45] In addition, for many low-income women, particularly those for whom English is a second language and/or non-citizens, air travel may pose psychological and emotional hurdles, as it requires security checks, identification that may not be regularly needed, and simply the unfamiliarity of airplane travel.

28. Finally, for those who have to travel long distances or inter-island—such as patients in Hawai‘i, Buffalo (Dallas County), MO (320 miles round-trip to Kansas City, KS), or Dalhart, TX (400 miles round trip to Lubbock)—travel for abortion may require overnight lodging,[46] for example, because of limited bus

[44] *Taxicab*, Hawaii.gov: Hilo Int’l Airport, http://airports.hawaii.gov/ito/getting-to-from/ground-transportation/taxicab (last visited April 7, 2021). For patients with cars, the cost of parking at the Hilo airport is $15 per day. *Parking*, Hawaii.gov: Hilo Int’l Airport, http://airports.hawaii.gov/ito/getting-to-from/parking/ (last visited April 7, 2021). Like many other places in the United States, Hawai‘i has poor public transportation options, especially outside of O‘ahu, and visitors to the counties of Hawai‘i and Kaua‘i, for example, are strongly urged to rent a car or use taxis for local transportation. *See* Sheila Beal, *What are the public transportation options in Hawaii*, Go Visit Hawaii (Oct. 23, 2017), https://www.govisithawaii.com/2017/10/10/what-are-the-public-transportation-options-in-hawaii/; *Transportation Rankings*, U.S. News, https://www.usnews.com/news/best-states/rankings/infrastructure/transportation (last visited April 7, 2021) (ranking the state of Hawaii 40th in terms of transportation infrastructure).

[45] *Adult Fare*, The Bus: City and County of Honolulu, http://www.thebus.org/Fare/Adultfare.asp (last visited April 7, 2021).

[46] *See, e.g.*, Caitlin Gerdts et al., *Impact of Clinic Closures on Women Obtaining Abortion Services After Implementation of a Restrictive Law in Texas*, 106 Am. J. Pub. Health 857, 861–63 (2016) (in study of Texas abortion patients whose nearest abortion clinic had closed as a result of a 2013 law, 16% reported having to stay overnight to access abortion care).

schedules, to accommodate early morning appointments, to obtain the least expensive bus or flight ticket, or if the round-trip distance is too far to travel in a single day.[47] Such costs are typically higher if reservations must be made just a few days or weeks ahead of time. According to a discount website, the cost of lodging starts around $83 in Honolulu, $43 in Lubbock TX, and $49 in Kansas City, KS.[48]

29. Especially for women already struggling to make ends meet, the added costs and logistical burdens of arranging transportation to a REMS-certified provider can be onerous, if not insurmountable.

Missed Work

30. Traveling to pick up a pill in person at a hospital, clinic, or medical office instead of receiving it by mail at home, or traveling to a second health care facility because the provider who diagnosed a patient's pregnancy cannot write them a prescription for Mifeprex, also may interfere with patients' work schedules. Women who have to travel long distances to reach a REMS-certified prescriber may

[47] For example, there is no direct bus service out of Buffalo, MO. To reach Kansas City, KS, a patient would first need to figure out how to get to Springfield, MO, 30 miles away. From there, she could take a Greyhound bus to Kansas City, MO, and then a shuttle to Kansas City, KS, at a cost of $62–104 round-trip (depending on how many days in advance she makes the reservation), not including the cost of getting to Springfield and back. In addition, there is only one bus per day between Springfield and Kansas City, departing at 2:15 p.m., and arriving at approximately 6:00 p.m. Accordingly, she would also likely need to travel the day before her appointment and stay overnight. *See* Greyhound, *supra* note 41 (no results for "Buffalo, MO"; results for travel to Kansas City, MO, from Springfield). Alternative options from Springfield include, *e.g.*, a 4.5-hour bus at a cost of $130 round-trip to St. Louis, MO, or a 3.5-hour bus ride each way at a cost of approximately $72–96 round trip to Tulsa, OK, which would also likely require an overnight stay. *Id.*

[48] *See* Hotels.com, https://www.hotels.com/ (last visited Apr. 11, 2021).

miss multiple days of work. Especially for low-income workers, the burdens associated with arranging time off work can result in delayed care, lost income, and even threats to job security.

31. About 40% of women workers in the United States have no paid time off.[49] Among low-wage workers (the bottom 25%), 93% lack paid family leave and 49% lack paid sick leave[50]; and almost two-thirds of workers in jobs that do not require a college degree lack paid personal days.[51] For part-time workers,[52] 92% lack paid family leave, three-quarters have no paid sick leave, and two-thirds lack any paid vacation or holidays.[53] For those without paid time off, any time away from work in order to access abortion care translates into lost wages. According to one study, the mean wages lost as a result of traveling for abortion care because of missed

[49] Cynthia Hess et al, Inst. for Women's Pol'y Res., The Status of Women in the States: 2015, at 88 (2015), https://iwpr.org/wp-content/uploads/2020/08/R400-FINAL-8.25.2015.pdf.

[50] Pronita Gupta et al., Paid Family and Medical Leave is Critical for Low-wage Workers and Their Families 1 (Dec. 2018), https://www.clasp.org/publications/fact-sheet/paid-family-and-medical-leave-critical-low-wage-workers-and-their-families.

[51] Gregory Acs & Pamela Loprest, Urb. Inst., Employers in the Low-Skill Labor Market, Brief No. 2: Low-Skill Jobs, Work Hours, and Paid Time Off 4 (2008), https://www.urban.org/sites/default/files/publication/32211/411802-Low-Skill-Jobs-Work-Hours-and-Paid-Time-Off.PDF.

[52] Twenty-five percent of women workers are employed in a part-time position. *Economics Daily: Percentage of Employed Women Working Full Time Little Changed Over Past 5 Decades*, U.S. Bureau of Lab. Statistics (Dec. 1, 2017), https://www.bls.gov/opub/ted/2017/percentage-of-employed-women-working-full-time-little-changed-over-past-5-decades.htm?view_full.

[53] Gupta, *supra* note 50, at 1; Hess et al, *supra* note 49, at 89.

work was $198 nationally.[54]

32. Missing one or more days from work not only means lost wages, but may also put the job itself at risk, leading to economic instability. In many cases, low-wage workers have unpredictable hours or are required as a condition of employment to regularly work overtime, both of which make it difficult to reliably plan appointments and related travel during non-work hours. It can be extremely difficult for low-wage workers to get a particular day off, particularly on short notice. And taking unapproved time off to keep an appointment or travel for abortion care can cost a patient her job.

33. Furthermore, some jobs that provide sick leave or paid leave may nonetheless require documentation of the reason for the leave. Women reluctant to disclose their abortions to their employers may therefore be unable to use paid or unpaid leave, even if their employer technically provides it; and those who do disclose their reason may have the request denied by a hostile employer or be vulnerable to retaliation as a result of their abortion.

Child Care

34. As noted, approximately 60% of women seeking an abortion have at least one child.[55] Consequently, traveling for an abortion, or making an unnecessary

[54] Rachel K. Jones et al., *At What Cost? Payment for Abortion Care by U.S. Women*, 23 Women's Health Issues e173, e174 (2013), https://www.ncbi.nlm.nih.gov/pubmed/23660430.

[55] *CDC Abortion Surveillance*, *supra* note 12, at Table 7.

or additional trip to a health care facility in order to obtain an abortion, may require child care arrangements, including when the abortion patient is the child's primary caregiver, or when the time needed for the appointment and travel to and from does not align with the child or children's regular childcare or school hours.

35. Child care costs can take up a significant proportion of a low-wage worker's income. In Hawai'i, costs range from $372 per month for part-time child care for a school-aged child to $589 per month for full-time infant care. Among the largest cities in the eight representative states analyzed above, full-time monthly child care for a preschooler ranges from $973 in Kansas City, MO (Jackson County), to $2,509 in Boston, MA. In rural counties across these states, a preschooler's full-time child care ranges in cost from $471 in Dallas County, MO, to $1,047 in Sandisfield, MA. Altogether, child care for just one preschooler ranges from 17% to 28% of the monthly needs budget across these eight states, averaging 21% of the budget.

36. But the daily rate for emergency short-term child care is often even greater than the daily rate for a month- or year-long slot. In addition, because many child care options, such as at a center or family home, are only available during regular daytime work hours, if a patient must be away overnight, the costs of child care are considerably higher. And if a woman cannot find or afford paid child care that aligns with her appointment and travel time, she may need to turn to a friend,

family member, or neighbor—which may require disclosing the reason she will be away, impinging on her privacy.

The Consequences of Attempting to Pay for Abortion-Related Travel

37. As detailed above, the total out-of-pocket costs involved in accessing abortion care can be substantial compared to income. For more than half of women attaining an abortion in a multi-state 2014 study, out-of-pocket costs (not including lost wages) averaged more than one-third of their personal monthly income.[56] In order to pay for these costs, low-income patients often end up making economic trade-offs that, as noted above, can carry serious consequences for their health, safety, and long-term economic stability.[57]

38. Indeed, a 2016 study concluded that two-thirds of women find it difficult or very difficult to pay for an abortion, and that doing so prevented or delayed nearly half of abortion patients from paying for at least one other basic need, including bills, food, rent, child care, and medical care.[58] Diverting funds from other basic needs in order to access an abortion can lead to additional costs and serious consequences. For instance, if a patient diverts any amount of rent funds and

[56] Roberts et al., *supra* note 6, at e211, e214.

[57] *Id.* at e216.

[58] Deborah Karasek & Sarah C.M. Roberts, *Abortion Patients' Experience and Perceptions of Waiting Periods: Survey Evidence before Arizona's Two-visit 24-hour Mandatory Waiting Period Law*, 26 Women's Health Issues 60, 63 (2016), https://www.whijournal.com/article/S1049-3867(15)00161-9/fulltext.

therefore cannot pay her full rent, she and her family risk eviction. Other consequences of having to divert funds include utility cut-offs, having to rely on food pantries or food banks, skipping meals, missing car payments, forgoing needed medical or dental care, or losing a scarce spot in a child care program.[59] Each of these in turn can lead to major long-term harms such as job loss, food insecurity, and medical harm.[60]

39. The most common source of money for an abortion is from the man involved in the pregnancy.[61] But borrowing from a partner can be problematic for some women, particularly where the relationship itself is unhealthy. The disclosure that results from the need for resources to cover travel and other costs (as well as

[59] Sandra S. Butler & Luisa S. Deprez, *The Parents as Scholars Program: A Maine Success Story*, 17 Me. Pol'y Rev. 40 (2008), http://digitalcommons.library.umaine.edu/mpr/vol17/iss1/7.

[60] Insurance does not change this calculus. Approximately two-thirds of the states restrict Medicaid coverage for abortion. Alina Salganicoff et al., *Coverage for Abortion Services and the ACA*, Kaiser Family Found. (Sept. 19, 2014), https://www.kff.org/womens-health-policy/issue-brief/coverage-for-abortion-services-and-the-aca/. Even in the states that do provide such coverage, many low-income women cannot access it because, for example, the income-eligibility threshold is too low, they are undocumented, or the time necessary to enroll will delay their abortion care beyond the time when they can access a medication abortion. *See* Kaiser Family Found., Health Care Coverage for Immigrants (2020), https://www.kff.org/racial-equity-and-health-policy/fact-sheet/health-coverage-of-immigrants/. A multi-state 2014 study found that nearly one-third of patients who appeared eligible for Medicaid coverage based on income and state of residency did not use Medicaid to pay for their abortions. Roberts et al., *supra* note 6, at e216. Many private or marketplace plans do not cover abortion either. Salganicoff et al., *supra*. Given this and other barriers, the same 2014 study found that only one in four patients with private insurance had their abortion covered by insurance. Roberts et al., *supra* note 6, at e216. And, the pandemic has increased the number of households that have lost health insurance coverage due to job loss and the associated loss of employer-provided health insurance. Furthermore, even for those who have coverage, Medicaid and private insurance do not cover other travel-related costs, such as meals, child care, and lost wages.

[61] Jones et al. (2013), *supra* note 54, at e177.

assistance with the travel itself) may increase the risk of domestic violence,[62] a widespread problem across the country.[63]

40. Other tactics to raise funds carry their own risks and consequences. Borrowing money from a payday lender or credit card company can help pay for an emergency expense, but repaying such loans may result in a cycle of refinancing, with additional fees and compounding interest leading to increasing debt.

41. Monetary costs alone do not fully capture how disruptive having to travel for abortion care can be. At each step, from arranging care for children, to informing supervisors or coworkers, to securing transportation and lodging, to obtaining resources (whether borrowed or diverted from other needs), the psychological harm increases and the circle of people aware of the reason for travel widens, breaching patient privacy, putting relationships or employment at risk, and increasing the risk of domestic violence.[64]

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[62] Sarah CM Roberts, *Risk of Violence from The Man Involved In Pregnancy After Receiving or Being Denied An Abortion*, BMC Med. 12:144 (2014), at 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4182793/.

[63] *See id.*; Ctrs. for Disease Control & Prevention, The National Intimate Partner and Sexual Violence Survey: 2015 Data Brief – Updated Release 2, 8 (2018) https://www.cdc.gov/violenceprevention/pdf/2015data-brief508.pdf (reporting that 43% of U.S. women had experienced some form of sexual violence in their lifetime, one in four experienced contact sexual violence, physical violence, or stalking by an intimate partner, and one in five experienced rape or attempted rape).

[64] Jill Barr-Walker et al., *Experience of Women Who Travel for Abortion: A Mixed Methods Systematic Review*, PLOS ONE 14(4), at 18 (2019), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209991 ("Participants discussed how the need to secure time off of work, arrange childcare, or borrow money for travel

C. Research Confirms That Increased Travel to Obtain an Abortion Delays or Blocks Care

42. An extensive body of research supports the analysis above, documenting that the burdens and costs associated with traveling for abortion care delay or prevent patients from accessing care, decrease confidentiality, and increase the likelihood of anti-abortion stigma from employers, families, and/or friends.[65]

43. Research confirms that the greater the distance a patient must travel to access abortion, the less likely that the abortion will occur. For instance, a 2017 study evaluating the impact of a 2013 law that closed 24 of 41 abortion clinics in Texas—and thus increased the distance to the nearest clinic for many Texas women—found that the number of abortions declined 17% across the state between 2012 and 2014.[66] The magnitude of the decline in abortion rates increased more substantially as the distance from a patient's county of residence to the nearest abortion clinic increased: when the change in distance to an abortion clinic was 25–49 miles, abortions decreased 25.3%; when the change was 50–99 miles, abortions decreased by 35.7%; and when the change was 100 miles or more, abortions decreased by 50.3%.[67]

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or the procedure necessitated disclosing their decision to have an abortion to people at work and in their personal lives.").

[65] *Id.* at 2 (summarizing findings of multiple studies).

[66] Daniel Grossman et al., *Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014*, 317 JAMA Network 437, 437–38 (2017), http://sites.utexas.edu/txpep/files/2017/10/Grossman-et-al-HB2-Change-in-Distance-Abortion-JAMA-2017.pdf.

[67] *Id.* at 438.

44. Other studies have documented this same inverse relationship between travel distance and abortion rates even for relatively short increases in distance. In Washington state, when a decline in the number of abortion providers led to a 12 mile increase in travel distance for rural women, the abortion rate among that population decreased by 27%.[68] In Georgia, for every 10 miles of distance from the major abortion providers in Atlanta, the number of abortions declined by 6.7 per 1,000 live births.[69] And in Ohio, when clinics in Toledo and Lima closed, necessitating greater travel distances to reach an abortion provider, abortions rates in those counties and surrounding areas dropped by 25% or more the following year.[70]

45. The research literature also shows a complex interrelationship between travel costs, distance, and delay that in turn impacts access to abortion. Travel

[68] Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241, 241–44 (1999), https://www.guttmacher.org/sites/default/files/article_files/3124199.pdf; *see also* Robert W. Brown et al., *Provider Availability, Race, and Abortion Demand*, 67 Southern Eco. J. 656, 658 (2001) (in Texas, an increase of 10% in the travel distance from a woman's county to the nearest city with an abortion provider was associated with a 2.3% decline in the abortion rate for white women, 2.7% for African-American women, and 5.0% for Hispanic women).

[69] James D. Shelton et al., *Abortion Utilization: Does Travel Distance Matter?*, 8 Fam. Plan. Persp. 260, 260–62 (1976), https://jstor.org/stable/pdf/2134397.pdf?seq=1#page_scan_tab_contents (also finding a significantly greater increase in abortions in two counties distant from Atlanta after new abortion providers opened there, as compared to other counties in the state).

[70] Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub Health 1228, 1232 (2020) (abortion rate in rural counties disproportionately affected by clinic closures decreased more than 30% over study period).

burdens and costs can lead to delays in obtaining an abortion, which in turn can result in a patient being unable to access medication abortion or being turned away from the abortion clinic because by the time the patient is able to obtain the funds and make the necessary arrangements to get there, her pregnancy has advanced beyond the window for medication abortion care or the latest point in pregnancy at which the clinic provides services.[71] At the same time, delays can increase both the cost of the procedure (which typically increases as pregnancy advances and is greater for procedural abortion than medication abortion) and the cost of travel (for instance, if a patient must pay for lodging for a two-day procedure during the second trimester), thus causing further delay.[72] A nationwide 2014 study found that, for patients who were near a clinic's limit or were turned away because they exceeded that limit, the most cited reason for the delay was costs, for both travel and the procedure.[73] A 2010

[71] *See* Jerman et al., *supra* note 33, at 95, 98 (in qualitative study of 29 women traveling across state lines or long distances to access abortion in New Mexico and Michigan, most common consequence of travel and related barriers was "obtain[ing] abortions at later gestations than desired because of delays"); *see also* Norris et al., *supra* note 70, at 1233 (finding that patients in Ohio have abortions later in pregnancy than the national average and that this disparity increased as the number of facilities offering care in the state diminished).

[72] Jerman et al., *supra* note 33, at 100 (describing the "negative feedback loop," in which delay caused by difficulty raising money can lead to higher procedure costs and further delay); Diane Greene Foster & Katrina Kimport, *Who Seeks Abortions at or After 20 Weeks?*, 45 Persp. on Sexual & Reprod. Health 210, 214–15 (2013), https://doi.org/10.1363/4521013 (women who were 20 weeks or more pregnant reported difficulty getting to an abortion facility, spent more on travel, and experienced more delay); Norris et al., *supra* note 70, at 1233 (period of legislative and regulatory changes in Ohio that reduced access and resulted in clinic closures coincided with Ohioans being increasingly more likely to access abortion at later gestational ages).

[73] Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, Am. J. Pub. Health 1687, 1689 (2014), https://doi.org/10.2105/AJPH.2013.301378 (finding that 58.3% of patients turned away and 67%

study in Illinois found that "[m]any women reported substantial difficulty locating a clinic, traveling long distances and finding transportation," and that such obstacles were associated with seeking abortion care in the second rather than the first trimester.[74]

III. CONCLUSION

46. At *least* three out of four abortion patients have income that is insufficient to meet their basic needs. The costs and burdens of traveling to obtain an abortion, arranging child care, and lost wages entirely prevent some women from obtaining abortion care. Even for those able to access care, these burdens force many patients to forgo other necessary expenses for themselves and their families and put them at risk of longer-term economic insecurity. In addition, these burdens force women to disclose their abortions to a wider circle of people than would otherwise be necessary, thus exposing some women and their families to domestic violence and/or longer-term economic insecurity.

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arriving just before the limit attributed their delay to "travel and procedure costs," while 29.8% cited "not knowing how to get to a provider"; for first trimester patients, travel and procedure cost was the second-most cited reason, after "not recognizing pregnancy").

[74] Jessica W. Kiley et al., *Delays in Request for Pregnancy Termination: Comparison of Patients in the First and Second Trimesters*, 81 Contraception J. 446, 449 (2010), https://doi.org/10.1016/j.contraception.2009.12.021.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed in Friday Harbor, WA on April 12, 2021.

Diana M. Pearce

Diana M. Pearce, Ph.D.

Pearce Decl.

Exhibit H-1

CURRICULUM VITAE

Diana May Pearce

EDUCATIONAL BACKGROUND

Ph.D.	University of Michigan, Social Work and Social Science (Sociology) Dissertation Title: "Black, White, and Many Shades of Gray: Real Estate Brokers and their Racial Practices."
M.S.W.	University of Michigan, School of Social Work
B.A.	College of Wooster, Wooster, Ohio, including Washington Semester (Spring 1963) at American University, Washington, DC

POSITIONS HELD

2020-present	Scholar in Residence (Director/Founder Emerita), Center for Women's Welfare, School of Social Work, University of Washington
2019-present	Senior Lecturer Emerita, School of Social Work, University of Washington; Affiliate, West Coast Poverty Center
2000-2019	Senior Lecturer, School of Social Work, University of Washington; Adjunct Faculty, Women's Studies; also, Affiliate, West Coast Poverty Center; member, REECAS (Russian East European Central Asia Studies) Faculty
2002-2020	Director, Center for Women's Welfare, School of Social Work, University of Washington
2009	Senior Specialist Fulbright, Tashkent (Institute of Culture) Samerkand University, Fergana University, all in Uzbekistan [consultancy on developing professional social work education]
2006 (Fall)	Fulbright Professor, Bishkek, Kyrgyz Republic (American University of Central Asia)
1998-2000	Visiting Assistant Professor, School of Social Work, University of Washington
1996-1997	Fulbright Professor, Uzbekistan (Tashkent State University, University of World Economy and Diplomacy)
1985-1996	Director, Women and Poverty Project, Wider Opportunities for Women Research and advocacy on broad range of issues concerning low-income women, including welfare, low-wage employment, child care, housing, poverty status, etc.
1991-1992	Visiting Scholar, Institute for Research on Women and Gender, Stanford University

1985-1986 Visiting Assistant Professor, American University, Department of Sociology , Courses taught: Quantitative Methods (advanced), Women in Society.

1980-1985 Director of Research, Center for National Policy Review, Catholic University Law School
Conducted research, including all phases, from design to grant writing to final report and journal articles; prepared and presented testimony as expert-witness in Congressional hearings, academic and non-academic conferences; editor, Civil Rights Research Review

1985 Adjunct Lecturer, Columbus School of Law, Catholic University of America:
Social Science and the Law.

1984-1993 Fellow by Courtesy, Center for Social Organization Schools, Johns Hopkins University.

1978-1979 Honorary Fellow, Institute for Research on Poverty, University of Wisconsin, Madison
Research on women in poverty and racial discrimination in housing

1975-1980 Assistant Professor, Department of Sociology, University of Illinois at Chicago Circle
Sociology Courses: Poverty and Social Welfare, Racial and Ethnic Minorities, Research Methods, Social Inequality, Graduate Research Practicum, Sex Roles, Urban Society

1975-1977 Assistant Professor, School of Social Work, University of Illinois at Chicago Circle,
Social Work Courses: Social Welfare Policy and Services, Race and Poverty, Social Science I

1973-1975 Teaching Fellow, Sociology Department, University of Michigan:
Sociological Methods (under supervision of Howard Schuman),
Introduction to Sociology (under supervision of Gayl Ness & Marilyn Rosenthal).

1974 Adjunct Lecturer, University of Michigan Extension (Social Work) Ann Arbor: Social Welfare Policy and Services I.

1972-1974 Lecturer, School of Social Work, University of Michigan: Courses: Complex Organizations (with Sheldon Siegel), Social Welfare Policy and Services (with Fred Cox).

1974 Adjunct Lecturer, University of Michigan, Flint and Dearborn:
Community Structure and Processes.

WORK EXPERIENCE

1970 English editor (translator), for Rushen Kelesh and Sherif Mardin (Ankara, Turkey)
1969 Interviewer, Institute of Social Research, University of Michigan
1968 Research Assistant to Thomas Powell (University of Michigan School of Social Work); research on developing consultation and liaisons between a community mental health center and local church pastors.
1968 Research Assistant to John Tropman (University of Michigan School of Social Work); research on ethnicity in the community
1965-67 Peace Corps Volunteer (Turkey). Community development in a small village (eastern Turkey), and English teacher in a small town (western Turkey)

1963 Summer Volunteer, Back Bay Mission (Biloxi, MS)
1961 Summer Volunteer, Beacon Neighborhood House (Chicago, IL)

SCHOLARSHIPS AND AWARDS

2005-present	Whiteley Center Scholar [University of Washington at Friday Harbor]
2003	Setting the Standard Award, Wider Opportunities for Women (Washington, DC)
2003	Visionary Research Award, Workforce Development Council (Seattle, WA)
1997	Pauline Bart Feminist Activist Award, Sociologists for Women in Society
1990	Sociological Practice Award from the Society for Applied Sociology
1977	Faculty Summer Fellowship, University of Illinois
1974	Rackham Dissertation Grant
1971-72, 1972-73	Rackham Prize Fellowship
1968-1970, 1974	National Institute of Mental Health Fellowship
1964	National Presbyterian Honor Scholarship

RESEARCH GRANTS AND PROJECTS

Principal Investigator, Ongoing, Development and Calculation of Self-Sufficiency Standard (including Updates), 1996 – 2020 (funded by Ford Foundation initially, [some via Wider Opportunities for Women until 2002] and later by many other foundations, state agencies, etc.), over $2,000,000 total

Principal Investigator, Update of the Self-Sufficiency Standard in 27 states (funded by IKEA), 2017-21

Principal Investigator, Wages, Work, and Poverty in Washington State, Center for Labor Studies (2006)

Principal Investigator, Demographic Study (using the Self-Sufficiency Standard) of Poverty in Colorado (2006).

Principal Investigator, Demographic Study (using the Self-Sufficiency Standard) of Poverty in New Jersey (2006).

Principal Investigator, Hardships Study (Pennsylvania), William Penn Foundation [via Women's Association for Women's Alternatives [WAWA] (now PathWays)], 2000-2002

Principal Investigator, Research Initiative of the NET (Nontraditional Education and Training) Project, Women's Bureau of the Department of Labor (1991-1992).

Director, Study of Doubled-Up Families, Poverty and Race Research Action Council (1991-1992)

Director, Evaluation of Transitional Housing Programs, Northwest Area Foundation and Minneapolis-St. Paul Family Housing Fund (1989-1990)

Project Director, Book on Women in Poverty and Related Activities, Ford Foundation (1983-85)

Principal Investigator, NSF grant on the nature of housing market practices in forty cities (1982-84)

Principal Investigator, National Institute of Education research grant on the relationship between school desegregation and housing discrimination (1980-81)

PUBLICATIONS

2016 The Feminization of Poverty: Lessons from the American Experience. In O. P. Mathur, V. Tandon & A. D. Sarkar, eds., *State of the Urban Poor Report 2015: Gender and Urban Poverty.* Oxford University Press, New Delhi, India.

2016 The Feminization of Poverty: Ever Present But Ever Changing, Women's Post [Kadinlari Postasi]. Turkey [online, translated into Turkish]

2014 Competing Poverty Measures: An Analysis. *Footnotes* [American Sociological Association]. Washington, D.C.: January.

2009 Battered by the Storm: How the Safety Net Is Failing Americans and How to Fix It, with Deepak Bhargava, Timothy Casey, John Cavanagh, Karen Dolan, Peter Edelman, Barbara Ehrenreich, Sarita Gupta, Dedrick Muhammad, Steve Savner, Kevin Shih. Institute of Policy Studies, Washington, D.C.

2008 "Biography of Molly Orshansky", *Encyclopedia of Gender*

2007 Introduction, *Child Poverty in America Today*. Barbara A. Arrighi and David J. Maume, eds., Praeger.

2007 "When Work is Not the Answer: New Challenges for the Millennium", [special issue on the working poor], Families in Society (Fall)

2004 "The Statistical Measure of Poverty", in *Poverty and Social Welfare in the United States: An Encyclopedia*, Gwendolyn Mink and Alice O'Connor, editors. ABC-CLIO.

2002 "Welfare Reform Now That We Know It: Enforcing Women's Poverty and Preventing Self-Sufficiency", p. 125-150 in Josefina Figueira-McDonough and Rosemary C. Sarri, eds., *Women at the Margins: Neglect, Punishment and Resistance*, New York: Haworth Press.

2002 "Measuring Welfare Reform Success by a Different Standard," p. 166-186 in *From Poverty to Punishment: How Welfare Reform Punishes the Poor*, Gary Delgado, Ed., Oakland, CA: Applied Research Center.

2001 "The Self-Sufficiency Standard: A New Tool for Evaluating Anti-Poverty Policy," *Poverty & Race*, Vol. 10, No. 2

2000 "Rights and Wrongs of Welfare Reform: a Feminist Approach to the New American Welfare State," *Affilia* (Special Issue on the New American Welfare- summer 2000)

1999 "Doing the Triple Combination: Negotiating the Domestic Violence, Child Welfare, and Welfare Systems" in Ruth Brandwein, ed., *Battered Women, Children, and Welfare Reform: The Ties that Bind* (Sage, Sage Series on Violence Against Women)

1997 "The State of Women in Uzbekistan," REECAS *Newsletter*, Vol. 3, no.2, p.3-10 (Spring).

1995 "Welfare, "Reform", and Women," *NCJW Journal* (Spring), p. 4-25.

1994 "When Sexual Harassment Happens: State Unemployment Insurance Coverage of Workers

Who Leave Employment Because of Sexual Harassment" with Monica Phillips, *Stanford Law and Policy Review* (Spring), Vol. 5:2, p. 75-82.

1993 "Welfare "Reform"?" *Equal Means* (Fall), p. 9-10.

1993 "Change in the Other America: Women's Poverty in the 1990s," *Women: A Cultural Review*, Vol. 4, No. 1 (Spring), p. 1-7.

1992 "Reading Between the Research Lines," *Equal Means*, Volume 1, No. 3 (Summer).

1992 Review of *The Feminization of Poverty: Only in America*?, Kremen, Eleanor, and Gertrude Schaffner Goldberg, eds., (New York: Praeger, 1990) *American Journal of Sociology,*97,5, p. 1479-1481.

1991 "Welfare is Not for Women: Why the War on Poverty Cannot Conquer the Feminization of Poverty," in Laura Gordon, ed., *Women, the State and Welfare* (Univ. of Wisconsin Press).

1990 "Bending the Twig in Yonkers: Creating a Segregated Community," National Conference on School Desegregation (November 1986); published in *Separate But Equal in the Metropolis: the Changing Shape of the School Desegregation Battle*, Gary Orfield, ed., (Brookings Press).

1990 "Women, Working and Poverty: Toward the Year 2000," in *Risks and Challenges: Compendium on Women, Work and the Future* (Wider Opportunities for Women).

1990 "The Feminization of Poverty," *Journal of Peace and Justice Studies*, Vol. 2, No.1 (Special Issue on Women and Social Justice).

1989 "Prison With No Parole: The Persistence of Women's Poverty," *WHY Magazine* (Fall/Winter, #3)

1989 "Welfare and Women's Poverty: Reform or Reinforcement?," (with Kelley Ellsworth), *Journal of Legislation*, Vol. 16 (May 1989).

1989 "'Children Having Children': Teen Pregnancy and Public Policy from a Women's Perspective," in *Adolescent Pregnancy: International Perspectives* (Yale University Press) and presented at the Symposium on teen pregnancy, Stanford University.

1988 "Life's Changes: A Life-cycle Perspective on Women's Economic Status," (with Nadia Moritz) *Social Thought* (Fall, Vol. IX)

1988 "Welfare Reform in 1988: A Missed Opportunity." *San Jose Mercury* and *National Forum* (A public service of AFSCME).

1987 "On the Edge: Marginal Women Workers and Employment Policy," in *Ingredients for a Women's Employment Policy*, C. Bose and G. Spitz, eds., (SUNY Press).

1986 "What Works for Welfare," *Food Monitor*, (December 1986).

1986 "Women and Unemployment Compensation: An Agenda," *The Women's Economic Justice Agenda, for the States Issues of 1987*, (National Center for Policy Alternatives).

1986 "Women and Poverty: An Agenda for the States," *America's States* (National Center for Policy Alternatives).

1986 "Women and Children in Poverty," *Southern Changes* (Feb.-March, 1986) Vol. 8, No. 1.

1985 (As member of Women's Economic Agenda Working Group), *Toward Economic Justice For Women: A National Agenda for Change* (Washington, DC: Institute for Policy Studies).

1985 "Toil and Trouble: Women and Unemployment Compensation," *Signs*, 10, 3, p.439-459 (Spring). Reprinted in *Women and Poverty*, B. Gelpi, N. Hartsock, C. Novak, M. Strober, eds., (Chicago: University of Chicago Press, 1986).

1985 "Beyond Busing: New Evidence on the Impact of Metropolitan School Desegregation on Housing Segregation" in R. Green, ed., *Metropolitan School Desegregation* (Plenum Press).

1984 "Farewell to Alms: Women's Fare Under Welfare," in Jo Freeman, 1988 ed., *Women: A Feminist Perspective*, (Palo Alto: Mayfield Pub. Co.) Revised in 1988 for 4th edition. Reprinted in R. Sadovnik, C. Persell, R. Mitchell, and E. Bauman, *Understanding Sociology: Readings in Sociology* (Harper and Row).

1983 "The Feminization of Ghetto Poverty," in special issues on the Black underclass of *Trans Action/Society*, William Wilson, ed. (November-December).

1981 "Deciphering the Dynamics of Segregation: The Role of Schools in the Housing Choice Process," *The Urban Review*, Vol. 13, No. 2, p. 85-101.

1981 "Women and Children: Alone and in Poverty," with Harriette McAdoo. Prepared for the National Advisory Council on Economic Opportunity (also published as Chapter 1 in the Council's Final Report); reprinted, edited version in R. G. Genovese, *Families and Change: Social Needs and Public Policy*. Also reprinted in the Congressional Record, the Grantsmanship News, the Illinois Women's Commission Newsletter, etc. (N.B.: As a government publication, it has no copyright; therefore, we are not always told of reprintings).

1979 "Gatekeepers and Homeseekers: Individual and Institutional Factors in Racial Steering," in *Social Problems* 26 (Feb. 1979) p. 325-342. Reprinted in Richard J. Paterson and Charlotte Vaughn, *Structure and Process: Readings in Introductory Sociology* (Belmont, CA: Wadsworth Publ. Co., 1986). Reprinted in Richard F. Larsen, ed., *The Sociological View* (Oxford University Press, 1984).

1978 "The Feminization of Poverty: Women, Work and Welfare," *The Urban and Social Change Review* (Special Issue on Women and Work) Vol. 11, p. 28-36. Republished in Vol. 4,

Women's Studies Yearbook, *Working Women and Families* (Sage, 1979).

1978 "Welfare in the Metropolitan Area," (with David Street) *Handbook of Contemporary Urban Life*, David Street, ed.

1973 "Attitude and Action: A Field Experiment joined to a General Population Survey," (with Robert Brannon, Gary Cyphers, Sharlene Hesse, Susan Hesselbart, Irwin Katz, Robert Keene, Howard Schuman, and Thomas Viccaro), *American Sociological Review* 38 (October): 625-36.

SOFTWARE

Colorado (statewide) Self-Sufficiency Calculator. (Similar to Seattle-King County Calculator, see below.)

Seattle-King County Self-Sufficiency Calculator. Together with Congruent, Inc. [local software firm], created the Seattle-King County Self-Sufficiency Calculator, including screen design and underlying formulas, available to the public online at www.seakingwdc.org. This online calculator provides social service agency clients as well as the public information on their Self-Sufficiency Standard and benefit eligibility (including requirements), provides an interactive worksheet that allows clients to "test" different wages and/or benefit combinations for its wage adequacy (given client's actual expenses and income), and provides links to public and private websites for further information and/or online applications for assistance. (Developed for Seattle-King County Workforce Development Council, Seattle, WA May 2003). *NOTE:* A subsequent statewide calculator, based on this model and again built around the Self-Sufficiency Standard, was the winner of Seattle's 2009 NPower Innovation Award (given for most innovative use of technology to reach and aid clients.)

New York City Self-Sufficiency Calculator. Wrote underlying formulas for this calculator. Available only with password; apply at www.wceca.org . Developed for Women's Center for Career Advancement and Education, New York City (2001-2002)

Pennsylvania Budget Worksheet (online and paper and pencil). Developed the original budget worksheet (which forms the basis of all subsequent Self-sufficiency online calculators), which allows clients to enter their actual costs, and determine benefit eligibility for various benefits/subsidies (Food Stamps, childcare assistance, Medicaid/CHIP, etc.), and calculate the overall "wage adequacy" of various combinations of wages and benefits. Worked with programmer to develop online version, and providing continued support to revise and improve the online version. Online version available at www.pathwayspa.org Developed for Women's Association for Women's Alternatives [WAWA], now known as PathWays, Swarthmore, Pennsylvania (1999-present).

REPORTS

2020 The Self-Sufficiency Standard for South Carolina [Update], Washington State [Update], Wyoming [Update]; Connecticut Healthcare Affordability Index (co-authored with Lisa Manzer), Prepared for Connecticut Office of Health Strategy, Connecticut Office of the State Comptroller [embargoed]

2019 The Self-Sufficiency Standard for Connecticut [Update], Demographic Characteristics of Households Below Economic Self-Sufficiency in Connecticut 2019, Overlooked and Undercounted 2019 Brief: Struggling to Make Ends Meet in Pennsylvania, The Self-Sufficiency Standard for Wisconsin [Update]

2018	The Self-Sufficiency Standard for Arizona [Update], The Self-Sufficiency Standard for Colorado [Update], On The Road Exploring Economic Security Pathways In Colorado 2018, Overlooked and Undercounted 2018: Struggling to Make Ends Meet in Colorado, New York City Special Series [combined update and demographic report briefs]: #1-Key Findings, #2-Defining Self-Sufficiency in New York City, #3-A City Evolving: How Making Ends Meet has Changed in New York City,#4-Race, Ethnicity, and Citizenship,#5-Gender and Family Structure,#6-Employment, Occupations, and Wages,#7-Work Supports, and Technical Brief,
2017	The Self-Sufficiency Standard for North Carolina [Update], North Carolina [Update], Michigan [Update], Oregon [Update], and Washington State [Update]
2016	On the Road: Economic Security Pathways for Wyoming 2016
2016	On the Road: Economic Security Pathways for South Carolina 2016
2016	Overlooked and Undercounted: Struggling to Make Ends Meet in Wyoming
2016	The Self-Sufficiency Standard for… Indiana [Update], Maryland [Update], Wisconsin [Update], Wyoming [Update], South Carolina [new]
2015	On the Road: Economic Security Pathways for Connecticut 2015
2015	The Self-Sufficiency Standard for… Connecticut [Update], Colorado [Update], Ohio [Update] and Oregon [Update],
2014	The Self-Sufficiency Standard for… California [Update], New York City [Update],New Jersey [Update], Oregon [Update], Washington State [Update]
2013	The Self-Sufficiency Standard for Ohio [Update].
2012	Overlooked and Undercounted: How the Great Recession Impacted Household Self-Sufficiency in Pennsylvania
2012	The Self-Sufficiency Standard for… Arizona [Update], Maryland [Update], New Jersey [Update], Pennsylvania [Update], Virginia [Update].
2011	The Self-Sufficiency Standard for… Colorado [Update], California [Update], New Jersey [Update], Ohio [Update] and Oregon [Update], Washington State [Update]
2010	The Self-Sufficiency Standard for…Nebraska [Update], New York City [Update], New York State [update], Pennsylvania [Update]
2010	Overlooked and Undercounted: Struggling to Make Ends Meet in California
2009	The Self-Sufficiency Standard for …. Indiana [Update], Washington State [Update], Mississippi [Update], Illinois [Update], Oklahoma [Update]

2009 Overlooked and Undercounted: Struggling to Make Ends Meet in Mississippi

2009 Overlooked and Undercounted: Struggling to Make Ends Meet in Pennsylvania

2008 The Self-Sufficiency Standard for…Montana [Update], Georgia [Update], Indiana [Update], California [Update], New Jersey [Update], Pennsylvania [Update], Ohio (new) and Oregon (new)

2008 Not Enough to Live On: Characteristics of Households Below the Real Cost of Living in New Jersey

2007 Overlooked and Undercounted: Wages, Work and Poverty in Washington State

2007 Overlooked and Undercounted: Income Inadequacy in Colorado

2007 Overlooked and Undercounted: Where Connecticut Stands

2007 The Self-Sufficiency Standard for…Massachusetts [Update], California [Update], Maryland [Update], Florida [Update], Wyoming [Update], Colorado [Update]

2006 The Self-Sufficiency Standard for…Pennsylvania [Update], Virginia [Update], Washington state [Update], Massachusetts [Update]

2005 The Self-Sufficiency Standards for…Wyoming, New Jersey [Update], West Virginia[Update], Washington, DC Metro Area[Update], Indiana [update], and Connecticut[Update]. Seattle, WA: University of Washington.

2004 Work – and Work Supports Study. Prepared for Wider Opportunities for Women [summarized as "Coming Up Short: A Comparison of Wages and Work Supports in 10 American Communities" available at www.wowonline.org]

2004 The Self-Sufficiency Standard for… Wisconsin [update], …Pennsylvania [Update], and New York City [Update], Colorado [Update]. Seattle, WA: University of Washington.

2003 The Self-Sufficiency Standard for… Alabama, California [update], Delaware, Hawaii, Louisiana, Massachusetts [Update], and Mississippi. Seattle, WA: University of Washington.

2003 Overlooked and Undercounted: A New Perspective on the Struggle to Make Ends Meet in California. With Rachel Cassidy. Prepared for Wider Opportunities for Women and Californians for Family Economic self-Sufficiency and Californians for Family Economic Self-Sufficiency, a project of the National Economic Development and Law Center. Available at www.nedlc.org.

2003 Public Policies & Private Strategies. Prepared with PathWaysPA, formerly Women's Association for Women's Alternatives.

2002 Report to NOVIB-OXFAM on Activities and Situation of Women's NGOs in Uzbekistan and Tajikistan: Efforts and Effects on the Issue of Violence Against Women. Co-author, Nodira Azimova, (Sociology Center *Sharhva Tavsiya* & National University of Uzbekistan)

2002 The Self-Sufficiency Standard for… Arizona, Florida, Georgia, Indiana [Update], Missouri, Montana, Nebraska, Nevada, New Jersey [update], Oklahoma, Virginia, Tennessee, and West Virginia [with Jennifer Brooks]. Seattle: University of Washington.

2001 The Self-Sufficiency Standard for Pennsylvania, (2nd Update), for Women's Association for Women's Alternatives. Seattle, WA: University of Washington.

2001 The Self-Sufficiency Standard for Washington State, with Jennifer Brooks, for the Washington Association of Churches, the Washington Living Wage Movement and the Washington Self-Sufficiency Standard Committee

2001 The Self-Sufficiency Standard for Colorado, with Jennifer Brooks, for Colorado Fiscal Policy Institute

2001 The Self-Sufficiency Standard for Kentucky, with Jennifer Brooks, for Kentucky Youth Advocates

2001 The Self-Sufficiency Standard for Maryland, with Jennifer Brooks, for Advocates for Children and Youth and the Center for Poverty Solutions

2001 The Self-Sufficiency Standard for Utah, with Jennifer Brooks, for Utah Children

2000 The Self-Sufficiency Standard for South Dakota, with Jennifer Brooks, for South Dakota Women Works and South Dakota Community Concepts

2000 The Self-Sufficiency Standard for New York State, with Jennifer Brooks, for the State of New York

2000 The Self-Sufficiency Standard for New York City, with Jennifer Brooks, for the Women's Center for Career Advancement and Education (NYC)

2000 The Self-Sufficiency Standard for Washington, DC Metro Area, with Jennifer Brooks, for Wider Opportunities for Women

2000 "The Self-Sufficiency Standard for Wisconsin, with Jennifer Brooks, for the Wisconsin Women's Network

1999 The Self-Sufficiency Standard for Connecticut, with Jennifer Brooks, for the State of Connecticut

1999 The Real Cost of Living: The Self-Sufficiency Standard for New Jersey, with Jennifer Brooks, for Legal Services of New Jersey Poverty Research Institute and The New Jersey

Center for Economic Policy and Education

1999 The Self-Sufficiency Standard for the Washington, DC Metropolitan Area, with Jennifer Brooks, for Wider Opportunities for Women (Washington, DC)

1999 The Self-Sufficiency Standard for Indiana, with Jennifer Brooks, for the Indiana Coalition on Housing and Homeless Issues

1999 When Wages Aren't Enough II: How the *Child Care Works* Program Impacts Family Self-Sufficiency. Prepared for the Women's Association for Women's Alternatives and the Philadelphia Citizens for Children and Youth

1999 The Self-Sufficiency Standard for Pennsylvania with Jennifer Brooks, for the Women's Association for Women's Alternatives (Pennsylvania- Update).

1998 The Self-Sufficiency Standard for Massachusetts with Jennifer Brooks, for the Women's Education and Industrial Union

1998 The Self-Sufficiency Standard for Illinois with Jennifer Brooks, for Women Employed

1998 "When Wages Aren't Enough: Using the Self-Sufficiency Standard to Model the Impact of Child Care Subsidies on Wage Adequacy", prepared for the Women's Association for Women's Alternatives and the Philadelphia Citizens for Children and Youth

1998 "The Road to Self-Sufficiency: Modeling the Impact of Subsidies Using the Self-Sufficiency Standard," prepared for the Pennsylvania Family Economic Self-Sufficiency Project and the Women's Association for Women's Alternatives

1997 "The Self-Sufficiency Standard for Pennsylvania," with Jennifer Brooks with the assistance of Janice Hamilton Outtz, for the Women's Association for Women's Alternatives

1997 "The Self-Sufficiency Standard for North Carolina," with Janice Hamilton Outtz and Jennifer Brooks, prepared for NC Equity Sustainable Family Initiative

1997 "The Self-Sufficiency Standard for the District of Columbia," with Janice Hamilton Outtz, Roberta Spalter-Roth, and Jennifer Brooks

1997 "The Self-Sufficiency Standard for the City of Alexandria, Arlington County and Fairfax County, Virginia" with Janice Hamilton Outtz and Jennifer Brooks

1997 "The Self-Sufficiency Standard for the Montgomery County and Prince George's County, Maryland" with Janice Hamilton Outtz and Jennifer Brooks

1997 "Report on Higher Education in Uzbekistan, With Particular Attention to Issues Facing Women Students, with Marfua Tokhtakhodjaeva", presented to the Ministry of Higher Education, Uzbekistan, and Human Rights Officer, United States Embassy, Tashkent

1997 "The Self-Sufficiency Standard for Texas," with Janice Hamilton Outtz and Jennifer Brooks.

1996 "The Self-Sufficiency Standard for California"

1996 "The Self-Sufficiency Standard for Iowa," prepared for the Department of Economic Development, State of Iowa

1995 "From Welfare to the Workplace: A Practitioners' Plan," Wider Opportunities for Women, Washington, D.C.

1994 "Women Work, Poverty Persists: A Census-Based Report on Displaced Homemakers and Single Mothers in 1990," prepared for Women Work!: A Network for Women's Employment [formerly the National Displaced Homemakers Network], Washington, D.C.

1994 "Living on the Edge: Doubled-Up Families in America," Women and Poverty Project, Washington, D.C.

1993 "Breaking with Tradition: Women and Nontraditional Training in the JTPA System", Final Report to the Women's Bureau, U.S. Department of Labor, on Contract #J-9-M-1-0074.

1990 The More Things Change...A Status Report on Displaced Homemakers and Single Parents in the 1980's," prepared for the National Displaced Homemakers Network.

1990 "Report on the Impact of Job Training and Welfare-to-Work Programs on Children and Their Families in Connecticut," Connecticut Children's Commission.

1990 "Keys to New Lives: A Report on Seven Transitional Housing Programs," prepared for the Northwest Area Foundation.

1989 "Final Report: Low Wage Jobs and Workers: Trends and Options for Change," (with Roberta Spalter-Roth), Institute for Women's Policy Research and Displaced Homemakers Network, for the Department of Labor, Employment and Training Administration.

1988 "High Skill and Low Pay: The Economics of Child Care Work" (with Heidi Hartmann), for the Child Care Action Campaign; presented at the Child Care Action Campaign Conference at Wingspread (WI).

1988 "Report of Key Findings From a Participant Follow-Up Study," conducted for the District of Columbia Private Industry Council (with Vikki Gregory), Gregory Resource Group.

1988 "A Woman's Guide to Welfare Reform," Women and Poverty Project/Institute for Women's Policy Research.

1987 "Magnet Schools and Milliken II: A Survey of Twenty Urban School Districts," prepared for David Tatel, Esq. of Hogan and Hartson, on behalf of the Council of Great City Schools.

1986 "Perspectives on Poverty: Welfare Reform," for the National League of Cities.

1984	"Final Report to the Potomac Institute on the Civil Rights Issues and Implications of School Closings," (September, 1984).
1983	"A Sheltered Crisis: The State of Fair Housing Opportunity in the Eighties." Prepared for the U.S. Civil Rights Commission Consultation on Persistent Mechanisms of Racial and National Origin Discrimination in Housing, (September, 1983).
1983	"The Annual Review of the Chicago Desegregation Plan, Spring 1983," with Joe T. Darden and Robert Crain, (March).
1981	"The Impact of Proposed School Closings and Related Changes on the level of Segregation in Montgomery County (Maryland)," prepared for the Montgomery County American Civil Liberties Union.
1981	"Housing and School Desegregation in Metropolitan Chicago," with Joe T. Darden and Reynolds Farley, report to the Chicago Board of Education, February 19, 1981.
1980	"Breaking Down Barriers: New Evidence on the Impact of Metropolitan School Desegregation on Housing Patterns," Final Report on Grant #G-78-01-25, to the National Institute of Education.

OTHER PAPERS (UNPUBLISHED) and PROFESSIONAL PRESENTATIONS

Alligator Economics: How Hidden Inflation is Driving Inequality and Impoverishing American Households, submitted for presentation at the American Sociological Association Annual Meeting, Chicago, Illinois [however, because of the COVID19 pandemic, will be held virtually]

Placing poverty/ Putting Poverty in its Place: Mapping the Geography of Poverty Using the Self-Sufficiency Standard, Presented at the American Sociological Association Annual Meeting, San Francisco, CA [because of the COVID19 pandemic, was held virtually] (August 2020)

Is There Still a Feminization of Poverty? Answering That Question Through an Intersectional Lens with an Alternative Poverty Measure, Presented at the Sociologists for Women in Society meeting, held concurrently with the American Sociological Association Annual Meeting, Philadelphia (August 2018)

Stretching and Breaking the Safety Net: Inequality Trends in Noncash Assistance After the Great Recession, Presented at the American Sociological Association Annual Meeting, Montreal, Quebec (August 2017)

What the Great Recession Hath Wrought, Presented at the American Sociological Association Annual Meeting, Seattle, Washington (August 2016)

A Bumpy Road Indeed: Managing the Transition from Orphanages to a New Vision of Prevention, Community-based and Volunteer Provision of Services to Vulnerable Children. Presented at “Welfare State and Collective Action in Central Asia”, put on by the Institut Francais d ’Etudes sur l’ Asie Centrale in Almaty, Kazakhstan at KIMEP University (May, 2015). Co-author: Lyudmila Kim.

Lifting Low-Wage Workers Out of Poverty: An Analysis of Washington State’s Higher Minimum Wage, Presented at the American Sociological Association Annual Meeting (August 2014)

What Difference Does a Measure Make? A Three-Fold Comparison with Policy Implications. Presented at the Association for Public Policy and Management, Washington, D.C. (November, 2012)

Counting the Poor with Competing Poverty Measures . Presented at the American Sociological Association Annual Meeting (August 2012)

Poverty Measures and Program Provision: Solving the Thresholds Problem, Association for Public Policy and Management, Washington, D.C. (November, 2011)

Changing the Federal Poverty Measure...or Not *The Huffington Post*, 2010

Poor Measurement: Changing How We Measure Poverty, [Commentary] *Spotlight on Poverty and Opportunity* (2009)

"Poverty Measures Old and New: A Comparison", Welfare Research and Education Conference, Administration for Children and Families, U.S.D.H.S., Washington, D.C. (May, 2009)

"What a Difference a Measure Makes: New Perspectives on Poverty and New Applications in Anti-Poverty Programs", Montana Family Impact Seminar, Helena, MT (June, 2008)

"A New Agenda for the New Poverty: an Approach Integrating Gender, Race/Ethnic and Working Poor Perspectives into "Anti-Poverty" Initiatives", Paper presented at the Institute for Women's Policy Research Women's Economic Justice Summit, Atlanta, Georgia (April, 2008)

"What a Difference a Measure Makes: New Perspectives on Washington State Poverty and New Applications in Anti-Poverty Programs", West Coast Poverty Center series, University of Washington (April, 2008)

"Voices of Women of Central Asia", AAUW Forum, Redmond, Washington.

"What Do We Know About the Working Poor in Washington State?", presented at Working Hard and Not Getting Ahead: A Conversation about the Working Poor In King County, sponsored by the King County Workforce Council, (October, 2007)

"Picking up the Pieces – Women's NGO's Responding to Families Under Economic and Social Stress in Muslim Central Asia", Annual Meeting of Central Eurasian Studies Society, Seattle, WA (October, 2007)

"Presentation, "Working Towards Self-Sufficiency: A New Look at Work, Welfare, and Poverty" Administration for Children and Youth, U.S. Dept of HHS, Washington, D.C. (June, 2007)

"Transforming under Transition: Issues and Potentials for Change in the Welfare System in post-Communist Central Asia", REECAS Northwest Conference (April, 2007)

"Is the Feminization of Poverty Happening in Central Asia? A consideration of the Evidence", Seminar, American University of Central Asia (December, 2006)

Presentation at Eurasia and Eastern European Conference on Women's Studies, Issyk Kul, Kyrgyzstan, "Innovative Teaching Methods/Use of Class Exercises" (August, 2006)

Preliminary Findings, Washington State Report on Income Inadequacy, Pierce County CAP Agency (April 2006)

How the Self-Sufficiency Standard Changes Our Understanding of Poverty, National Association for State Community Services Programs, Portland, OR, (October 2005).

Analyzing Poverty Using the Self-Sufficiency Standard, Utilities and Transportation Commission Workshop Olympia, WA, (September 2005).

Changing Measures, Changing Perspectives: How The Self-Sufficiency Standard Yields New Understandings Of The Nature Of Poverty (presented at ASA, August, 2005).

The Self-Sufficiency Standard and Child Poverty, Conference on Child Welfare and Child Poverty, Northwest Institute and DSHS, Tacoma, Washington (June, 2004).

Creating and Using Self-Sufficiency Standards, for Rediscovering The Other America: A National Forum on Poverty and Inequality, Society for the Study of Social Problems, Chicago, Illinois (August 2002).

"New Research Tools", Setting the Standard for American Working Families: the Self-Sufficiency Summit [conference], Washington, D.C. (November, 2003).

"How Come Hardships: Using The Self-Sufficiency Standard to Explain Who Experiences Hardships and to Explore Strategies Used to Make Ends Meet Among Post-Welfare and Working Poor Single Mothers", presented at the American Sociological Association Annual Meeting, Atlanta, Georgia (August, 2003)

"The Self-Sufficiency Standard: The New Questions Asked, the New Answers That Result--
A Report from Fifteen States", APPAM (Association for Public Policy and Management), Washington, DC (November 2001)

"Making the Transition: Using the Self-Sufficiency Standard to Make A Comparative Assessment of Welfare Reform", (January 2000) (submitted to ASA 2000)

"Where Massachusetts Families Stand: Using the Self-Sufficiency Standard and the 1990 Census to Estimate Poverty in Massachusetts, by Town" by Laura Russell and Jean Bacon, with Diana Pearce, (January 2000)

"Closing the Door: Barriers to Women's Access to Higher Education in Independent Uzbekistan,"
by Diana Pearce and Marfua Tokhtakhodjaeva, presented at the REECAS (Russian, East European and Central Asia Studies) Conference, Portland, Oregon, April 1998; presented revised version at American Sociological Association Annual Meeting, Chicago, Illinois (August, 1999)

"The Self-Sufficiency Standard: How Much is Enough?", poster presentation at Society for Social Work Research, Charleston, South Carolina (January 1999)

"What is Enough? Measuring Adequacy of Income Using the Self-Sufficiency Standard", presented at the American Sociological Association Annual Meeting, Toronto, Ontario, Canada (August, 1997)

"Limited Visions: An Analysis of the Clinton Welfare Reform Plan" (June, 1994; revised, November, 1994).

"Making Welfare Work: Performance Standards in Welfare Reform" (May, 1994).

"Filling the Half-Full Glass: Designing a Welfare System that Works for Women", presented at Women and Welfare Reform: Women's Poverty, Women's Opportunities, and Women's Welfare, U.S. House of Representatives, Cannon Office Building, Washington, D.C. (October, 1993).

"The Self-Sufficiency Standard: A Briefing Paper", (November, 1993)

"Chutes and Ladders: Playing the Low-Wage Employment Game," presented at the American Sociological Association Annual Meeting, Cincinnati, Ohio (August, 1991).

"The Herstory of Homelessness: A Women's Perspective on the Housing Crisis," presented at the American Sociological Association Annual Meeting, Washington, D.C. (August 1990).

"The Feminization of Poverty: A Second Look," presented at the annual meeting of the American Sociological Association, San Francisco, California (August 1989)

"Back to the Future: Women and the Welfare State at the End of the Twentieth Century," presented at the Women in the Welfare State Conference, University of Wisconsin, Madison, Wisconsin (June 1989)

"The Invisible Homeless: Women and Children," presented at Locked Out: Women and Housing, Women's Research and Education Institute. (1988)

"Taking a Second Look at the Feminization of Poverty," presented at the Women and Public Policy Seminar, Harvard University (October 1987).

"The Deservedly Poor and the Unruly Needy: Women and Welfare Reform," (unpublished paper, 1986).

"Part-time Women Workers," presented at the Eastern Sociological Meetings, (April, 1986).

"The Now and Future Impact of the Feminization of Poverty on American Society: Children, Racial Inequality and the Social Welfare Debate," (American Sociological Association/Society for the Study of Social Problems Annual Meeting, August, 1985).

"Changing Poverty: Comments on Women and Minorities in the Bishop's Letter" delivered at the Santa Clara Conference on the Bishops' Pastoral Letter on Catholic Social Teaching and the U.S. Economy, University of Santa Clara, (CA), January, 1985.

"Recovery for Whom? Women and Poverty in the U.S. in the Eighties," presented at the Conference on Religion, the Economy and Social Justice, held at the State University of New York, Stoneybrook (November, 1984).

"New Knots or New Nets: Towards a Model of Advocacy to Meet the Needs of Single Parent Heads of Household," prepared for the Conference on Poor Clients Without Lawyers: What Can Be Done, held at the University of Wisconsin Law School (October, 1984) and published in the *Clearinghouse Review*.

"Lessons Not Lost: The Impact of School Desegregation on the Racial Ecology of Large American Central Cities," with Robert L. Crain, Reynolds Farley, and Karl Taeuber. Paper presented at the American Educational

Research Association Annual Meeting (New Orleans, April, 1984).

"They Never Knocked on My Door: Women and the War on Poverty," paper presented at the American Political Science Association Annual Meeting, (Chicago, Illinois, September, 1983).

"Farewell to Alms: Women and Welfare Policy in the Eighties." Paper presented at the American Sociological Association Annual Meeting (San Francisco, September, 1982).

"Back to Basics in School Segregation: The Three R's of Race, Residence, and Resegregation," (unpub. paper).
"Women's Fare Under Welfare," at conference, Women and Work in the Eighties: Perspectives From the Thirties and Forties, Berkeley, CA, May, 1981.

"Is Racial Steering a Form of Institutional Racism?" presented at Institutional Racism Seminar, University of Illinois at Champaign-Urbana, September, 1980.

"Institutional Racism in Housing: Myths and Realities," in *For the Record: Fair Housing, Laws and Social Reality*, published by the League of Women Voters, Lexington, KY, April, 1980.

EXPERT WITNESS AND TESTIMONY

Stinnie et al v. Holcomb, Civ. No: 3:16-cv-004. [Summary judgement that Dept. of Motor Vehicles could not suspend driver's licenses for nonpayment of court fees and fines (unrelated to traffic offenses) without regard to ability to pay, using the Self-Sufficiency Standard to determine plaintiff's ability to meet their basic needs]

City of Richland v. Wakefield (2016), http://www.courts.wa.gov/opinions/index.cfm?fa=opinions.showOpinion&filename=925941MAJ [found could not impose fines on persons with SSDI income only, as indigent, but indicated other measures, including Standard could be used to determine whether any LFO (Legal Financial Obligation, including fines, court fees, etc.) could be imposed on low income defendants

Testimony before Baltimore City Council, on legislation on establishing a commission on Wages and Compensation, sponsored by SEIU (Service Employees International Union) (July 2004)

Statement before the Advisory Council on Unemployment Compensation, "Reframing the Issues: the UI Program in a time of Block Grants and Working Mothers", (May, 1995).

"Moving from Welfare to the Workplace," Testimony before the Subcommittee on Human Resources, Committee on Ways and Means, U.S. House of Representatives *Contract With America* Hearings on Welfare Reform (February, 1995).

Statement before the Working Group on Welfare Reform, Family Support and Independence, Washington, D.C. (August, 1993).

Testimony before the Subcommittee on Human Resources, Committee on Ways and Means, U.S. House of Representatives, Washington, D.C. (September, 1992).

Expert Witness, school segregation and housing patterns, Rocky Mount, North Carolina, for the NAACP Legal Defense Fund (1991).

Testimony before the Subcommittee on Human Resources, Committee on Ways and Means, U.S. House of Representatives, on Women and Unemployment Insurance Issues (February, 1991)

Testimony before the Joint Select Task Force on the Changing Family, California Legislature, on Housing and Homelessness Trends and the Single Parent Family (April, 1989).

Testimony before the Subcommittee on Housing and Community Development, Committee on Banking, Finance, and Urban Affairs, U.S. House of Representatives, on the Invisible Homeless and Federal Housing Policies (March, 1989).

Testimony before the U.S. Senate, Committee on Labor and Human Resources, Subcommittee on Children, Drugs, and Alcoholism, on Child Care Workers' Salaries (March, 1988).

Testimony before the U.S. Senate, Judiciary Committee, Subcommittee on the Constitution, on amending Title VIII of the Civil Rights Act (the Fair Housing Act) to forbid housing discrimination against families with children (April, 1987).

Testimony before the U.S. House of Representatives, Education and Labor Committee, on the costs of child care in proposed welfare reform legislation (May, 1987).

Testimony before Montgomery County (MD) Council on Crossways, proposed housing project for women-maintained families in transition (May, 1987).

Expert Witness, NAACP, Milwaukee, on school and housing segregation (1987).
Testimony before the U.S. House of Representatives, Employment Opportunities Subcommittee on the "invisible ghetto" of part-time and temporary workers (July, 1987)

Testimony before the U.S. Congress, House of Representatives, Agriculture Committee, Subcommittee on Domestic Marketing, Consumer Relations and Nutrition, on "workfare" and food stamps (September, 1986).

Testimony before the Advisory Council on Intergovernmental Relations, White House Hearings on Welfare Reform (September, 1986).

Expert Witness, school desegregation, white flight and housing, for the NAACP Legal Defense Fund in Savannah, Georgia (1986).

Testimony before the U.S. Congress, House of Representatives, Subcommittee on Civil and Constitutional Rights, Hearing on Proposed Fair Housing Legislation, on the extent and impact of discrimination against families with children in the rental of housing (July, 1986).

Testimony before the Montgomery County Women's Commission, Women and Homelessness (April, 1986).

Testimony at hearings before the Human Services Committee, DC City Council on Workfare Legislation (April, 1986).

Testimony at DC Wage and Hours Board, Hearing on Minimum Wage Levels for Household and Day Care

Workers (August, 1984).

Testimony at hearings on the Feminization of Poverty, Illinois Commission on the Status of Women (February, 1984).

Expert Witness for the NAACP on the relationship of public housing policies, school and housing segregation in Yonkers, New York, (1983-84). (*United States v. City of Yonkers, et al.* Civil Action #80CIV 6761 LBS (Southern District of New York)

Testimony before the U.S. Congress, U.S. House of Representatives, Select Committee on Children, Youth and Families, on Impact of Demographic Trends, the Recession, Economy and Federal Budget cuts on the income levels and viability of poor families (July, 1983).

Leadoff Witness, Hearings before the California State Assembly on the "Feminization of Poverty" (April, 1983).

Expert Witness, Maryland State Board of Education on impact of proposed school closings and pupil reassignments on school and housing segregation in Montgomery County (1982).

Testimony before the U.S. Congress, U.S. House of Representatives, Committee on Civil and Constitutional Rights, September, 1981, on my research on the relationship between school and housing segregation/integration.

Expert Witness, hearing before Maryland State Board of Education regarding effects of closing a racially integrated school in Baltimore County on the future stability of the neighborhood and its schools (1981).

Expert Witness (for the Justice Department) on school and housing segregation, Ouachita Parish/Monroe, Louisiana (July, 1979).

COMMUNITY AND PROFESSIONAL (ACADEMIC) SERVICE

Member, Center for Women and Democracy Delegation to Morocco, November 2009; Vietnam, 2011

Member, Fulbright Association Board, 2007-2012

Member, Award Committee for Public Sociologist, American Sociological Association, 2005-2008

President (2009-2015) and Board Member (1999-2015t), Seattle-Tashkent Sister City Association, [hosts delegations from Tashkent and sends delegations to Tashkent, and related public forums and lectures on Tashkent, Uzbekistan & Central Asia]; Participant, official STSCA delegation visits to Tashkent, March 2002 & March 2004; Leader, 40th Anniversary Official Delegation to Tashkent (August-September, 2013)

Founding Board Member, Shalom Zone/Young Adult Shelter d.b.a. R.O.O.T.S. [provides shelter, food, mental health/counseling and other services for young adults 18-25 in the University District]. (1999-2005).

Chair, Session “Human Development in Eurasia”, From the Cold War to Post-Communism: Sixty Years of REECAS (1947-2007), REECAS Northwest: The Thirteenth Annual Russian, East European and Central Asian Studies Northwest Conference (April, 2007)

Chair, Session “Gender Issues in Central Asia: Empirical Studies in Uzbekistan,” Central Eurasian Studies

Society, Fifth Annual Conference, Indiana University (Bloomington) (October 2004)

Member, Community Advisory Committee, *Nickel and Dimed* [play based on book by Barbara Ehrenreich], Intiman Theatre, Seattle, WA, [included creating mock online Self-Sufficiency Calculator] (July-August, 2002)

School of Social Work, University of Washington

Committees served on: Diversity (1998-2001); International Committee (including International Social Work Extravaganza [fair]), (2000-present); Task Force on Policy for new curriculum; Task Force on new Poverty and Inequality course for the new curriculum; role-playing participant, Legislative Simulations [Nancy Amidei] (1998-present); BASW Curriculum Committee (1998-2006).

REECAS (Russian East European Central Asian Studies) Center Faculty member, University of Washington, (1998-present)

Executive Committee (Spring, 2007-2014)
Committee on Admissions (Spring, 2003; Spring, 2014).

Women's Studies, University of Washington, Adjunct faculty

Academic advisor to both graduate and undergraduate students

Reviewer for *Social Problems*, *Signs: Journal of Women in Culture and Society, Social Science Review* National Science Foundation grants. Member, Editorial Board, *The American Family*.

External Reviewer for Tenure, Karen Christopher, University of Louisville (Kentucky), 2005.

Outside Member, Dissertation Review Committee of Beth Harris, Department of Political Science, University of Washington, Summer 1999

Session Presider, Northwest REECAS (Russian, East European, Central Asian Studies) Conference (April, 1999)

Member, Coalition on Human Needs, Task Force on Welfare, 1988-1996; Board Member, Executive Committee Member and Secretary, 1989-1996

Member, Board of the National Low Income Housing Coalition (1989-1996).

Member, Interfaith Coalition for Affordable Housing in Montgomery County, Steering Committee and Research Committee, 1988-1989.

Board Member, Suburban Maryland Fair Housing (1984-1989).

Board Member, National Neighbors (1981-83).

Member (1981-84), and Chair (1984-85), Catholic University President's Commission on Affirmative Action.

Member (1985-87), and Chair (1987-1989), A.S.A. Committee on National Statistics.

Member, Thesis Committee of Julia Parks, Department of Sociology, American University (1984-86).

Member, Research Committee and Methods Exam Committee, Department of Sociology, American University (1985-86).

S.W.S. Observer, A.S.A. National Council Meetings (1981).

Session Organizer and Chair, 1981, A.S.A. Meetings (Toronto) on "New Approaches to School Desegregation."

Member, A.S.A. Selection Committee for the Award for a Career of Distinguished Scholarship (1980).

Session Presider, 1979 A.S.A. Meetings, September, 1979, on Sex Roles.

Session Organizer for Midwest Sociological Society Meetings, April, 1979, on school desegregation and housing discrimination.

Member and Chair, Minority Affairs Committee, School of Social Work, University of Illinois (1975-77).

TASK FORCE, STUDY AND WORKING GROUP PARTICIPATION

Member, Advisory Board, Kerner Commission 40th Anniversary Report, Milton Eisenhower Foundation

Invited Participant, The Mobility Agenda Consultation on Low-Wage Jobs, Seattle, Washington, April, 2007

Presenter, Labor Caucus, Washington State Legislature (on poverty and self-sufficiency in Washington state) March 2007

Convenor, Task Force on Housing Issues in Welfare Reform, 1994-1996

Member, Coalition on Women and Job Training, and Welfare Reform Task Force, 1992-1996
Founding Member and Co-Chair, Women and Housing Task Force, National Low-Income Housing Coalition, 1988-present; Chair of Research Committee, 1990-present.

Member, Conference Advisory Committee, Conference on Transitional Housing for Families, National Alliance to End Homelessness, 1990.

Member, Experts Committee to Review Findings of Focus Groups on Teenage Mothers' Poverty, La Raza, June 1990.

Participant, Housing Strategy Group, 1988-1991.

Member, National Child Care Staffing Study Council, 1988-1990.

Member, Strategic Task Force, National Congress of Neighborhood Women, 1988-89.

Member, Steering Committee to Create the Institute for Women's Policy Research, 1987.

Organizer and Steering Committee Member, Women Working for Economic Justice Conference (June, 1986).

Member, Food Research and Action Committee-Organized Coalition of Organizations Concerned with Welfare

Reform (1986-1987).

Charter Member (1985-present), National Coalition on Women, Work and Welfare Reform, and Contributor, Perspectives on Women and Welfare Employment (September, 1986).

Member, Working Group on Female-Headed Families in Poverty, Institute for Policy Studies (1986).

Presenter and Participant, Institute for Policy Studies seminar series on the feminization of poverty, new technology, and internationalization of jobs; member and co-author, Women's Economic Agenda Working Group (1983-85).

Participant, Working Group on Women and Employment, and Contributor to A Report on Women and Unemployment (released November 1, 1985, by the National Employment Action Council) (1985).

Participant and Presenter, Chicago Women in Research Seminar, Chicago Metropolitan Seminar, and the Regional Housing Study and Action Group (1975-80).

Workshop Evaluator, Tenth Anniversary Conference of Title VIII (Fair Housing) of the Civil Rights Act, Washington, DC, (1978).

Member, Taeuber-Loewen Writing Group on Schools and Housing, which wrote "School Segregation and Residential Segregation: A Social Science Statement," which was submitted as an appendix to the "Brief for Respondents" in the case of *Columbus Board of Education v. Penick* which was before the Supreme Court in the 1979 session; it was published in *Society* 16:5 (July/August, 1979), and in Walter Stephan and Joe R. Feagin, eds., *School Desegregation: Past, Present and Future*, (New York: Plenum Press, 1980).

Discussant, Center for Study of Democratic Institutions, papers presented on Welfare Policy and Trends in Poverty (1977).

Participant, Working Group on Women and Employment, and Contributor to A Report on Women and Unemployment (released November 1, 1987 by the National Employment Action Council).

CONSULTATIONS/INVITED CONFERENCES/WORKSHOPS

"A New Agenda for the New Poverty: An Approach Integrating Gender, Race/Ethnic and the Working Poor", Women's Economic Justice Summit, (April, 2008), Atlanta, GA

"Women's Lives in Central Asia: Contemporary Issues", AAUW, Redmond, WA (Feb, 2008)

"What do we Know About the Working Poor in Washington State?" Workforce Council of Seattle-King County Forum, Working Hard and Not Getting Ahead: A conversation About the Working Poor in King County, Seattle, WA (October, 2007)

"Self-Sufficiency and Poverty in Montana", MT State Council on Economic Opportunity (Aug 2007)

Presentation, "Aspects of Culture and Social Welfare in Central Asia", Northwest Social Studies Teachers Association, Chelan, Washington (March, 2007)

Presentation at Eurasia and Eastern European Conference on Women's Studies, Issyk Kul, Kyrgyzstan, "Innovative Teaching Methods/Use of Class Exercises" (August, 2006)

Delegation Member, Seattle-Tashkent Sister City Domestic Violence Training Team, Tashkent, Uzbekistan (funded by the U.S. State Department), (March, 2002)

Consultant (with Nodira Asimov, Uzbek Academy of Sciences) to NOVIB-Oxfam (Netherlands) on Activities of Women's Organizations in Uzbekistan and Tajikistan Regarding Domestic Violence and related issues of Violence Against Women, (August-September 2002)

Principal Presenter, Briefing for Governor Locke (Washington State) on Self-Sufficiency Standard and Impact of Proposed Changes in Washington State Minimum Wage Law, Olympia, Washington (September 2002)

Consultant, Evaluation of Women's Initiative Outcome Evaluation of Micro-Enterprise Project, 1999-2000

Family Budget "Summit" Meeting, Economic Policy Institute, Washington, DC, October 1999
Workshop Presider and Presenter, *Paths Out of Poverty: Wider Opportunities for Women National Conference*, Washington, DC, October 1999

Workshop Organizer and Presenter, "Getting from Here to There: Achieving Economic Self-Sufficiency in Washington State", Ellensburg, WA, November, 1999

Consultant, Abt Associates/Uzbekistan and Central Asia, World Bank-Government of Uzbekistan Health Reform Initiative [helped design and pretest survey, train local social scientists in survey sampling, questionnaire design, interviewing, coding, and analysis], 1999

Consultant, Susquehanna [PA] Legal Services, Spring, 1999 [using the self-sufficiency standard in a court case to determine need/ability to repay a school loan]

Consultant, Yonkers Family and Community Project, 1997 [overseeing outcomes of Yonkers settlement of *United States v. City of Yonkers, et al.* Civil Action #80CIV 6761 LBS (Southern District of New York), November 1985

Invited Participant, Working Group on the Contingent Labor Force, Spring 1995

Invited Participant, Urban Institute Forum on Poverty and Welfare Reform, Fall 1994-Spring 1995

Invited Participant, Friedan Seminar on Downsizing, Corporate Restructuring, and Workplace Flexibility, Fall 1994

Consultant, SOZA, Inc., Project Evaluating Role of Child Care Provision in Promoting Success among Job Corps Student/Parents, Fall 1994-Spring 1995

Invited Participant, National Housing Conference Convening on "Revisioning Housing Policy" March, 1994

Invited Participant, Low Wage Workers Conference, Department of Labor, March, 1994

Invited Participant, Arlington Hill II Conference, Xerox University, January 1994

Consultant, LINC Project [women and literacy], Spring, 1994

Consultant, Children's Commission of Connecticut, Impact of Job Training on Children and their Mothers, Spring-Fall 1990

Consultant, Battered Women's Alternatives, Contra Costa County, CA (April, 1990).

Participant, Women's Agenda Projects Convening, Chicago (July, 1988).

Participant, Conference on MDRC Research on Welfare Reform (May, 1987).

Blue Mountain, Conference on Family Policy (May, 1987).

Participant, Framingham Conference on Welfare Reform (June, 1987).

Participant, Conference on Women and Mental Health (October, 1987).

Judge, National Council of Working Women, Media Awards (November, 1987).

Organizer and Participant, Convening for Women's Economic Justice, Bishops Ranch, California (June, 1986).

LECTURES/PRESENTATIONS ON WOMEN AND POVERTY

The U.S. Economic Crisis and Its Impact on Poverty and Inequality Trends: Challenges and Opportunities from a Women's Perspective, U.S. Embassy, Tashkent, Uzbekistan (February 2009)
Women, Poverty and the New Administration, ByteBack Forum (January, 2009)
The Feminization of Poverty: Only in America or a Globalizing Phenomenon?, Center for Gender Studies, American University of Central Asia [Bishkek, Kyrgyzstan] (December 2006)
Women and Social Security: the Gendered Impact of Proposed Reforms, University of Washington, (April 1999)
Poverty Post Welfare Reform, Center for Social Demography and Ecology, University of Washington (Feb 1999)
How we Measure Success in Welfare Reform, University of Chicago-Welfare Forum, Chicago, IL, (December, 1998)
Gender and Research on Welfare Reform, Feminist Research Forum, University of Washington, (October, 1998)
Why Work May Not End Women's Poverty, at "Does Work End Poverty? People, Policies, and Strategies in Reforming Welfare", State University of New York, Albany (June 1998)
Women's Poverty and the Self-Sufficiency Standard, Hearing of the Commission on the Status of Women, California Legislature, Sacramento, CA (February, 1998)
The Impact of Proposed Welfare reform on the Implementation of the VAWA [Violence Against Women Act], NOW-LDEF Congressional Briefing (May 1995)
Welfare Reform as if People Mattered, Partnership with Hope, San Antonio TX (April, 1995)
The Other Entitlement, Women's Initiative of AARP (November, 1994)
Welfare Reform from a Women's Perspective, University of Buffalo School of Law, Buffalo, New York (November, 1994)
Welfare Reform and Women, Healthy Choices for Women and Children Conference, Waterbury, CT (November, 1994)
Welfare Reform as If Women Really Mattered, IRWG [Institute for Research on Women and Gender, Stanford]

Associates, New York City, NY (October, 1994)
Welfare Reform Panel, Advocates for Youth Board Meeting, Washington, D.C. (October, 1994)
Welfare Reform in Washington and the States: An Update, Displaced Homemakers' Regional Conference, Atlantic City, NJ (September, 1994)
Unemployment Insurance and the Contingent Worker: Getting out of the Employer-as-Devil Box, NAIUB Conference, Detroit, MI, (June, 1994)
Unemployment Insurance and Welfare Reform: Preventing Welfare Dependency, Employment Law Conference, Washington, D.C. (March 1994)
Unemployment Insurance and Women, Employment Law Conference, Washington, D.C. (March 1993)
Women Workers and Unemployment Insurance Reform, Conference of State Women Legislators, Center for the American Women in Politics at Rutgers University, San Diego, California (November 1991)
Homelessness and Poverty, Lehigh University (November 1991)
Childcare, Welfare Reform and Women's Poverty, at the World Conference on Education for All, Washington, D.C. (October, 1991)
Teen Motherhood: What is Its Role in Women's Poverty?, Stanford University (October 1991)
Children and Women's Poverty, Connecticut Women's Assembly (October 1991)
Women, Work and Poverty, Global Ministries, Women's Division, United Methodists (January 1991)
Debate (with Lawrence Mead), causes and solutions for Poverty, Colby college (January, 1991)
If Not for Us, Who? If Not Now, When? A conference on women in housing, Loyola College, Baltimore, MD. (June, 1990)
Women and Homelessness, Univ. of Cincinnati (Feb. 1990)
Feminization of Poverty, Univ. of California, Santa Cruz. (April, 1990)
The Invisible Homeless, Virginia Commonwealth University (November, 1989)
Insight, a Public Affairs program (CNN), (June, 1989)
A Conference on Women and Poverty, Center for Peace and Justice Education of Villanova University (March, 1989)
Addressing the Staffing Crisis, First Annual National Association for the Education of Young Children Symposium for Early Childhood Policy and Advocacy (January, 1989)
Legislative Corps, Seminar on Day Care, American Association of School Administrators (January, 1989)
Setting Tomorrow's Agenda: A Symposium on the Emerging Needs of Women, Chicago Women in Philanthropy and Chicago Foundation for Women (November, 1988)
Confronting the Challenge of Realizing Human Rights, Howard University Law School (November, 1988)
Chicago Foundation for Women, on Women's Economic Status in the Future (November, 1988)
Civil Rights in the United States, on Women's Struggle for Economic Justice, The Sorbonne (The Universities of Paris), Paris, France (October, 1988)
Focus on the Family: Needs and Opportunities, Pennsylvania Directors' Association for Community Action, Inc. (October, 1988)
Montgomery County Co-op Nursery Schools, on Child Care Workers' Salaries (May, 1988)
Conference of Sex Equity Coordinators, on Women and Welfare Reform (May, 1988)
Fair Housing: The Unfinished Agenda (Montgomery County, MD) on Women, Housing and Homelessness (April, 1988)
Brookings Institution, Welfare reform consultation (April, 1987)
National Association of Neighborhoods, Welfare Reform Session (April, 1987)
University of New Mexico, Conference on Welfare Reform (April, 1987)
Congressional Caucus on Women's Issues, Briefing on Welfare Reform (April, 1987)
Bread for the World, Briefing on the Minimum Wage (April, 1987)
Ad Hoc Child Care Coalition, Briefing on Welfare Reform (May, 1987)

Dayton Interfaith Council of Churches, Briefing on Welfare Reform (July, 1987)
Dayton Women Empowered, Briefing on Welfare Reform (July, 1987)
Kansas Association of CAP Agencies, Women in Poverty (September, 1987)
Wider Opportunities for Women/Displaced Homemakers Network "All in a Day's Work" Conference, Women and Welfare Reform (November, 1987)
Donors' Forum, Council on Foundations, Chicago (March, 1987)
National Council of Churches, Consultation on Poverty and Welfare Reform (January, 1987)
Women, Homelessness and Poverty, University of Maryland-Baltimore (January, 1987)
NETWORK Board Meeting (December, 1986)
Commenter, White House Report on the Family, WAMU Radio (November, 1986)
Keynote Speaker, Women Against Poverty Conference, Wisconsin (October, 1986)
National Anti-Hunger Coalition (October, 1986)
National Nutrition Educators Conference (July, 1986)
National Council of Senior Citizens, Annual Meeting (July, 1986)
Montgomery County Nutrition Seminar (June, 1986)
California Democratic State Senators Retreat (May, 1986)
New Directions Conference (May, 1986)
"The Feminization of Poverty Today," Kansas City Catholic Charities Conference (May, 1986)
"Women & Workfare," Grey Panthers (April, 1986)
"Women and the Increase in Economic Inequalities," Institute for Policy Studies (March, 1986)
"Women, Work & Welfare," WKYS Radio (February, 1986)
Women in Leadership Seminar, Washington Center (DC) (January, 1986)
Women's Studies Department, American University (November, 1985)
Council on Foundations, Presentation on Demographics of Poverty (November, 1985)
Southern Regional Council Annual Meeting, New Agendas on Poverty (November, 1985)
Cleveland City Club (Luncheon address rebroadcast on radio/TV) (November, 1985)
WSOS (Fremont, Ohio) 20th anniversary of War on Poverty (September, 1985)
Seattle Diocese (Conference on Bishops' letter on the Economy) (May, 1985)
University of Notre Dame (May, 1985)
World Feminization of Poverty Conference, Ann Arbor, MI (April, 1985)
Keynote Speaker, Women's Commission Annual Dinner, Catholic University (April, 1985)
Health and Human Services Institute, Federation for Community Planning (March, 1985)
American Jewish Committee Leadership Conference (November, 1985)
Urban Planners and Architects (October, 1984)
Washington Theological Union (October, 1984)
Catholic Laymen's Committee on the Economy (July, 1984)
Chicago Urban League (June, 1984)
Women's Equity Action League, Annual Meeting (May, 1984)
UCLA Graduate School of Architecture and Urban Planning (April, 1984)
Arizona State University Conference on Women in Poverty (March, 1984)
Johns Hopkins University (March, 1984)
National Conference of Jewish Women (January, 1984)
Workshop Speaker, Conference of State Women Legislators (December, 1983)
Bryn Mawr Conference on the Feminization of Poverty (October, 1983)
Keynote Speaker, Kansas University Social Work Day (April, 1983)
Morning Edition, National Public Radio (October, 1983)
Women's Legal Defense Fund (April, 1983)

Funding Friends (Women foundation officers in the Washington, DC area)
Lecture, "The Feminization of Poverty," Capital Area Sociologists for Women in Society (March, 1983)
Keynote Address, "Feminization of Poverty," Hull House Association Annual Meeting (May, 1983)
The Campaign for Human Development (November, 1982)
Women Employed (November, 1982)

LECTURES/PRESENTATIONS ON SCHOOL DESEGREGATION AND/OR HOUSING DISCRIMINATION

Presentations on the relationship between school and housing segregation and desegregation at U.S. Department of Housing and Urban Development, Center for Urban Education (Chicago schools), League of Women Voters, National Neighbors, Fair Housing Center Directors' Conference, Howard University, Center for Social Organization of Schools (Johns Hopkins University), South Suburban Housing Center (Chicago) Conference, Milwaukee Board of Education, Montgomery County (MD) Fair Housing Day, Wisconsin State-Wide Conference on Fair Housing (1979-84).

Moderator and Speaker, "Changing Demographic Patterns: The Impact of Fair Housing," Fifteenth Anniversary of the Fair Housing Act Conference (April, 1985).

Presentations on effect of planned school closings on levels of segregation in Montgomery County before the Maryland Advisory Committee of the U.S. Commission on Civil Rights, Suburban Education Forum, and Martin Luther King Forum (1981-82).

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Pearce Decl.

Exhibit H-2

APPENDIX: Comparison of Basic Needs Budgets in Eight States With Poverty Rates Close to National and Regional Averages

State Selection Methodology: To select states for this analysis, I used states that had poverty rates closest to the national and regional averages, according to U.S. Census Bureau data, and for which current Self-Sufficiency Standard data was available. State poverty rates and the national poverty rate refers to the latest two-year average (2018–19) provided by the Census Bureau.[1] To calculate regional averages, states were grouped by Census region: Northeast, Midwest, South, and West. The average regional percentage was then calculated using the state poverty rates for all states within that region. Finally, each state's percentage below-poverty was compared to the national average and the regional average, respectively, to determine the state or states closest to each average. If 2021 Self-Sufficiency Standard data was not available for the state with the closest rate to the national or regional average, the second-closest was used instead.

State Needs Budgets: For each state, I compared the Standard (*i.e.*, needs budget) for a family with one adult and one preschooler to the local or state minimum wage for (a) the county with the largest city; (b) the county with the median Standard in the state; and (c) the county with the lowest Standard in the state. The Standard was then compared to the minimum wage for each locality, assuming full-time work. Wherever possible, the cost of a given need in the Standard is based on the amount of financial assistance that the government (federal or state) has deemed minimally adequate for that basic need (such as housing, child care, or food expenses):

- Housing: maximum rent allowed for Section 8 voucher (housing assistance) recipients as set by the U.S. Department of Housing and Urban Development
- Child care: maximum amount set by the state for reimbursement for those receiving child care assistance (minus copayments)
- Food: the U.S. Department of Agriculture's "Low-Cost" Food Plan, which covers *only* the cost of basic groceries, without any take-out or restaurant food
- Transportation: cost of a monthly pass for local public transportation, or (if no adequate option) average cost of a private car, assuming use to/from work and one weekly shopping trip, based on national data such as U.S. Highway Administration's National Household Travel Survey, and U.S. Bureau of Labor Statistics' Consumer Expenditure Survey
- Health care: assuming employer-sponsored insurance and out-of-pocket costs based on the Medical Panel Survey, the most complete national source for health and insurance costs
- Miscellaneous: 10% of all other costs, and accounting only for essentials such as clothing, nonprescription medicines, and personal hygiene items, and not including any recreation, entertainment, savings, or debt repayment
- Taxes: federal and state income tax, payroll taxes, and state and local taxes (if applicable), and accounting for federal and applicable state tax credits

[1] *Income and Poverty in the United States*, U.S. Census Bureau, at Table: Percentage of People in Poverty by State Using 2- and 3-Year Averages: 2016–17 and 2018–19, https://www.census.gov/data/tables/2020/demo/income-poverty/p60-270.html (last visited Apr. 9, 2021).

National Average Poverty Rate (2018–19): 11.1%

Northeast
Average Poverty Rate (2018–19): 9.0%

	Closest to National Average			Closest to Regional Average		
	New York[2]			**Massachusetts[3]**		
	Largest city (Queens County)[4]	Median (Schoharie County)	Least expensive (Cattaraugus County)	Largest city (Boston)	Median (Phillipston)	Least expensive (Sandisfield)
Housing	$2,091	$938	$734	$2,509	$976	$1,175
Child care	$1,285	$840	$840	$1,502	$1,047	$1,047
Food	$471	$415	$371	$559	$470	$476
Transp'n	$127	$328	$315	$90	$308	$320
Health care	$535	$485	$451	$542	$534	$534
Misc.	$451	$301	$271	$520	$333	$355
Taxes	$1,469	$588	$434	$1,615	$789	$869
Earned Income Tax Credit	$0	$0	-$75	$0	$0	$0
Child Care Tax Credit	-$50	-$50	-$58	-$50	-$50	-$50
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,212	$3,678	$3,116	$7,120	$4,240	$4,559
Minimum Wage	$15.00	$12.50	$12.50	$13.50	$13.50	$13.50
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.7**	**1.4**	**3.0**	**1.8**	**1.9**

[2] The Northeastern state closest to the national average was Maine (11.0%), but current Standard data for Maine is not available. The second-closest to the national average was New York (11.8%).

[3] The Northeastern state closest to the national average was Rhode Island (9.0%), but current Standard data for Rhode Island is not available. The second-closest to the regional average was Massachusetts (8.1%). Standard data in Massachusetts is grouped by town, not county, because towns are the more meaningful local geographic unit under Massachusetts's government structure.

[4] The largest city in New York (New York City) spans multiple counties; of those, Kings County is the most populous, but its Standard data is divided into two sub-regions to capture cost variations within the county. Queens County, the second-largest, has county-wide Standard data and is used instead for ease of comparison.

Midwest
Average Poverty Rate (2018–19): 9.7%

	Closest to National Average			Closest to Regional Average		
	Missouri[5]			**Illinois[6]**		
	Largest city (Jackson County)	Median (Adair County)	Least expensive (Dallas County)	Largest city (Cook County)	Median (Jersey County)	Least expensive (Pike County)
Housing	$973	$662	$662	$1,197	$791	$700
Child care	$782	$486	$471	$1,179	$647	$547
Food	$388	$347	$378	$384	$380	$358
Transp'n	$352	$331	$337	$100	$275	$266
Health care	$603	$720	$646	$446	$594	$565
Misc.	$310	$255	$249	$331	$269	$244
Taxes	$739	$443	$418	$857	$600	$473
Earned Income Tax Credit	$0	-$95	-$110	$0	-$41	-$137
Child Care Tax Credit	-$50	-$60	-$63	-$50	-$55	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$3,929	$2,922	$2,823	$4,277	$3,293	$2,787
Minimum Wage	$10.30	$10.30	$10.30	$13.00	$11.00	$11.00
Ratio (Self-Suff. to Min. Wage)	**2.2**	**1.6**	**1.6**	**1.9**	**1.7**	**1.5**

[5] Missouri's 2018–19 average poverty rate was 10.8%, the closest to the national average among Midwestern states.

[6] Illinois's 2018–19 average poverty rate was 9.8%, the closest to the regional average for Midwestern states.

South
Average Poverty Rate (2018–19): 13.2%

	Closest to National Average — **Texas**[7]			Closest to Regional Average — **North Carolina**[8]		
	Largest city (Harris County)	Median (Dallam County)	Least expensive (Uvalde County)	Largest city (Mecklenburg County)	Median (Jackson County)	Least expensive (Person County)
Housing	$1,129	$762	$734	$1,237	$718	$757
Child care	$788	$665	$509	$1,053	$688	$521
Food	$376	$374	$296	$435	$397	$375
Transp'n	$355	$311	$318	$301	$270	$276
Health care	$637	$683	$682	$495	$607	$454
Misc.	$329	$279	$254	$352	$268	$238
Taxes	$606	$458	$367	$880	$543	$405
Earned Income Tax Credit	$0	-$39	-$111	$0	-$47	-$136
Child Care Tax Credit	-$50	-$55	-$63	-$50	-$58	-$65
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$161
Monthly Self-Sufficiency Standard	$4,004	$3,272	$2,820	$4,536	$3,219	$2,664
Minimum Wage	$7.25	$7.25	$7.25	$7.25	$7.25	$7.25
Ratio (Self-Suff. to Min. Wage)	**3.2**	**2.6**	**2.2**	**3.6**	**2.6**	**2.1**

[7] The Southern state closest to the national average was Oklahoma (12.1%), but current Standard data for Oklahoma is not available. The second-closest to the national average was Texas (12.4%).

[8] North Carolina's 2018–19 average poverty rate was 12.9%, the closest to the regional average for Southern states.

West
Average Poverty Rate (2018–19): 10.2%

	Closest to National Average **California**[9]			Closest to Regional Average **Arizona**[10]		
	Largest city (Los Angeles County)	Median (Riverside County)	Least expensive (Modoc County)	Largest city (Maricopa County)	Median (La Paz County)	Least expensive (Santa Cruz County)
Housing	$2,058	$1,417	$807	$1,259	$952	$788
Child care	$1,447	$1,054	$757	$879	$630	$700
Food	$448	$408	$435	$408	$396	$334
Transp'n	$342	$340	$323	$269	$241	$241
Health care	$507	$511	$849	$518	$624	$484
Misc.	$480	$373	$317	$333	$284	$255
Taxes	$1,145	$727	$571	$688	$524	$399
Earned Income Tax Credit	$0	$0	$0	$0	-$15	-$103
Child Care Tax Credit	-$50	-$50	-$50	-$50	-$53	-$63
Child Tax Credit	-$167	-$167	-$167	-$167	-$167	-$167
Monthly Self-Sufficiency Standard	$6,210	$4,613	$3,842	$4,138	$3,417	$2,868
Minimum Wage	$15.00	$14.00	$14.00	$12.15	$12.15	$12.15
Ratio (Self-Suff. to Min. Wage)	**2.4**	**1.9**	**1.6**	**2.0**	**1.6**	**1.4**

[9] California's 2018–19 average poverty rate was 11.0%, the closest to the national average among Western states.

[10] The Western state closest to the regional average was also California (11.0%). The second-closest was Arizona (11.4%).

Exhibit I

Declaration of Jared Garrison-Jakel, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 JARED GARRISON-JAKEL, M.D., 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

Jared Garrison-Jakel, M.D., 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.

2. I am a board-certified family medicine and addiction medicine doctor in Guerneville, California, and a member of the California Academy of Family Physicians ("CAFP"). I understand that CAFP is a plaintiff in this litigation challenging the U.S. Food and Drug Administration's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write in support of that litigation. The Mifeprex REMS causes injury to me and my patients. But for the REMS, I could and would provide Mifeprex to my patients.

3. I received my undergraduate degree from Pomona College in 2005, a Master's in Public Health from the University of California Berkeley in 2009, and my medical degree from the University of California Irvine School of Medicine in 2010. I subsequently completed an internship and residency in family medicine at Sutter Medical Center of Santa Rosa in California.

4. I am trained in both medication and surgical abortion and provided those services while in my residency at Sutter Medical Center of Santa Rosa.

5. Since 2013, I have practiced at Russian River Health Center in Guerneville, California ("Russian River"). I submit this declaration in my individual capacity and— besides CAFP—not on behalf of any institution with

which I am associated, including the health center.

6. Russian River is a federally qualified health center ("FQHC"). FQHCs offer primary health care services to low-income populations in medically underserved areas. Guerneville, where Russian River is located, is an economically depressed city with virtually no other health care facilities. Our health center is located about 30 minutes away from any other doctor's office.

7. Many of my patients have little access to transportation outside of the community where Russian River is located. This lack of transportation makes it difficult to access even urgent health care services. For example, I treated one patient who had a terrible cut in her hand—the laceration reached the tendon. I told this patient that she needed to see a hand surgeon due to the severity of the laceration, but the patient explained that such travel would be impossible for her. She told me, "Doc, either you fix it now or no one's fixing it."

8. As explained below, because of the REMS, medication abortion is not available in the health center where I work. As a result, I have had to turn away patients who need abortion care. The closest clinic that offers abortion services is a one-hour round-trip from our health center. Traveling such a distance is a significant impediment for the populations I serve, who generally struggle to afford and arrange for things like transportation and child care. And, making this journey may very well also require my patients to miss work, and therefore lose wages—

that is, if they can get time off work at all; at the low-wage jobs where my patients typically work, there is often no paid leave. The reality is that it can be difficult or impossible for my patients to overcome all of these barriers.

9. I am medically qualified to provide Mifeprex to my patients who request a medication abortion. The only reason why I am not able to do so is because of the requirement that I stock and dispense Mifeprex on site.

10. I am aware that at least one of my colleagues, who holds a position of authority at our institution, is opposed to abortion and would not consent to Mifeprex being stocked and dispensed in our health center. (For the same reason, we cannot provide surgical abortion services here.) However, I am also aware that this colleague would not interfere with my writing a prescription for Mifeprex in the privacy of my office for a patient to fill at a pharmacy—and there are two pharmacies very close to the health center where I work; one is only a block away. But for the REMS, I could and would provide medication abortion care to my patients (and would do so in compliance with all federal segregation guidelines for FQHCs that provide abortion services).

11. Because of the REMS, I have been unable to treat my patients in accordance with my medical judgment. Multiple patients have come to me with unwanted pregnancies at less than ten weeks, who requested—and were eligible for—medication abortions. However, because of the REMS, I had to deny them

this care—delaying their abortion, to the extent that they could obtain the abortion at all. Indeed, I am always reluctant to refer a patient to another health care facility, whether for abortion or any other medical service; given the financial challenges that my patients almost uniformly face, which are often compounded by other barriers and stressors (such as mental health disorders, substance use disorders, or homelessness), such a referral usually means that they will be significantly delayed in accessing medical care, or not obtain it at all.

12. There are three central concerns with delaying abortion care. First, if a patient is delayed past ten weeks of pregnancy, she typically will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure, which may be an inferior option given her circumstances. Second, while abortion is extremely safe, and far safer than remaining pregnant and carrying to term, the risk of complications increases as the pregnancy progresses. I can recall at least one patient who came to me at a point in pregnancy when she was still eligible for a medication abortion but, because I could not write her a prescription for Mifeprex, ended up having a more invasive and time-consuming second-trimester dilation and evacuation abortion procedure over a month later. Third, delaying a patient's abortion means that the patient stays pregnant longer, and thus must incur the serious risks and discomforts associated with pregnancy for longer.

13. Moreover, because of the REMS, at least one of my patients was prevented from having a desired abortion at all. This patient had a history of sexual trauma and struggled with substance use disorders. She was extremely distressed to learn that she was pregnant, and presented to me seeking a medication abortion. To add to the complications of her situation, she did not feel that she could disclose her desire for an abortion to her partner. I initially referred her to the nearest clinic providing first-trimester abortion services, but she was unable to make the journey to that clinic for her appointment. I saw her again in her second trimester, when she reiterated that she did not want to carry the pregnancy to term. At that point, I referred her to the nearest provider of second-trimester abortions, which is approximately three hours round-trip from Guerneville. I know that the care team at that facility worked diligently to support her in accessing abortion care, including trying to arrange transportation for her. Nevertheless, because of the many challenges in her life, she missed multiple appointments there as well. This patient ultimately ended up carrying the pregnancy to term. I have grave concerns about how this unintended pregnancy has affected her life; when I'd seen her, she communicated that the pregnancy had worsened her suffering around her sexual trauma history and medication dependency. Moreover, this patient did not obtain adequate prenatal care during her first or second trimesters because this was not a pregnancy she had intended to carry to term. Needless to say, denying this patient

the care she so desperately wanted and needed was not in accordance with my best medical judgment.

14. In short, the Mifeprex REMS has prevented me from fulfilling my personal, professional, and ethical obligations to provide my patients with the medical care they need, which I am qualified to and would otherwise provide.

15. I am aware that the FDA just announced that, for the remainder of the COVID-19 Public Health Emergency, it is suspending enforcement of the requirement that patients obtain Mifeprex in person at a health center and instead allowing patients to obtain their medication by mail or from a mail-order pharmacy acting under the supervision of a certified REMS prescriber. Although this is an important step in the right direction, even under this short-term policy, the FDA continues to treat Mifeprex differently than any other drug I prescribe. I am working to understand what this "supervision" requirement entails (such as with regard to billing) and determine whether or not I will be able to take advantage of this temporary policy shift. Regardless, a permanent fix is essential to ensure that my patients can access medication abortion care without facing needless, and sometimes insurmountable, hurdles.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 14th, 2021, in Guerneville, California.

Jared Garrison-Jakel, M.D.

Exhibit J

Declaration of Joey Banks, M.D.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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 JOEY BANKS, M.D., 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

Joey Banks, M.D. 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.

2. I am a family medicine physician. I work at Blue Mountain Clinic in Missoula, Montana, where I have been providing care since 2011. I currently provide and train residents in reproductive health care, including abortion, at the Blue Mountain Clinic and also provide such care at a clinic in Tulsa, Oklahoma.

3. In addition, I serve as the Chief Medical Officer for Planned Parenthood of Montana, a position I have held since 2019. In this capacity, I supervise the medical staff at all Planned Parenthood sites statewide and also provide reproductive health care to patients.

4. In my practice I prescribe mifepristone (brand name Mifeprex®) to my patients both for pregnancy termination and in cases of pregnancy loss (where mifepristone assists in safely and efficiently completing the miscarriage). I have provided abortion and miscarriage care to patients for 20 years and, over the years, have provided such care to many people who lived in areas where care is difficult to obtain—including in Alaska, Maine, Montana, and, most recently, in Oklahoma.

5. I am a member of the National Abortion Federation, the American Academy of Family Physicians, and the Montana Academy of Family Physicians. I am also a member of the Society of Family Planning ("SFP"). I understand that

SFP is a plaintiff in litigation challenging FDA's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone, and write this declaration in support of SFP's Motion for Summary Judgment. I do so in my individual capacity and as an SFP member, and do not speak on behalf of Blue Mountain Clinic, Planned Parenthood, or any other institution.

6. Until a couple of years ago, Blue Mountain Clinic was the only clinic in Missoula where patients could access abortion care. The Blue Mountain Clinic is located near a perinatologist's office. A perinatologist is an obstetrician who specializes in maternal-fetal medicine and has special training in high-risk pregnancy care. Perinatologists sometimes use mifepristone to induce labor in late pregnancy.

7. The perinatologist near my clinic did not stock mifepristone, but occasionally wanted to administer it to his patients to induce labor in late pregnancy. Knowing that I stocked and provided mifepristone to my patients, in 2018 the perinatologist approached me about whether I would be amenable to his sending his patients to see me just to obtain the mifepristone, and then he would re-assume care after the patient left my clinic.

8. When I asked the perinatologist why he didn't stock mifepristone himself, he said it was because he was worried that by stocking mifepristone he would unwittingly be placed on a list of abortion providers. The perinatologist was

aware of the history of violence and harassment by anti-abortion activists and was concerned that if the list of mifepristone prescribers required by the REMS were somehow made public, it would put him in danger.

9. The perinatologist was affiliated with and provides services at a local hospital in Missoula, Montana. When I asked why he didn't just ask the hospital to stock mifepristone in its formulary, he said that he did not want anyone in the hospital to presume he was pro-choice.

10. This is not the only instance in which I have encountered clinicians who are unwilling to stock mifepristone even though it would benefit their patients. For instance, since 2013, I have been providing reproductive health care training to family medicine residents at Blue Mountain Clinic. My training includes, among other things, medication abortion, procedural (sometimes called "surgical") abortion, and miscarriage management. For many years, I have taught residents to treat patients seeking medication abortion with a regimen of 200mg of mifepristone followed by 800mg of misoprostol; and, since 2018, based on new, high-quality medical research, I also began teaching them this two-drug regimen for the medical management of miscarriages. Although both can be accomplished with misoprostol alone, evidence supports the two-drug regimen as the superior regimen.

11. On numerous occasions, I have been contacted by physicians I

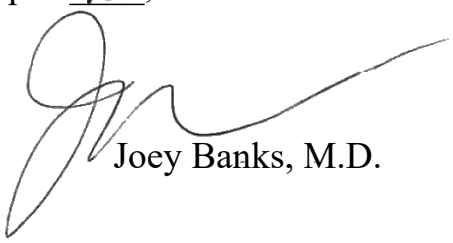
previously trained, telling me that the health care facility where they work does not stock mifepristone, and that they felt uncomfortable asking leadership at their health care facility to begin stocking mifepristone, or that they knew their clinic simply would not stock mifepristone. They all wanted to know whether they could still care for patients who sought a medication abortion or suffered a miscarriage, even without mifepristone. In light of these conversations, I now explain to the residents I train that if their health care facility does not stock mifepristone, they can consider prescribing misoprostol alone for either early abortion or miscarriage treatment, but that it is less effective and that the two-drug regimen, including mifepristone, is the superior regimen

12. In my experience, the mifepristone REMS is interfering with practitioners' provision of evidence-based medicine. Some clinicians fear professional repercussions if they try to persuade their colleagues to stock and dispense mifepristone onsite. And some are so concerned about the stigma and threat of violence surrounding the provision of abortion that they are unwilling to register their names and addresses with the mifepristone distributer, as required by the REMS. The prospect of this "abortion provider list" being leaked to the public is enough to prevent clinicians from providing what they deem the best medicine for their patients.

13. In sum, the mifepristone REMS prevents clinicians from providing

solid evidence-based medicine due to the stigma and fear associated with having to register with the drug manufacturer and stock the medication onsite.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct. Executed on April 12, 2021.



Joey Banks, M.D.

Exhibit K

Declaration of Charisse M. Loder, M.D., M.Sc.

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

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

Plaintiffs,

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Defendants.

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

[CIVIL RIGHTS ACTION]

DECLARATION OF CHARISSE M. LODER, M.D., M.Sc., 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

Charisse M. Loder, M.D., M.Sc., 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.

2. I am an obstetrician-gynecologist trained in abortion care and a member of the Society of Family Planning ("SFP"). I am a Clinical Assistant Professor of Obstetrics and Gynecology at the University of Michigan Medical School. My practice is located at the Women's Clinic at Von Voigtlander Women's Hospital in Ann Arbor, Michigan. I have also practiced as an obstetrician-gynecologist at Planned Parenthood in Ann Arbor.

3. I received my undergraduate degree from Cornell University in 2003, and my medical degree from Pennsylvania State University in 2011. I did my residency in Obstetrics and Gynecology at the University of Rochester, where I served as Chief Resident, and then completed a fellowship in Family Planning and received a Master of Science degree in Health and Health Care Research at the University of Michigan.

4. In my current practice, I provide a range of obstetrics and gynecology care, and specialize in miscarriage management, complex contraception and sterilization, and abortion care.

5. I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and as a member of SFP, not on behalf of any institution with which I am affiliated.

6. Mifeprex is an important drug for the provision of abortion and miscarriage care. I advocated to make this medication available within the Women's Clinic in order to offer our patients the best possible care at our own institution, without having to refer them elsewhere.

7. While I am currently able to prescribe mifepristone to my patients, attempting to bring the Women's Clinic at the University of Michigan into compliance with the mifepristone (brand name Mifeprex®) Risk Evaluation and Mitigation Strategy ("REMS") was an extremely complicated process that took five years (and a substantial investment of time, resources, and professional capital by me and other colleagues). During these five years, my colleagues and I were forced to refer patients who needed medication abortion care to other institutions. When patients are referred elsewhere for abortion care, many experience delays or are even prevented from accessing this time-sensitive care. We were also unable to offer Mifeprex for miscarriage and second-trimester abortion care, even though Mifeprex enhances the efficacy of those treatments. There is absolutely no medical reason for FDA to impose these barriers to patients obtaining this safe and effective medication.

8. My involvement in the process of trying to make Mifeprex available at the University of Michigan began when I arrived at the University six years ago, in 2015. But conversations surrounding Mifeprex at the University of Michigan began seven years ago, in 2014. As of 2014, the only patients who could access mifepristone through the University of Michigan were those seeking treatment for Cushing's syndrome: University clinicians were able to prescribe mifepristone under the brand name Korlym, and the patients filled those prescriptions through a mail-order pharmacy. However, patients in need of mifepristone under the brand name Mifeprex, for reproductive health care, could not access the medication through any University provider.

9. As a first step, I had to get approval to add Mifeprex to the University's drug formulary from the University's Pharmacy and Therapeutics Committee ("the Committee"), which is composed of pharmacists and physicians from a variety of clinical specialties. As discussed above, I was not the first physician to attempt to do so; in 2014, other physicians had participated in multiple meetings with the Committee during which they advocated for adding Mifeprex to the formulary. Ultimately, these conversations stalled because those physicians were unable to invest the immense amounts of time required to move this process forward.

10. Between 2015 and 2016, I participated in approximately four Committee meetings relating to Mifeprex. To assist in the Committee's evaluation of Mifeprex, the Committee asked me and my colleagues to provide literature on Mifeprex's safety and indications for use, which we did. These meetings were each about an hour long, and I individually spent at least 20 additional hours researching and preparing presentations about Mifeprex's safety and efficacy, as well as writing guidelines for its use.

11. Finally, in 2016, the Committee approved Mifeprex for the University formulary. None of this would have been necessary—the Committee would not have been involved at all—if we could simply issue our patients a prescription to fill at a pharmacy instead of having to stock and dispense Mifeprex onsite.

12. But getting Mifeprex on our hospital's formulary still did not mean that University of Michigan clinicians could start prescribing Mifeprex to patients. Placing a drug "on formulary" means that the drug is approved for safe use by the hospital. But, in order to make Mifeprex available "in clinic" for patients, the University of Michigan first had to order and stock this medication. And it took me *three* more years of advocacy to achieve this second step.

13. In 2018, a pharmacist in the gynecology department suggested that I form a task force to develop protocols for Mifeprex use in-clinic because the process had stalled out. I believe that my colleague suggested that I create such a

task force in order to alleviate concerns throughout the University about how to comply with the Mifeprex REMS and to accelerate the process of actually stocking and dispensing Mifeprex. I have never heard of such a task force being formed for the introduction of other drugs or devices into University practice. For example, we frequently integrate new intrauterine contraceptive devices (IUDs) into our practice, and have never had to develop protocols about how to prescribe them. But I believed that without a physician champion and a committee specifically focused on this issue, Mifeprex would never be made available in our clinic.

14. Accordingly, I organized and created a multidisciplinary task force to develop various protocols for ordering, stocking, prescribing, and dispensing Mifeprex at the Women's Clinic. This task force is made up of gynecology and family medicine physicians, nurses, clinic managers, pharmacists, and electronic medical record (EMR) specialists. The task force was charged with finalizing protocols to address how Mifeprex is ordered, administered, and stored, as well as addressing safety and reimbursement concerns surrounding the storage and dispensing of Mifeprex at our clinic. In a large health care institution like ours, where every organizational decision requires approval from multiple stakeholders, none of these decisions were simple.

15. I first convened this task force in October 2018, and the task force met every six weeks until Mifeprex was available in clinic. The task force met for

about an hour each time—and that is only the tip of the iceberg. Since October 2018, I have spent at least 80 hours of my time preparing for and/or completing follow-up work relating to task force meetings (such as preparing education materials for clinical staff), as well as participating in numerous *non*-task force meetings with stakeholders to discuss protocols to ensure compliance with the REMS as we integrate Mifeprex into clinical practice. For instance, I met with EMR representatives to propose edits to our electronic medical records in order to track Mifeprex administration in patient records. I attended separate meetings with the Women's Clinic manager, insurance verification team, and billing team related to the University's financial and reimbursement concerns around the dispensing of Mifeprex onsite. And I consulted on strategies to communicate guidelines for Mifeprex administration with staff, including developing REMS-compliant protocols for nurses who may want to "opt-out" of any involvement in the dispensing of Mifeprex. If not for the REMS, I would not have had to involve all of these other clinicians and stakeholders within the University and invest so many hours of my time and professional resources into developing system-wide protocols to integrate Mifeprex into hospital practice. I would simply have written my patients a prescription.

16. The Mifeprex REMS also requires that clinicians register with the drug's distributor in order to become a certified prescriber. As an initial matter, this

requirement is medically unnecessary: Mifeprex is a safe and straightforward medication; the clinical competencies necessary to safely prescribe it are very common; and in general, and as a legal and ethical matter, my colleagues and I do not prescribe any treatment unless it is within our competency to do so. But the prescriber certification requirement also posed numerous obstacles to the provision of Mifeprex at the University of Michigan.

17. First, task force members raised concerns that the University would face legal liability if clinicians who were not acting pursuant to a REMS prescriber agreement prescribed this drug. We spent many meetings discussing protocols to prevent violations of the REMS.

18. Second, members of the task force were concerned about how to store Mifeprex to ensure that only certified prescribers can access it. As a result, the task force spent numerous meetings discussing how to properly secure the Mifeprex stock with locks, and how to determine which clinicians have access to the locked area.

19. Third, because of the prescriber certification requirement, the University of Michigan must update its EMR system and pharmacy database each time a physician registers as a certified provider. These updates are costly and require staff time. These systems must be updated constantly to alleviate a concern that someone will prescribe Mifeprex in violation of the REMS.

20. These organizational concerns related to prescriber certification stem not from any mistrust of physicians, but from concerns about compliance with the REMS.

21. I would never have been able to provide mifepristone to my patients if it were not for the tenacious advocacy and time commitment my colleagues and I invested into this effort. As it was, for more than five years, the REMS prevented me and all of my colleagues from providing that care to our patients and necessitated that we refer patients outside of the University of Michigan system. I know that many of my colleagues have had the same experience, because over the years, I have frequently been contacted by colleagues inquiring whether they were permitted to prescribe Mifeprex to their patients, and I had to tell them that—because of the REMS—the answer was no.

22. And my situation at the University of Michigan is by no means unique. I am regularly contacted by clinicians at other academic medical centers who are seeking advice on how to navigate the REMS in order to stock and dispense Mifeprex at their institutions.

23. Clinicians outside the University of Michigan have also shared with me that they have not integrated Mifeprex into their practice because they fear that completing the REMS prescriber certification requirement would place them on a registry of abortion providers and thus make them targets of anti-abortion

harassment or violence. If clinicians could simply write a prescription for Mifeprex without this obstacle and the other obstacles the REMS imposes, I believe that many more clinicians, in a wider swath of our state, would do so.

24. While abortion care is extremely safe, the risks associated with abortion increase as pregnancy advances. Therefore, delaying a patient's abortion care increases the risks she faces.

25. This delay also pushes patients past the point at which a medication abortion, or any abortion care, is available to them at all. When I worked at Planned Parenthood, I often saw patients who had been referred there by their primary provider because their provider does not provide medication abortion care. But, because of the delay caused by this referral, by the time these patients got to Planned Parenthood, they were frequently too far along in their pregnancies to be eligible for a medication abortion—even though they preferred that option and that option would have been most clinically suitable for them. Because of this delay, these patients were only eligible for aspiration or dilation and evacuation ("D&E") abortion, in-clinic procedures that are significantly more expensive than medication abortion. And some of these patients could not afford these more expensive in-clinic procedures and ultimately were unable to get an abortion at all.

26. My patients at Planned Parenthood frequently told me about the burdens they faced traveling to us for care: paying for transportation, arranging

child care, taking time (often unpaid) off from work, and more. Some of these patients traveled great distances: there are very few abortion providers in Northern Michigan or in Michigan's Upper Peninsula, and many of our patients traveled more than one and a half hours, and up to 10 hours, to obtain abortion care. Many of these patients shared that they could not access abortion care in their local community.

27. In addition to being an important part of safe, effective early abortion care, Mifeprex has other clinical indications, such as in medical management of pregnancy loss (miscarriage) and labor induction abortions during the second trimester. In both of these clinical circumstances, pretreatment with mifepristone reduces the length of the treatment and, as a result, reduces the risk of complications.

28. At the University of Michigan, my colleagues and I care for patients undergoing second-trimester labor induction in cases of pregnancy loss, or where the patient seeks abortion because of a diagnosis of fetal anomalies or due to significant risk to maternal health or life. During this process the patient experiences all the pain and physical consequences of labor. Clinicians often prescribe Mifeprex to patients going through this process, in order to make it easier and faster. When clinicians are unable to add Mifeprex to their treatment regimen,

many patients and their families suffer both emotional and physical tolls from longer labor inductions.

29. After five years of advocacy and hundreds of hours of advocacy by a few dedicated clinicians and stakeholders, Mifeprex finally became available onsite at the University of Michigan in late September 2019. But even now, the work continues: although Mifeprex is available at the Von Voigtlander Women's Hospital (where the Women's Clinic is located), I am still expending hours of effort to work to make Mifeprex available at our six OB/GYN outpatient sites, where clinicians continue to struggle to develop systems to stock and store Mifeprex consistent with the REMS. As a result, patients in those communities must travel longer distances (up to 40 miles round-trip) to get to our hospital for care, rather than being able to obtain a prescription for Mifeprex at their local outpatient site to then fill through a retail or mail-order pharmacy.

30. The Mifeprex REMS made this process extremely burdensome, requiring both an institutional champion (myself) willing to expend more than 80 hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

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.

Charisse M. Loder, M.D., M.Sc.

Exhibit L

2012 Korlym REMS Review

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202107Orig1s000

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

RISK MANAGEMENT REVIEW

Date:	January 27, 2012
Risk Management Analyst:	Suzanne Robottom, Pharm.D. Division of Risk Management (DRISK)
Team Leader:	Cynthia LaCivita, Pharm.D., DRISK
Division Director:	Claudia Karwoski, Pharm.D., DRISK
Drug Name:	Korlym (mifepristone)
Dosage and Route:	300 mg tablets; by mouth
Application Type/Number:	NDA 202-107
Applicant/sponsor:	Corcept
OSE RCM #:	2011-2351

EXECUTIVE SUMMARY

The purpose of this review is to document DRISK's determination that a risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU) is not necessary for the approval of mifepristone for the treatment of the signs and symptoms of endogenous Cushing's syndrome.

Corcept submitted a 505(b)(2) application for approval of Korlym (mifepristone) for the treatment of the signs and symptoms of endogenous Cushing's syndrome. Mifepristone (Mifeprex) is currently approved for pregnancy termination with a REMS with ETASU. Based on FDA feedback provided at the September 14, 2010 pre-NDA meeting, Corcept proposed a REMS with ETASU with their NDA submission.

After extensive research and multiple discussions with the review team, DRISK and the Division of Metabolism and Endocrinology Products (DMEP) determined that:

- A REMS with ETASU is not necessary to ensure that the benefits outweigh the risks of Korlym *in the Cushing's population*.
- A REMS with ETASU for Korlym would not improve the benefit/risk balance for the intended use (Cushing's) population and would add burden.
- Use of Korlym outside of Cushing's syndrome cannot be prospectively quantified.

The REMS Oversight Committee and the Center Director provided additional guidance and affirmed that although a REMS is required for Mifeprex, a REMS for Korlym is not necessary to ensure that the benefits of the drug outweigh its risks at this time. Korlym's safety and drug utilization should use be monitored through post marketing requirements (PMR). If data indicate that the current approach compromises the integrity of the Mifeprex REMS and results in serious adverse events, or additional serious safety signals arise, further regulatory action must be considered.

1 INTRODUCTION

The purpose of this review is to document DRISK's determination that a REMS with ETASU is not necessary for the approval of mifepristone for the treatment of the signs and symptoms of endogenous Cushing's syndrome.

1.1 BACKGROUND

Corcept submitted a 505(b)(2) application on April 15, 2011 for approval of Korlym (mifepristone) to treat the clinical and metabolic effects of hypercortisolism in adult patients (≥ 18 years of age) with endogenous Cushing's syndrome including:

- Patients with Cushing's disease who have not adequately responded to or relapsed after surgery
- Patients with Cushing's disease who are not candidates for surgery

(b) (4)

Korlym is manufactured as 300 mg tablets. The proposed dosing for the aforementioned indication is 300 to 1200 mg daily by mouth.

1.2 REGULATORY HISTORY

Mifepristone if currently marketed as Mifeprex and approved on September 28, 2000 under 21 CFR 314 Subpart H for the medical termination of intrauterine pregnancy through 49 days' pregnancy. The approved dosing is 600[1] mg (three (3), 200 mg tablets) followed by misoprostol on Day 4. Since approval, mifepristone is available only through a restricted distribution program that requires prescribers to be enrolled to be able to order Mifeprex and should only be distributed to/through a clinic, medical office, or hospital, by or under the supervision of a specially certified prescriber. Mifeprex is not distributed to or dispensed through retail pharmacies. The restricted distribution program was approved as a REMS on June 8, 2011.[2]

In 2007, Corcept initiated a clinical development program to evaluate the clinical benefit of mifepristone in patients with Cushing's syndrome and received orphan drug designation on July 5, 2007.

A pre-NDA meeting with Corcept was held on September 14, 2010. Corcept informed the FDA that they intended to submit a REMS and requested comments on the draft REMS. The FDA informed Corcept that for this NDA/indication, a REMS with restricted distribution would be necessary to address the risk of termination of pregnancy. The proposed REMS must be sufficient to maintain the integrity of the current Mifeprex restricted distribution program. The sponsor was instructed that a complete review of the proposed REMS, and REMS materials would be done in conjunction with the full clinical review after the NDA is submitted.

On April 15, 2011 Corcept submitted NDA 202107 for review with a proposed REMS.

2 MATERIALS REVIEWED

The following materials were reviewed:

- Weber J. Pre-NDA Meeting Preliminary Comments for September 14, 2010. Signed under IND 76480 on September 9, 2010 by Weber J.
- NDA 202107 submitted on April 15, 2011 and received on April 18, 2011 with a proposed REMS with ETASU.
- Bhatnagar U. Maternal Health Team review for Mifepristone. Signed September 15, 2011 by Bhatnagar U, Feibus K, and Mathis L.
- Greene P. Drug use review of Mifeprex. Signed September 19, 2011 by Greene P, Chai G, and Governale L.

[1] Standard practice is to dispense a single, 200 mg tablet of mifepristone, not 600 mg. In addition, the standard misoprostol dose is 800µg (4 tablets), not 400 µg.
[2] Mifepristone was included on the list of products deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under section 505-1 of the Federal Food, Drug, and Cosmetic Act with the passage of the Food and Drug Administration Amendments Act (FDAAA) of 2007.

- November 3, 2011 Center Director Briefing on Mifepristone for Cushing's syndrome. Signed into DAARTS for NDA 202107 on November 15, 2011 by Egan A.
- (b) (6) Division of Reproductive and Urology Products consult response. Signed November 18, 2011 by (b) (6).

3 RISK BENEFIT CHARACTERIZATION

3.1 CUSHING'S SYNDROME AND TREATMENT OPTIONS

Cushing's syndrome is a serious, multisystem disorder that results from overproduction of cortisol by the adrenal glands. For those not cured by surgery, it is a chronic and debilitating condition.[4] If left untreated, Cushing's syndrome limits survival to 4 to 5 years following initial diagnosis.[3]

Surgical resection of the offending tumor remains first line treatment, and initial cure or remission is obtained in 65-85% of patients with Cushing's disease.[4] In cases that surgery only partially or temporarily controls glucocorticoid hypersecretion (or for patients who are not candidates for surgery),[5] radiation and/or pharmacologic treatment is used for disease control. A two to three fold increase in mortality is observed in most studies and this excess mortality seems confined to patients in whom initial cure was *not* obtained (the indicated population for mifepristone).[4]

There is an unmet medical need for additional drug treatment options for Cushing's syndrome. The following table lists the drug treatment options, none of which are approved for Cushing's syndrome:[2,6]

Steriodogenic inhibition	Adrenolytic	Neuromodulators of ACTH release	Glucocorticoid receptor antagonism
• Metyrapone (not available in US) • Aminoglutethimide (discontinued)^ • Ketoconazole	• Mitotane^^ • Etomidate	• Cyproheptidine* • Bromocriptine* • Valproic acid* • Octreotide*	• Mifepristone
^Aminogluthethimide was approved in 1980 and indicated "for the the suppression of adrenal function in selected patients with Cushing's syndrome." ^^Mitotane was approved in 1970 and indicated for "the treatment of inoperable adrenal cortical carcinoma of both functional and nonfunctional types." *Agent has not demonstrated consistent clinical efficacy.[3]			

[3] Gums JG, Smith JD. Adrenal Gland Disorders. Pharmacotherapy: A pathophysiologic approach. 4th ed. Ed Dipiro JT. Stamford, Appleton & Lange, 1999. Print.
[4] Steffensen C, Bak AM, Rubeck KZ, Jorgensen JO. Epidemiology of Cushing's syndrome. Neuroendocrinology 2010;92(supp 1):1-5.
[5] Johanssen S. Allolio B. Mifepristone (RU 486) in Cushing's syndrome. Euro J Endocrin (2007)156; 561-569.
[6] Heyn J, et al. Medical suppression of hypercortisolemia in Cushing's syndrome with particular consideration for etomidate. Pituitary (online May 10, 2011).

3.1.1 Size of Population

Cushing's syndrome is a rare disorder with incidence ranging from 0.7 to 2.4 per 1 million persons per year.[7] Ninety percent of all cases of Cushing's syndrome occur during adulthood; the incidence of Cushing's syndrome in children is estimated at approximately 0.2 cases per 1 million persons per year.

It is estimated that at any given time there are approximately 20,000 patients with Cushing's syndrome in the U.S. The peak incidence of Cushing's syndrome due to an adrenal or pituitary tumor occurs in persons 25-40 years of age; females are 8 times more likely than males to develop hypercortisolemia from a pituitary tumor and 3 times more likely to develop a cortisol-secreting adrenal tumor.

In the US, it is estimated that approximately 5,000 patients would be considered candidates for treatment with Korlym.

3.2 EXPECTED DRUG BENEFIT

Mifepristone works by binding to glucocorticoid receptors, preventing cortisol from binding, and thereby blocking cortisol's activity and effects. It does not decrease the amount of circulating cortisol. It has a rapid onset of action (~90 minutes for peak plasma concentrations).

According to the sponsor in Study 400 (open label, 24 week prospective trial), 60% of the diabetes patients met the primary endpont of at least a 25% reduction in $AUC_{glucose}$, and antidiabetic medication use was reduced in half of the patients. The Data Review Board determined that 72% of patients met the secondary endpoint of a change in signs and symptoms at week 24.

Mifepristone may be used as an adjunct to radiation, palliative treatment, or when rapid onset of anti-glucocorticoid effect is required (e.g., psychosis).

3.3 DURATION OF TREATMENT

Cushing's syndrome that is not cured by surgery is a chronic condition. Patients may be treated indefinitely (weeks, months, years/decades) with mifepristone.

3.4 SEVERITY OF THE RISK

The observed risks (adverse events documented in the safety database; adrenal insufficiency, hyopkalemia, and endometrial hyperplasia) in patients with Cushing's syndrome were considered. After discussion with DMEP, we agree that these risks can be adequately addressed through labeling.

[7] Newell-Price J, Bertagna X, Grossman AB, Nieman LK. Cushing's syndrome. Lancet. 2006 May 13;367 (9522):1605-17.

Two risks were identified that are anticipated to occur in the post-marketing setting. These risks were the focus of the risk management discussion.

3.4.1 Fetal Loss (unintended pregnancy termination)

3.4.1.1 Cushing's Syndrome Patients

Mifepristone blocks progesterone receptors at lower doses than necessary for glucocorticoid receptor inhibition. Therefore, the lowest treatment dose studied for the treatment of Cushing's syndrome is effective for terminating pregnancy. However, mifepristone alone is less effective for pregnancy termination when compared to the combined regimen mifepristone/prostaglandin.[8]

Women with Cushing's syndrome are not at substantial risk for fetal loss because they are unlikely to be pregnant. The review by the Maternal Health Team (MHT) states that amenorrhea and ovulatory disturbances are associated with untreated Cushing's syndrome and therefore pregnancy occurs "rarely" in this population. Pregnancy may occur in a small subset of patients with Cushing's syndrome who are of childbearing age. MHT recommends that this possibility be noted in labeling.[9]

At the time treatment is initated with mifepristone, a woman has a low likelihood of conception due to her underlying disease. During treatment, if she is not compliant with mifepristone treatment, she would be amenorrheic due to worsened disease condition. If she is compliant with medication, mifepristone would prevent a sustained pregnancy. Therefore, the risk of fetal loss before and during treatment in the intended patient population appears low.

Pregnancy tests were performed in Study 400 as part of enrollment and repeated after any significant interruption of treatment. No pregnancies were reported.

3.4.1.2 Non-Cushing's Syndrome Patients

There are a variety of uses for mifepristone (b) (4). It has been studied to treat the following:

(b) (4)

(b) (4).

[8] (b) (6) Division of Reproductive and Urology Products consult response. Signed November 18, 2011 by (b) (6).

[9] Bhatnagar U. Maternal Health Team review for Mifepristone. Signed September 15, 2011 by Bhatnagar U, Feibus K, and Mathis L.

At present, mifepristone is only commercially available in blister packages (3 pills per carton) that are sold through the Mifeprex REMS. If Korlym is approved without restrictions (e.g. REMS), mifepristone will be more readily available to treat females of child bearing potential with other chronic conditions. The extent of off-label use of mifepristone, for the above conditions, in the post-marketing setting is unknown.

3.4.2 Intended Termination of Pregnancy with Korlym

If Korlym is approved without a REMS with restricted distribution, there will be increased access to mifepristone. This could lead to 1) prescribers prescribing Korlym for the termination of pregnancy without following the safeguards that are in place for Mifeprex and/or 2) misuse, pilfering, and diversion of Korlym for the termination of pregnancy not under the supervision of a healthcare provider.

The risk mitigation tools for the Mifeprex REMS are physician certification and controlled access to assure safe use. A Mifeprex prescriber must agree that he/she meets the required qualifications to assure the drug is used safey and appropriately. Compliance with the REMS requirements is not enforced beyond a one-time completion of the enrollment form (e.g., signed Patient Agreements are not collected). The certification requirement is the tool that provides controlled access for Mifeprex. Without restricted distribution, a prescriber using Korlym for pregnancy termination would not have to attest to having certain skills, agree to document certain information/activities, or report adverse events. The patient would not receive a Patient Agreement or Mifeprex Medication Guide that would provide the most relevant and important information to her for pregnancy termination. The current REMS does not prevent use beyond 49 days gestation, termination of an ectopic pregnancy, bleeding, incomplete abortion, and infection.

In considering if there is increased potential for pilfering and misuse with Korlym, we note that Mifeprex is distributed only to medical facilities and dispensed to the patient in small quantities (a single tablet) by certified prescribers. Korlym will be distributed directly to patients, in larger quantities and each Korlym tablet is an effective dose for pregnancy termination. Moreover, Korlym is proposed to be packaged in bottles of 28 and 280, making diversion and pilfering presumably easier relative to the Mifeprex packaging. Similar to Korlym, there is potential for Mifeprex to be pilfered or diverted from a distribution facility, during shipping, or at the place of dispensing. Mifeprex has processes in place to prevent drug loss during distribution and shipping that can be done outside a REMS for Korlym. It is not known if clinics keep careful stock and dispensing records of Mifeprex.

3.5 RISK IN CONTEXT OF DRUGS IN CLASS AND AMONG OTHER DRUGS USED TO TREAT THE DISEASE

There are no other glucocorticoid receptor antagonists approved in the U.S. for comparison.

Ketoconazole, metapyrone (not approved in U.S.), mitotane, etomidate are anti-corticolic drugs that are used for the treatment of Cushing's syndrome. Because these drugs have a

different mechanism of action, they are not associated with the same potential risks as mifepristone. These drugs are associated with serious risk(s) although none of these drugs have a REMS.

3.6 HOW THE RISK(S) ARE MANAGED ACROSS OTHER PRODUCTS AND/OR DISEASES

3.6.1 Fetal Loss

Other drug products are associated with fetal loss (e.g., methotrexate, misoprostol; see Attachment 1). At present, this risk is addressed through labeling for these drugs. There are no REMS approved that address only fetal loss without also the accompanying risk of birth defect.

3.6.2 Intended Termination of Pregnancy with Korlym

We identified two drugs, misoprostol and methotrexate, that are associated with a risk of pregnancy termination and are approved for other uses. See the table in Attachment 1. The extent to which misoprostol and methotrexate are used off-label to terminate pregnancy is unknown. With each drug, the risk of termination of pregnancy is managed through labeling (Contraindication, Boxed Warning) and neither product has a REMS.

3.6.3 Misuse

Misuse has been addressed in different ways as follows:

Voluntary Restricted Distribution:

- *Example: Egrifta/growth hormone*: Growth hormones are at risk for misuse and abuse. None of the growth hormone products have a REMS. However, the sponsor has voluntarily decided to distribute this product through a non-REMS restricted distribution system which allows tracking "of each box of Egrifta to determine the volume of product dispensed and evaluate if the projected number of boxes dispensed correlates with prescription use in the intended population."[10] Egrifta was approved in 2010 with no REMS and no PMR for monitoring drug use.

Required Restricted Distribution Program

- *Example: Xyrem*[11]
  - At the time Xyrem was initially approved in 2002, the Sponsor agreed as a condition of approval to distribute and dispense Xyrem through a primary and exclusive central pharmacy, implement a program to educate physicians and patients about the risks and benefits of Xyrem, fill the initial prescription only after the prescriber and patient received and read the educational materials, and maintain patient and prescribing physician registries.[12]

[10] LaCivita C. Review of REMS for Egrifta. Signed September 3, 2010.
[11] Xyrem was included on the list of products deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under section 505-1 of the Federal Food, Drug, and Cosmetic Act with the passage of the Food and Drug Administration Amendments Act (FDAAA) of 2007.
[12] Choudhry Y. REMS Interim Comment Set #1. Signed August 1, 2011 by Choudhry Y and Worthy K.

3.6.4 Same Active Ingredient, Different Indication and Different Risk Management Approaches

The agency evaluates an active ingredient based on the risk benefit profile for the intended population. To date, the Agency has not required a REMS for a product based only on the fact that the active ingredient already has a REMS for one population. For example, denosumab was originally approved under two tradenames for different indications. Prolia was initially approved for the treatment for post-menopausal osteoporosis (PMO). At that time, a REMS for Prolia was required and approved consisting of a Medication Guide and communication plan to "inform healthcare providers about the risks of serious infections, dermatologic adverse reactions, and suppression of bone turnover, including osteonecrosis of the jaw." Under the tradename Xgeva, denosumab was approved for prevention of skeletal-related events in patients with bone metastases from solid tumors. A REMS was not required given the resulting differences in the risk benefit profile when considering the patient populations (post-menopausal women vs cancer patients with bone metastases) and prescribing populations (internists vs oncologists).

3.7 PRODUCTS AFFECTED

Mifeprex (and pending generics) are potentially affected because they are or will only be available under a restrictive REMS.

4 RISK MANAGEMENT CONSIDERATIONS

The following factors are important to consider:

- Burden to the intended population

  It is important to ensure that the intended treatment population can receive Korlym in a timely, dependable manner in the least burdensome way. Any restrictions will impede access with little to no benefit to Cushing's syndrome population.

- Confidentiality/Privacy

  Confidentiality and patient privacy is a significant issue with Mifeprex. To what extent do stakeholders who make, distribute, dispense, prescribe, and use Korlym need protection from a confidentiality perspective?

  The purpose of a REMS is to ensure the benefits of the drug outweigh its risks. Confidentiality and concern regarding the safety of the prescribers, pharmacists, and patients does not meet criteria. Confidentiality can be maintained without a REMS. Privacy may be better maintained if there are no systems in place to track formally prescribers and patients. Risk to pharmacies that stock the drug should be considered but it is outside the purview of a REMS.

- Reproductive potential for various possible Korlym off-label use populations

As stated in section 3.4.1.2. above, there are a variety of uses for mifepristone (b) (4). The therapeutic areas included below are more likely to include females of reproductive potential than other uses (b) (4). A formal epidemiologic review was not conducted to estimate of the proportion of females of reproductive potential for each use. However, the following observations and/or assumptions were made:

(b) (4)

The degree to which Korlym will be used off label for the above uses is unknown.

- Extent of current off-label use

  Current Mifeprex drug utilization information is not informative in predicting broader uses for Korlym. In the September 19, 2011 mifepristone drug use review using commercial databases was conducted, off-label use was described as "uncommon" based on information obtained through a *sample* of medical offices and outpatient clinics. Sales distribution data was not available. The lack of findings are not surprising given the design of the Mifeprex REMS.

5 RISK MANAGEMENT OPTIONS

DRISK analyzed more than six risk management options to address intended termination of pregnancy by:

- HCPs outside of Mifeprex REMS
- women who seek to terminate a pregnancy and are not under the care of an HCP

Ultimately, three options were considered.

1. No REMS and voluntary restricted distribution through specialty pharmacies/distributors

   This REMS option may minimize diversion and subsequent misuse by minimizing the number of pharmacies stocking and dispensing Korlym for outpatient use. This option is in alignment with DMEP and DRISK's assessment that a REMS is not necessary to assure the safe use of mifepristone for treating patients with Cushing's syndrome because we believe the likelihood that a Cushing's patient experiences "serious complications" relating to pregnancy termination are low.

This approach is also consistent with misoprostol and methotrexate, both of which are known abortifacents and do not have a REMS to address that risk. This approach is used to prevent misuse of the growth hormone products.

2. REMS with ETASU – dispensing through certified specialty pharmacies

This REMS option may minimize diversion and subsequent misuse by minimizing the number of pharmacies stocking and dispensing Korlym for outpatient use. In addition, Corcept would be required to provide FDA an assessment of how the REMS is achieving its goals.

This option does not address intended termination of pregnancy with Korlym.

3. REMS with ETASU – prescriber certification (agreement not to use for termination of pregnancy) and distribution through certified specialty pharmacies that are willing to track inventory

This REMS option would minimize diversion and subsequent misuse as described above. In addition, certified pharmacies (for outpatient dispensing, not inpatient hospital pharmacies) would verify that prescribers were certified. Prescriber certification would consist of agreement not use Korlym for pregnancy termination. The addition of prescriber certification would address the risk of intended termination of pregnancy with Korlym.

These options assume that the safety labeling is maximized to address Korlym use in pregnancy.

6 DISCUSSION

The issue of how to address intended termination of pregnancy was discussed at the REMS Oversight Committee meeting on September 29, 2011 and at a Center Director Briefing on November 3, 2011.

DMEP and DRISK presented at both meetings that women with Cushing's syndrome are unlikely to be or become pregnant given the effects of their disease on the reproductive system and the effects of daily mifepristone treatment. Therefore, addressing the risk of fetal loss associated with Korlym was not discussed because 1) pregnancy is not a likely event in the intended population and; 2) the use of Korlym for "off-label" uses (in women more likely to be pregnant) is unknown and available data do not indicate that mifepristone would be first line treatment for any diseases or conditions at this time. For these reasons, there was general agreement that fetal loss can be adequately addressed through labeling and is not necessary to require additional safe use measures through a REMS at this time.

The team stated that for any risk management approach, it is important to ensure that the intended treatment population can receive Korlym in a timely, dependable manner in the least burdensome way. Any restrictions could impede access without benefit to the intended population.

The primary focus shifted to whether or not a REMS is necessary for Korlym to maintain the integrity of the Mifeprex REMS. While the absence of any restrictions on Korlym could undermine the safe use conditions required by the Mifeprex REMS, a number of other factors are important considerations including:

- The burden (reduced access, treatment delays) of a restrictive REMS to the Cushing's population without any benefit from the REMS for this population.
- Overall drug exposure and subsequent access is anticipated to be small given the small size of the intended use population and lack of a signal for substantially broader use.
- The sponsor's plan to distribute Korlym through a specialty pharmacy regardless of the REMS. If necessary, this provides the sponsor the ability to monitor use more closely.
- The cost - If the cost of this orphan product is substanial, it may be expensive to obtain and deter use for pregnancy termination as well as other off label uses. In addition, third party payors/reimbursement may play a substantial role in influencing prescribing behavior. It is unknown how much Korlym will cost and how cost will impact prescribing behavior.[13]

The need for some monitoring of use was discussed. Commercial drug use databases will not provide FDA with adequate estimates of Korlym use because Korlym will be dispensed through a specialty pharmacy. As noted above, using a single specialty pharmacy does allow the sponsor the ability to monitor use more closely through its business contract with the specialty pharmacy. Similarly, commercial drug use databases are not able to provide an accurate estimate of Mifeprex use due to how it is distributed and dispensed. The first REMS assessment for Mifeprex is due June 2012 which we anticipate will provide a baseline to quantify current Mifeprex use. Given these considerations and the discussion with the Center Director, we agree that a post-marketing requirement (PMR) study to obtain Korlym use data (age, gender, dose, duration of treatment) "to better characterize the incidence rates of adverse events with Korlym" is prudent. Monitoring drug use data for both Mifeprex and Korlym, in conjunction with reports of serious adverse events resulting from pregnancy terminations outside of the Mifeprex REMS, will be important factors in future regulatory action to address any compromise to the Mifeprex REMS.

7 CONCLUSION

A REMS for Korlym is not necessary to ensure that the benefits of the drug outweigh its risks at this time. We agree that it is prudent to monitor use through a PMR. If data indicate that this approach compromises the integrity of the Mifeprex REMS and results in serious adverse events, or additional serious safety signals arise, further regulatory action must be considered.

ATTACHMENTS

[13] Planned parenthood charges $300-800 for a medical abortion (includes diagnostic testing, mifepristone, and misoprostol).

ATTACHMENT 1: Drugs with a risk associated with an off-label use

Drug	Abortifacient Efficacy	Indication	Off-label use*	Contraindication	Boxed Warning
Misoprostol (Cytotec)	When used alone – variable (~40-60%); used in combination with MTX or MFP efficacy is higher (Source - Micromedex)	NSAID-induced gastric ulcers	• Postpartum hemorrhage • Cervical ripening, labor induction • Pregnancy termination	"Cytotec should not be taken by pregnant women to reduce the risk of ulcers induced by NSAIDs "	"Cytotec administration to women who are pregnant can cause abortion … Cytotec should not be taken by pregnant women to reduce the risk of ulcers induced by NSAIDs… Patients must be advised of the abortifacient property and warned not to give the drug to others … "
Methotrexate (MTX)	When used alone – (IM injxn – variable); in combination with misoprostol efficacy is higher (80-90%; small Ns) (Source - Micromedex)	• Cancer • Psoriasis • Rheumatoid arthritis including juvenile	• Other Autoimmune diseases • More cancer • Pregnancy termination	"MTX can cause fetal death or teratogenic effects when administered to a pregnant woman MTX is contraindicated in pregnant women with psoriasis or rheumatoid arthritis and should be used in the treatment of neoplastic diseases only when the potential benefit outweighs the risk to the fetus Women of childbearing potential should not be started on MTX until pregnancy is excluded and should be fully counseled on the serious risk to the fetus should they become pregnant while undergoing treatment "	"MTX has been reported to cause fetal death and/or congenital anomalies Therefore, it is not recommended for women of childbearing potential unless there is clear medical evidence that the benefits can be expected to outweigh the considered risks Pregnant women with psoriasis or rheumatoid arthritis should not receive MTX "

*The off-label uses are general and based on tertiary sources; not on a formal drug use analysis.

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/s/

SUZANNE C BERKMAN ROBOTTOM
01/27/2012

CLAUDIA B KARWOSKI
01/27/2012
concur

ACLU of Hawaii Foundation
JONGWOOK "WOOKIE" KIM
11020
P.O. Box 3410
Honolulu, HI 96801
T: (808) 522-5905
F: (808) 522-5909
wkim@acluhawaii.org

American Civil Liberties Union Foundation
LORIE CHAITEN*
1640 North Sedgwick Street
Chicago, IL 60614
T: (212) 549-2633
F: (212) 549-2650
rfp_lc@aclu.org

**admitted pro hac vice*

Attorneys for Plaintiffs

American Civil Liberties Union Foundation
JULIA KAYE*
RACHEL REEVES*
WHITNEY WHITE*
RUTH HARLOW*
125 Broad Street, 18th Floor
New York, NY 10004
T: (212) 549-2633
F: (212) 549-2650
jkaye@aclu.org
rreeves@aclu.org
wwhite@aclu.org
rharlow@aclu.org

Arnold & Porter Kaye Scholer LLP
JOHN A. FREEDMAN*
601 Massachusetts Ave., NW
Washington, DC 20001
T: (202) 942-5000
F: (202) 942-5999
john.freedman@arnoldporter.com

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

CERTIFICATE OF SERVICE

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on April 16, 2021, true and correct copies of the foregoing documents were electronically transmitted to the Clerk's Office using the CM/ECF System, which will send notification of such filing to all counsel of record.

DATED: Honolulu, Hawaii, April 16, 2021.

Respectfully submitted,

/s/ Jongwook "Wookie" Kim
JONGWOOK "WOOKIE" KIM
ACLU of Hawaii Foundation

Attorney for Plaintiffs