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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its member organizations, their members, and these members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

COMPLAINT

1. The U.S. Food and Drug Administration (FDA) must protect the health, safety, and welfare of all Americans by rejecting or limiting the use of dangerous drugs.

2. But the FDA failed America's women and girls when it chose politics over science and approved chemical abortion drugs for use in the United States. And it has continued to fail them by repeatedly removing even the most basic precautionary requirements associated with their use.

3. To date, the FDA's review, approval, and deregulation of chemical abortion drugs has spanned three decades, correlated with four U.S. presidential elections, and encompassed six discrete agency actions. Plaintiffs challenge these six FDA actions and ask that the Court hold them unlawful, set them aside, and vacate them.

4. Beginning in January 1993, on his second full day in office, President Bill Clinton directed his cabinet to legalize chemical abortion drugs in the United States.

5. President Clinton and his agency officials then pressured the French manufacturer of the key chemical abortion drug, mifepristone (also known as "RU-486" and "Mifeprex"), to *donate for free* the U.S. patent rights of the drug to the Population Council—as its name suggests, an entity focused on population control.

6. After receiving the patent rights to mifepristone, the Population Council submitted a new drug application, worked closely with the Clinton FDA during the review process, and, not surprisingly, obtained the agency's approval on

September 28, 2000—just over one month before the closely contested 2000 U.S. presidential election.

7. The *only* way the FDA could have approved chemical abortion drugs was to use its accelerated drug approval authority, necessitating the FDA to call pregnancy an "illness" and argue that these dangerous drugs provide a "meaningful therapeutic benefit" over existing treatments.

8. But pregnancy is not an illness, nor do chemical abortion drugs provide a therapeutic benefit over surgical abortion. In asserting these transparently false conclusions, the FDA exceeded its regulatory authority to approve the drugs.

9. What's more, the FDA needed to disavow science and the law because the FDA never studied the safety of the drugs under the labeled conditions of use despite being required to do so by the Federal Food, Drug, and Cosmetic Act (FFDCA). The agency also ignored the potential impacts of the hormone-blocking regimen on the developing bodies of adolescent girls in violation of the Pediatric Research and Equity Act (PREA). And the FDA disregarded the substantial evidence that chemical abortion drugs cause more complications than even surgical abortions.

10. Since then, the FDA has not followed the science, reversed course, or fixed its mistakes—all to the detriment of women and girls. Instead, the FDA has doubled down on its actions and removed the few safeguards that were in place.

11. In March 2016—*fourteen years* after two Plaintiffs filed a citizen petition with the FDA asking the agency to withdraw its approval of chemical

abortion drugs—the FDA rejected these Plaintiffs' petition despite their explanations that the agency violated federal laws by approving these drugs and ignoring the substantial evidence that these drugs harm women and girls.

12. On the *same day* that the FDA rejected the citizen petition and mere months before another U.S. presidential election, the FDA also made "major changes" to the chemical abortion drug regimen, eliminating crucial safeguards for pregnant women and girls.

13. For example, the FDA extended the permissible gestational age of the baby for which a pregnant woman or girl may take chemical abortion drugs—from seven weeks to ten weeks.

14. Numerous studies have demonstrated that there is an increased risk from chemical abortion drugs to pregnant women and girls as the baby's age advances from seven weeks to ten weeks because the surface area of the placenta as well as the size of the baby significantly grow during these three weeks.

15. Also in 2016, the FDA changed the dosage and route of administration for the chemical abortion drugs, reduced the number of required in-person office visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for abortionists to report non-fatal complications from chemical abortion drugs—without requiring any objective clinical investigations or studies that evaluated the safety and effectiveness of this new chemical abortion regimen or any safety assessment of its effects on the developing bodies of girls under 18 years of age.

16. These major changes failed to satisfy the rigorous scientific standards of the FFDCA and violated PREA's requirement for a specific safety assessment of these changes on pregnant girls who undergo the revised chemical abortion drug regimen.

17. Realizing a profit-making opportunity in the rapidly growing chemical abortion business, another entity sought the FDA's approval to market and distribute a generic version of mifepristone. In 2019, the FDA obliged and approved the generic drug—without requiring any new clinical investigations or studies that evaluated the drug's safety and effectiveness under the requirements of the FFDCA, nor any specific safety assessments on girls as set forth under PREA.

18. A couple of years later, in April of 2021, shortly after President Joe Biden took office, the FDA's new management issued a "Non-Enforcement Decision" by which the agency would stop enforcing its requirement that abortionists provide in-person dispensing of mifepristone and instead would temporarily allow mail-order chemical abortions during the COVID-19 public health emergency.

19. In December 2021—*two-and-a-half years* after two Plaintiffs filed a citizen petition asking the FDA to restore and strengthen the pre-2016 chemical abortion drug regimen or, at minimum, to preserve the few remaining safeguards for women and girls—the FDA rejected almost all of these Plaintiffs' citizen petition. The FDA issued its denial despite their discussion of how the agency violated the law by ignoring the growing and substantial evidence that these dangerous drugs harm women and girls.

20. On the *same day* that it rejected the citizen petition, the Biden FDA also announced that it would permanently allow abortionists to send chemical abortion drugs through the mail.

21. This decision not only harms women and girls who voluntarily undergo chemical abortions, but it also further helps sex traffickers and sexual abusers to force their victims into getting abortions while preventing the authorities from identifying these victims.[1] In fact, the State of Texas has recognized that "[d]ue to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking."[2]

22. In addition to the legal and scientific infirmities referenced above, all of the FDA's actions on chemical abortion drugs—the 2000 approval, the 2016 major changes, the 2019 generic drug approval, and the two 2021 actions to eliminate the in-person dispensing requirement—failed to acknowledge and address the federal laws that prohibit the distribution of chemical abortion drugs by postal mail,

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[1] *See, e.g.,* Ex. 1, Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, Annals of Health Law, Winter 2014 at 61Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, Annals of Health Law, Winter 2014 at 61, 73, 77–78 (noting that survivors in study "reported that they often did not freely choose the abortions they had while being trafficked," these "[s]urvivors [] had significant contact with clinical treatment facilities, most commonly Planned Parenthood clinics," and that "these points of contact with healthcare represent rare opportunities for victim identification and intervention.").

[2] Ex. 2, C.S.H.B. 3446, H. Comm. Rpt., 84th Legis. (Mar. 12, 2015), https://capitol.texas.gov/tlodocs/84R/analysis/pdf/HB03446H.pdf (a subsequent, similar version was codified at Tex. Health & Safety Code § 245.025).

express company, or common carrier. *See* 18 U.S.C. §§ 1461, 1462. Instead, the FDA's actions permitted and sometimes even encouraged these illegal activities.

23. After two decades of engaging the FDA to no avail, Plaintiffs now ask this Court to do what the FDA was and is legally required to do: protect women and girls by holding unlawful, setting aside, and vacating the FDA's actions to approve chemical abortion drugs and eviscerate crucial safeguards for those who undergo this dangerous drug regimen.

JURISDICTION AND VENUE

24. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action raises federal questions under the Administrative Procedure Act (APA), 5 U.S.C. §§ 553, 701–06, and the FFDCA, 21 U.S.C. § 301 *et seq*.

25. This Court also has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

26. Additionally, this Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

27. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the APA, 5 U.S.C. §§ 553, 701–06.

28. This Court has jurisdiction to issue equitable relief to enjoin ultra vires agency action under an equitable cause of action. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

29. This case seeks declaratory, injunctive, and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–02, 5 U.S.C. §§ 705–06, Federal Rule of Civil Procedure 57, and the Court's inherent equitable powers.

30. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

31. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of the action is situated here. This district and this division are where Plaintiffs Alliance for Hippocratic Medicine, including the doctors of its member associations, and Dr. Shaun Jester are situated and are injured by Defendants' actions. Defendants are United States agencies or officers sued in their official capacities. A substantial part of the events or omissions giving rise to the Complaint occurred within the Northern District of Texas.

PLAINTIFFS

32. Four national medical associations and four doctors experienced in caring for pregnant and post-abortive patients bring this case. They seek to protect women and girls from the documented dangers of chemical abortion drugs.

33. Plaintiff Alliance for Hippocratic Medicine is a nonprofit membership organization that upholds and promotes the fundamental principles of Hippocratic medicine: protecting the vulnerable at the beginning and end of life; seeking the ultimate good for the patient with compassion and moral integrity; and providing health care with the highest standards of excellence based on medical science. The

Alliance for Hippocratic Medicine's members currently are the American Association of Pro-Life Obstetricians and Gynecologists, the American College of Pediatricians, the Catholic Medical Association, the Christian Medical & Dental Associations, and the Coptic Medical Association of North America. The Alliance for Hippocratic Medicine is incorporated in the State of Texas and has its registered agent in Amarillo, Texas. The Alliance for Hippocratic Medicine seeks relief on behalf of itself, its current and future member organizations, their members, and these members' patients. Mr. Mario Dickerson and Drs. Donna Harrison, Jeffrey Barrows, and Quentin Van Meter submit declarations in support of the Alliance for Hippocratic Medicine.[3]

34. Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) is a nonprofit organization that encourages and equips its members and other concerned medical practitioners to provide an evidence-based rationale for defending the lives of both the pregnant mother and her unborn child. AAPLOG aims to make known the evidence-based effects of abortion on women as well as the scientific fact that human life begins at the moment of fertilization, with the goal that all women, regardless of race, creed, or national origin, will be empowered to make healthy and life-affirming choices. AAPLOG is incorporated in the State of Florida, and headquartered in Indiana. AAPLOG has individual members in Texas. AAPLOG seeks relief on behalf of itself, its current and future

[3] Ex. 3, Dickerson Decl. ¶ 7; Ex. 4, Harrison Decl. ¶ 6, 13; Ex. 5, Barrows Decl. ¶ 2; Ex. 6, Van Meter Decl. ¶ 6.

members, and their patients. Drs. Donna Harrison, Christina Francis, Ingrid Skop, and Nancy Wozniak submit declarations in support of AAPLOG.[4]

35. Plaintiff American College of Pediatricians is a national organization of pediatricians and other health care professionals. The American College of Pediatricians is a nonprofit organization founded in 2002, is incorporated in the State of Tennessee, and has its registered agent in Tennessee. The American College of Pediatricians' membership includes more than 600 physicians and other health care professionals drawn from 47 different states across the nation. The American College of Pediatricians has members within this judicial district and elsewhere in the State of Texas. The American College of Pediatricians seeks relief on behalf of itself, its current and future members, and their patients. Dr. Quentin Van Meter submits a declaration in support of the American College of Pediatricians.[5]

36. Plaintiff Christian Medical & Dental Associations is a national nonprofit organization, headquartered in the State of Tennessee, of Christian physicians, dentists, and allied health care professionals, with over 13,000 members nationwide, including 1,237 overall members in Texas, of whom 607 are practicing or retired physicians, and 35 are OB/Gyns. The Christian Medical & Dental Associations sues on behalf of itself, its current and future members, and their

[4] Ex. 4, Harrison Decl. ¶ 5; Ex. 7, Francis Decl. ¶ 4; Ex. 8, Skop Decl. ¶ 4; Ex. 9, Wozniak Decl. ¶ 3.

[5] Ex. 6, Van Meter Decl. ¶ 6.

patients. Drs. Jeffrey Barrows and Steven Foley submit declarations in support of the Christian Medical & Dental Associations.[6]

37. Plaintiff Dr. Shaun Jester, D.O, is a board-certified obstetrician and gynecologist and the Medical Director of Moore County OB/Gyn in Dumas, Texas. His practice includes cesarean section deliveries, hysterectomies, and other women's health treatments. He has treated women who have had abortions, including one woman who suffered an adverse event from a chemical abortion, for which he submitted an adverse event report to the FDA. Dr. Jester sues on his own behalf and on behalf of his current and future patients.

38. Plaintiff Dr. Regina Frost-Clark, M.D., is a board-certified doctor in obstetrics and gynecology. She practices with Ascension Medical Group St. John OB/Gyn Associates in Saint Clair Shores, Michigan. Dr. Frost-Clark has treated several women who have suffered complications from chemical abortions, many who presented to the emergency room. Dr. Frost-Clark sues on her own behalf and on behalf of her current and future patients.

39. Plaintiff Dr. Tyler Johnson, D.O., is an emergency department physician certified by the American Board of Emergency Medicine. Based out of Leo, Indiana, Dr. Johnson serves as the director of emergency medicine at Parkview Dekalb Hospital and practices in the emergency departments of hospitals throughout northern Indiana. He has treated women in the emergency department

[6] Ex. 5, Barrows Decl. ¶ 2; Ex. 10, Foley Decl. ¶ 5.

suffering complications from chemical abortion. Dr. Johnson sues on his own behalf and on behalf of his current and future patients.

40. Plaintiff Dr. George Delgado, M.D., is board-certified in family medicine and in hospice and palliative medicine. He serves as the director of medical affairs of Culture of Life Family Services, which based out of Escondido, California, and provides comprehensive medical care and pro-life pregnancy clinic services for women and children. He also serves as a medical advisor to the Abortion Pill Rescue Network. Dr. Delgado established the Abortion Pill Reversal program—a process that can reverse the effects of the chemical abortion drug regimen and allow women and girls to continue their pregnancies.[7] He has treated women suffering complications from chemical abortion and seeking to reverse the effects of chemical abortion. Dr. Delgado sues on his own behalf and on behalf of his current and future patients.

DEFENDANTS

41. Defendant FDA is an agency of the United States government within the United States Department of Health and Human Services (HHS). The Secretary of HHS has delegated to the FDA the authority to administer the provisions of the FFDCA for approving new drug applications and authorizing a risk evaluation and mitigation strategy (REMS) for dangerous drugs. The address of the FDA's headquarters is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

[7] Abortion Pill Reversal, https://www.abortionpillreversal.com/abortion-pill-reversal/overview (last visited Nov. 17, 2022).

42. Defendant Robert Califf, M.D., who is being sued in his official capacity, is the Commissioner of Food and Drugs at the FDA. He is responsible for supervising the activities of the FDA, including the approval of new drug applications and the issuance, suspension, waiver, or removal of a REMS. Defendant Califf's address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

43. Defendant Janet Woodcock, M.D., who is being sued in her official capacity, is the Principal Deputy Commissioner, Office of the Commissioner, at the FDA. She works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and oversees the agency's day-to-day functions. Defendant Woodcock served as the Acting Commissioner of Food and Drugs from January 20, 2021, until February 17, 2022, and previously was the Director of the FDA's Center for Drug Evaluation and Research. Defendant Woodcock's address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

44. Defendant Patrizia Cavazzoni, M.D., who is being sued in her official capacity, is the Director of the FDA's Center for Drug Evaluation and Research. She is responsible for the regulation of drugs throughout their lifecycle, the development of new and generic drugs, the evaluation of applications to determine whether drugs should be approved, the monitoring of the safety of drugs after they are marketed, and the taking of enforcement actions to protect the public from harmful drugs.

Defendant Cavazzoni's address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

45. Defendant HHS is a federal agency within the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). Its address is 200 Independence Avenue SW, Washington, D.C. 20201.

46. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity. He is responsible for the overall operations of HHS, including the FDA. His address at HHS is 200 Independence Avenue SW, Washington, D.C. 20201.

47. Collectively and as applicable, all defendants are referred to herein as the "FDA" or "Defendants." Plaintiffs also sue Defendants' employees, agents, and successors in office.

48. The federal officials are subject to the APA. 5 U.S.C. § 701(b); 5 U.S.C. § 551(1).

FACTUAL ALLEGATIONS

I. Introduction

49. This case challenges the FDA's failure to abide by its legal obligations to protect the health, safety, and welfare of women and girls[8] when the agency authorized the chemical abortion drugs mifepristone and misoprostol for use in the

[8] The FDA's approval of chemical abortion lacks an age restriction and, therefore, permits the use of the drug regimen by a pregnant girl of any age under 18 years.

United States and subsequently eliminated necessary safeguards for pregnant women and girls who undergo this dangerous drug regimen.

50. *First*, the FDA never had the authority to approve these drugs for sale. In 2000, the FDA approved chemical abortion drugs under 21 C.F.R. § 314, Subpart H (Subpart H). This regulation authorizes the FDA to grant "accelerated approval" of "certain 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." 21 C.F.R. § 314.500 (emphasis added).

51. But chemical abortion drugs do not treat serious or life-threatening illnesses. Indeed, pregnancy is a normal physiological state that many females experience one or more times during their childbearing years. Pregnancy rarely leads to complications that threaten the life of the mother or the child. Following delivery, almost all women return to a normal routine without disability.[9]

52. Likewise, chemical abortion drugs do not provide a "meaningful therapeutic benefit" to women and girls over existing treatments.

53. To the contrary, the FDA's approval of chemical abortion drugs has potentially serious and life-threatening effects on women and girls, especially when

[9] Ex. 11, Byron Calhoun, *The maternal mortality myth in the context of legalized abortion,* 80 The Linacre Quarterly 264, 264–276 (2013); James Studnicki & Tessa Longbons, *Pregnancy Is* Not *More Dangerous Than Abortion*, Nat'l Rev. (Aug. 28, 2022, 6:30 AM), https://www.nationalreview.com/2022/08/pregnancy-is-not-more-dangerous-than-abortion/.

compared to surgical abortion, which uses medical devices and tools to physically remove a baby from inside the pregnant mother.

54. Even though endocrine disruptors such as mifepristone could have significant impacts on an adolescent girl's developing body and reproductive system, the FDA never required an assessment that evaluated the safety and effectiveness of chemical abortion drugs on pregnant girls under 18 years of age.

55. *Second*, the FDA has not only continued to keep chemical abortion drugs on the market, but the agency has also eliminated the few safeguards it initially established to protect women and girls who go through the chemical abortion drug regimen.

56. In particular, in 2016, the FDA (1) increased the gestational age for which a pregnant woman or girl may have a chemical abortion from 49 days' gestation to 70 days' gestation; (2) changed the dosage and route of administration for the chemical abortion drugs; (3) reduced the number of required in-person office visits from three to one; (4) allowed non-doctors to prescribe and administer chemical abortions; (5) failed to require a clinical study to determine the safety of these changes to the chemical abortion drug regimen on pregnant girls under 18 years of age; and (6) eliminated the requirement for prescribers to report nonfatal adverse events from chemical abortion—thus ensuring that the FDA and the public would never learn of the dangers and injuries that would befall women and girls from removing these safeguards.

57. What is more, in 2021, the FDA announced that it would allow abortionists to dispense the chemical abortion drugs by mail or mail-order pharmacy—an action that a longstanding federal law independently and expressly prohibits.

58. Plaintiffs now ask this Court to protect women and girls by holding unlawful, setting aside, and vacating the FDA's actions to approve and eliminate the safeguards for those who take chemical abortion drugs.

II. The Chemical Abortion Regimen and Its Adverse Health Effects

59. The chemical abortion drug regimen requires the use of two drugs: (1) mifepristone (also known as "RU-486" and "Mifeprex") and (2) misoprostol.

60. As an endocrine disruptor, mifepristone is a synthetic steroid that blocks progesterone receptors in the uterus of a woman or girl. The hormone progesterone is necessary for the healthy growth of a baby and the maintenance of a pregnancy. When a woman or girl ingests the chemical abortion drug mifepristone, the drug blocks the action of the natural hormone progesterone, chemically destroys the baby's environment in the uterus, blocks nutrition to the baby, and ultimately starves the baby to death in the mother's womb.[10]

61. Because mifepristone alone works less than 25 percent of the time to complete the abortion, the FDA's chemical abortion drug regimen mandates the use

[10] *See* Ex. 4, Harrison Decl. at ¶ 21; Ex. 8, Skop Decl. at ¶ 10; Ex. 12, *The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform*, 109th Cong. 4 (2006).

of a second drug—misoprostol—to induce cramping and contractions in an attempt to expel the baby from the mother's womb.[11]

62. The only other FDA-approved use of misoprostol is to reduce the risk of gastric ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs) in patients at high risk of complications from gastric ulcers and patients at high risk of developing gastric ulceration.[12] Misoprostol's label warns that the drug "should not be taken by pregnant women to reduce the risk of ulcers" by NSAIDs.[13]

63. The use of these two chemical abortion drugs causes significant injuries and harms to pregnant women and girls.

64. For example, upwards of ten percent (10%) of women who take chemical abortion drugs will need follow-up medical treatment for an incomplete or failed chemical abortion,[14] with an average of thirty-nine percent (39%) of women requiring surgery if taken in the second trimester.[15]

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[11] *See* Ex. 4, Harrison Decl. at ¶ 21; Ex. 13, 2002 Citizen Petition of AAPLOG to FDA at 41 n.187 (Aug. 8, 2002); *see also* FDA-Approved Label for Mifepristone (Mifeprex) (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[12] *See, e.g.,* Ex. 14, FDA-Approved Label for Misoprostol (Cytotec) (Jan. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf.

[13] *Id.*

[14] Ex. 18, Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BJM, April 20, 2011, at 4.

[15] Ex. 15, Maarit J. Mentula et al., *Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study*, 26 Hum. Reprod. 927, 931 (2011).

65. Twenty percent (20%) of females will have an adverse event after taking chemical abortion drugs—a rate four times higher than with surgical abortion. This includes over fifteen percent (15%) of females experiencing hemorrhaging and two percent (2%) having an infection during or after taking chemical abortion drugs.[16]

66. Chemical abortions are over fifty percent (50%) more likely than surgical abortions to result in an emergency department visit within thirty days, affecting one in twenty females.[17]

67. The number of chemical abortion-related emergency room visits increased by over five hundred percent (500%) between 2002 and 2015.[18]

68. For those women and girls who take chemical abortion drugs, there is a significant increase in risk of complications as the baby's gestational age increases. One study found that, after nine weeks' gestation, almost four times as many women and girls experience an incomplete abortion, nearly twice as many suffer an infection, and over six times as many women and girls require surgical abortion after consuming the chemical abortion drugs.[19]

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[16] Ex. 16, Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

[17] Ex. 17, James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions*, *1999-2015*, Health Serv. Rsch. & Managerial Epidemiology, Nov. 9, 2021.

[18] *Id* at 5.

[19] Ex. 18, Niinimaki, *supra* note 14, at 5.

69. Chemical abortion drugs have heightened risks for women and girls with certain blood types. In fact, if a woman or girl with a Rh-negative blood type is not administered certain medication (Rhogam) at the time of her chemical abortion, she could experience isoimmunization, which threatens her ability to have future successful pregnancies. If an Rh-negative woman or girl is left untreated, her future baby will have a fourteen percent (14%) chance of being stillborn and a fifty percent (50%) chance of being born alive but suffering neonatal death or brain injury. Around fifteen percent (15%) of the U.S. population is at risk of this blood condition.[20]

70. Some abortion activists encourage women to lie to an emergency department doctor by saying they are having a miscarriage if they suffer complications requiring urgent care.[21] If a chemical abortion is miscoded as a miscarriage in the emergency room (which occurred sixty percent (60%) of the time in one study), the treating doctor's lack of knowledge results in the woman or girl

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[20] Ingrid Skop, *The Evolution of "Self-Managed" Abortion: Does the Safety of Women Seeking Abortion Even Matter Anymore?*, Charlotte Lozier Institute (Mar. 1, 2022), https://lozierinstitute.org/the-evolution-of-self-managed-abortion/.

[21] *See, e.g., Will a doctor be able to tell if you've taken abortion pills?*, Women Help Women (Sept. 23, 2019), https://womenhelp.org/en/page/1093/will-a-doctor-be-able-to-tell-if-you-ve-taken-abortion-pills; *How do you know if you have complications and what should you do?*, AidAccess, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do (last visited Nov. 14, 2022).

being at significantly greater risk of needing multiple hospitalizations and follow-up surgery.[22]

71. The risk of chemical abortions is not only physical: women and girls have described that their chemical abortion experiences harmed their mental health and left them feeling unprepared, silenced, regretful, or left with no other choice before undergoing a chemical abortion.[23]

72. Abortionists exacerbate this harm to a woman's or girl's mental health by not adequately informing her about what she will see when she self-administers chemical abortion drugs at home or in a hotel. For example, one woman was surprised and saddened to see that her aborted baby "had a head, hands, and legs" with "[d]efined fingers and toes."[24]

73. Given the FDA's refusal to require an ultrasound, abortionists can egregiously misdate the gestational age of a baby with devastating consequences. One young woman has alleged that she did not receive an ultrasound or any other physical examination to determine her baby's gestational age prior to receiving

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[22] Ex. 19, James Studnicki et al., *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, Health Servs. Rsch. & Managerial Epidemiology, May 20, 2022.

[23] Ex. 20, Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Commc'n 1485 (2021).

[24] Caroline Kitchener, *Covert network provides pills for thousands of abortions in U.S. post Roe*, Wash. Post: Politics (Oct. 18, 2022, 6:00 am), https://www.washingtonpost.com/politics/2022/10/18/illegal-abortion-pill-network/.

chemical abortion drugs from Planned Parenthood.[25] The abortionist misdated the baby's gestational age as six weeks, resulting in the at-home delivery of a "lifeless, fully-formed baby in the toilet," later determined to be around *30-36 weeks old*.[26] Because of this chemical abortion, the woman alleges that she "has endured significant stress, trauma, emotional anguish, physical pain, including laceration and an accelerated labor and delivery unaided by medication, lactation, soreness, and bleeding."[27]

III. The FDA's Authority to Review, Approve, or Deny New Drug Applications

74. The FDA's approval of new drugs must comply with federal laws and regulations that directly govern the agency, in addition to other laws that broadly govern the federal government's actions. Specifically, the FDA must comply with the Federal Food, Drug, and Cosmetic Act (FFDCA), the Pediatric Research Equity Act of 2003 (PREA), and the agency's regulations. When taking regulatory action on new drugs, the FDA must also meet the requirements of other federal laws restricting the distribution of certain drugs.[28]

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[25] Complaint at 9, *Doe v. Shah*, No. 501531/2021, (Sup. Ct. of N.Y., Cnty. of Kings Jan. 20, 2021), https://www.liveaction.org/news/wp-content/uploads/2022/10/Kings-Co-501531_2021_JANE_DOE_v_MEERA_SHAH.pdf.

[26] *Id.* at 10–11.

[27] *Id.* at 11.

[28] For a general overview of the FDA's drug approval process, *see How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, Congressional Research Service (May 8, 2018), https://crsreports.congress.gov/product/pdf/R/R41983.

A. New Drug Applications Under the Federal Food, Drug, and Cosmetic Act

75. Under the FFDCA, anyone seeking to introduce into commerce and distribute any new drug in the United States must first obtain the FDA's approval by filing a new drug application (NDA). 21 U.S.C. § 355(a).

76. A drug may be considered "new" by reason of the "newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body." 21 C.F.R. § 310.3(h)(4). A drug may also be considered "new" by reason of the "newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug . . . is not a new drug." *Id.* § 310.3(h)(5).

77. The NDA must contain extensive scientific data showing the safety and effectiveness of the drug. 21 U.S.C. § 355(d); 21 C.F.R. § 314.125.

78. Under the FFDCA, the FDA must reject an application if the clinical investigations "do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(2).

79. The FDA must also reject an application if "the results of such tests show that such drug is unsafe for use under such conditions or do not show that

such drug is safe for use under such conditions." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(3).

80. The FDA shall refuse an application if, based upon information submitted to the agency or upon the basis of any other information before the agency, the FDA "has insufficient information to determine whether such drug is safe for use under such conditions." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(4).

81. Finally, the FDA must deny an application if "there is a lack of substantial evidence that the new drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(5).

82. The FFDCA defines "substantial evidence" as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d).

83. If a sponsor of an approved drug subsequently seeks to change the labeling, market a new dosage or strength of the drug, or change the way it manufactures a drug, the company must submit a supplemental new drug

application (sNDA) seeking the FDA's approval of such changes. 21 U.S.C. § 355(b); 21 C.F.R. §§ 314.54, 314.70.

84. Only the sponsor "may submit a supplement to an application." 21 C.F.R. § 314.71(a).

85. "All procedures and actions that apply to an application under [21 C.F.R.] § 314.50 also apply to supplements, except that the information required in the supplement is limited to that needed to support the change." 21 C.F.R. § 314.71(b); *see also* 21 C.F.R. § 314.54(a) ("application need contain only that information needed to support the modification(s) of the listed drug").

86. The sNDA must also show that the drug is safe and effective for "the conditions of use prescribed, recommended, or suggested in the proposed labeling." 21 U.S.C. § 355(d).

87. The FFDCA allows a generic drug manufacturer to submit an abbreviated new drug application (ANDA) for approval to introduce into commerce and distribute a generic version of an approved drug. 21 U.S.C. § 355(j).

88. In the ANDA, the generic drug manufacturer must show, among other things, that (a) the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed and (b) the drug product is chemically the same as the already approved drug, allowing it to rely on the FDA's previous finding of safety and effectiveness for the approved drug. The route of administration, dosage form, and strength must also be the same. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94.

B. Assessments on Pediatric Populations

89. In 1998, the FDA issued a regulation, called the Pediatric Rule, requiring an assessment specifically powered to determine the safety and effectiveness of a new drug on pediatric patients.[29] This rule allowed for full or partial waivers of its pediatric assessment requirements, set forth under then 21 C.F.R. § 314.55(c).

90. A federal district court subsequently held that the FDA had exceeded its statutory authority when issuing the Pediatric Rule and thus enjoined the FDA from enforcing the regulation. *See Ass'n of Am. Physicians & Surgeons v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002).

91. In response, President George W. Bush and Congress enacted PREA to codify the Pediatric Rule legislatively. This law expressly requires studies on the safety and effectiveness of drugs intended for pediatric populations, unless certain exceptions apply. The FDA may require an assessment on the drug's safety and effectiveness, extrapolate findings from studies on adult populations, or waive the assessment for pediatric populations. 21 U.S.C. § 355c.

92. In general, PREA requires an application or supplement to an application for a drug to include an assessment on the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations. 21 U.S.C. § 355c(a)(2)(A)(i). This assessment must also support dosing and

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[29] Ex. 21, Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998).

administration for each pediatric subpopulation for which the drug is safe and effective. 21 U.S.C. § 355c(a)(2)(A)(ii).

93. Under limited circumstances, PREA allows the FDA to avoid this assessment and, instead, extrapolate the safety and effectiveness of a drug for pediatric populations: "If the course of the *disease* and the effects of the drug are sufficiently similar in adults and pediatric patients, the [FDA] may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients." 21 U.S.C. § 355c(2)(B)(i) (emphasis added).

94. To support this extrapolation, the FDA must include "brief documentation of the scientific data supporting the conclusion" that the course of the *disease* and the effects of the drug are sufficiently similar in adults and pediatric patients. 21 U.S.C. § 355c(B)(iii) (emphasis added).

95. In addition, PREA also allows the FDA to grant a full or partial waiver of the requirement for pediatric assessments or reports on the investigation for a drug if one of the following situations exists: (1) "necessary studies are impossible or highly impracticable"; (2) "there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups"; or (3) the drug "does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients" and it "is not likely to be used in a substantial number of pediatric patients." 21 U.S.C. § 355c(a)(5)(A), (B).

96. PREA also deemed a waiver or deferral issued under the Pediatric Rule between April 1, 1999, and December 3, 2003, to be a waiver or deferral under 21 U.S.C. § 355c(a). 21 U.S.C. § 355c note.

C. Subpart H Regulations for Accelerated Approval of Certain New Drugs for Serious and Life-Threatening Illnesses

97. Both the FFDCA and PREA serve as the primary laws governing the FDA's review and approval of new drugs. The FDA has also implemented certain regulations to effectuate its legal obligations under these laws and to address certain public health crises over the years.

98. For example, on December 11, 1992, the FDA published the final rule, "New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval."[30]

99. This final rule established procedures "under which FDA will accelerate approval of certain new drugs and biological products for *serious or life-threatening illnesses*, with provision for required continued study of the drugs' clinical benefits after approval or for restrictions on distribution or use, where those are necessary for safe use of the drugs."[31]

100. The FDA intended these procedures "to provide expedited marketing of drugs for patients suffering from *such illnesses* when the drugs provide a *meaningful therapeutic advantage* over existing treatment."[32]

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[30] Ex. 22, New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942 (Dec. 11, 1992).

[31] *Id.* (emphasis added).

[32] *Id.* (emphasis added).

101. As codified under Subpart H, the FDA defined the scope of the new regulations:

> This subpart applies to certain 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 (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

21 C.F.R. § 314.500 (emphasis added).

102. If the FDA's review under Subpart H concludes that a drug is effective but can be safely used *only if* distribution or use is restricted, the agency must "require such postmarketing restrictions as are needed to assure safe use of the drug product." 21 C.F.R. § 314.520(a).

103. Such restrictions may include distribution (1) "restricted to certain facilities or physicians with special training or experience" or (2) "conditioned on the performance of specified medical procedures." 21 C.F.R. § 314.520(a)(1), (2).

104. The limitations must "be commensurate with the specific safety concerns presented by the drug product." 21 C.F.R. § 314.520(b).

105. Under 21 C.F.R. § 314.530, the FDA may withdraw approval of drugs approved under Section 314.520 if:

> (1) A postmarketing clinical study fails to verify clinical benefit;
>
> (2) The applicant fails to perform a required postmarketing study with due diligence;
>
> (3) Use after marketing demonstrates that postmarketing restrictions are inadequate to assure safe use of the drug product;
>
> (4) The applicant fails to adhere to the postmarketing restrictions agreed upon;

(5) The promotional materials are false or misleading; or

(6) Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

106. The FDA's preamble to the Subpart H rulemaking stated that "[t]he burden is on the applicant to ensure that the conditions of use under which the applicant's product was approved are being followed."[33]

107. The *only* way the FDA can terminate an applicant's Subpart H restrictions is to notify the applicant that "the restrictions . . . no longer apply" because the "FDA [has] determine[d] that safe use of the drug product can be assured through appropriate labeling." 21 C.F.R. § 314.560.

D. Drugs Approved with Previous Subpart H Restrictions Deemed to Have Risk Evaluation and Mitigation Strategies

108. Congress decided to codify into law the FDA's postmarketing regulations under Subpart H when it enacted the Food and Drug Administration Amendments Act of 2007 (FDAAA) and created a new section of the FFDCA under 21 U.S.C. § 355-1. This new section authorizes the FDA to require persons submitting certain new drug applications to submit and implement a risk evaluation and mitigation strategy (REMS) if the FDA determines that a REMS is "necessary to ensure that the benefits of a drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a).

109. Section 909(b)(1) of the FDAAA specified that a "drug that was approved before the effective date of this Act is . . . deemed to have in effect an

[33] Ex. 22, 57 Fed. Reg. at 58,952.

approved [REMS] . . . if there are in effect on the effective date of this Act elements to assure safe use [pursuant to Subpart H, 21 C.F.R. § 514.520]." H.R. 3580, 110th Cong. (2007). Thus, if the FDA previously attached postmarketing restrictions on a drug approved under Subpart H, the FDAAA converted those restrictions into a REMS.

110. Under the FDAAA, to allow safe access to drugs with known serious risks, the FDA may require that the REMS "include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness" if the agency determines that the drug "is associated with a serious adverse drug experience." 21 U.S.C. § 355-1(f)(1).

111. These "Elements to Assure Safe Use" (ETASU) may require (1) prescribers of the drug "have particular training or experience" or be "specially certified," (2) practitioners or health care settings that dispense the drug be "specially certified," (3) doctors dispense the drug to patients "only in certain health care settings, such as hospitals," (4) doctors dispense the drug to patients "with evidence or other documentation of safe-use conditions, such as laboratory test results," (5) each patient be subject to "certain monitoring," and (6) each patient be enrolled in a "registry." 21 U.S.C. § 355-1(f)(3).

112. The FDA may also require an applicant to monitor and evaluate implementation of the REMS, in addition to working to improve those elements. 21 U.S.C. § 355-1(g).

113. The FDA may also include a communication plan to health care providers as part of the REMS to disseminate certain information about the drug and its risks. 21 U.S.C. § 355-1(e)(3).

114. An applicant "may propose the addition, modification, or removal of [the REMS] . . . and shall include an adequate rationale to support such proposed addition, modification, or removal." 21 U.S.C. § 355-1(g)(4)(A).

IV. Federal Laws Restrict Distribution of Chemical Abortion Drugs

115. Two federal laws restrict the distribution of abortion-inducing drugs. 18 U.S.C. §§ 1461–62. These laws apply to both upstream and downstream distribution.

116. *First*, 18 U.S.C. § 1461 prohibits the use of postal "mails" to convey or deliver chemical abortion drugs. Specifically, it prohibits the mailing or delivery by any letter carrier of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article, instrument, substance, drug, medicine, or thing, which is advertised or described in a manner calculated to lead to another to use or apply it for producing abortion."

117. *Second*, 18 U.S.C. § 1462 broadly prohibits the use of "any express company or other common carrier" to transport abortion drugs in interstate or foreign commerce. Specifically, it prohibits the use of any express company or common carrier to distribute "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion."

V. The FDA's Review of the Population Council's Application to Market Chemical Abortion Drugs in the United States

118. The French pharmaceutical company Roussel Uclaf S.A. first developed and tested mifepristone under the name RU-486. By April 1990, the drug had become fully available in France.[34]

119. But Roussel Uclaf's German parent company, Hoechst AG, prohibited the drug manufacturer from attempting to enter the U.S. market and filing a new drug application with the FDA.[35] Hoechst's resistance and desire to keep a low profile was due, in part, to its corporate history and complicity in previous mass genocide.[36]

120. Nevertheless, on January 22, 1993—his second full day in office—President Bill Clinton directed then-HHS Secretary Donna Shalala to assess initiatives to promote the testing and licensing of RU-486 in the United States.[37]

121. According to a Roussel Uclaf official, President Clinton also wrote to Hoechst asking the company to file a new drug application with the FDA, which Hoechst refused to do.[38]

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[34] Ex. 13, 2002 Citizen Petition at 7–8.

[35] *Id* at 8.

[36] Julie A. Hogan, *The Life of the Abortion Pill in the United States*, at 23–24 (2000), http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852153 ("Hoechst traces its corporate history to I.G. Farben, the manufacturer of Zyklon-B, which was used in the gas chambers of Auschwitz," and therefore "did not want to be credited with doing to fetuses what the Nazis had done to the Jews.").

[37] Ex. 13, 2002 Citizen Petition at 8.

[38] *Id.*

122. In early 1993, as HHS later reported, Secretary Shalala and then-FDA Commissioner David Kessler likewise "communicated with senior Roussel Uclaf officials to begin efforts to pave the way for bringing RU-486 into the American marketplace."[39]

123. Specifically, according to HHS, "[i]n April 1993, representatives of FDA, Roussel Uclaf and the Population Council, a not-for-profit organization, met to discuss U.S. clinical trials and licensing of RU-486." Between April 1993 and May 1994, the parties continued their negotiations.[40]

124. "The Population Council is a nonprofit founded in 1952 by John D. Rockefeller III to address supposed world overpopulation. . . . [Rockefeller] served as the organization's first president."[41]

125. The talks between the FDA, the Population Council, and Roussel Uclaf culminated in what HHS called a "donation": Roussel Uclaf transferred, "without remuneration, its United States patent rights to mifepristone (RU-486) to the Population Council."[42]

126. After obtaining the American patent rights to mifepristone, the Population Council conducted clinical trials in the United States.[43]

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[39] *Id.* (quoting HHS Fact Sheet, *Mifepristone (RU-486): Brief Overview* (May 16, 1994)).

[40] HHS Fact Sheet, *Mifepristone (RU-486): Brief Overview*.

[41] Population Council, https://www.influencewatch.org/non-profit/population-council/ (last visited Nov. 15, 2022).

[42] Ex. 13, 2002 Citizen Petition at 8–9 (quoting HHS Press Release, *Roussel Uclaf Donates U.S. Patent Rights for RU-486 to Population Council*, (May 16, 1994)).

[43] *Id.* at 9.

127. The Population Council then filed a new drug application for "mifepristone 200 mg tablets" on March 18, 1996.[44]

128. The FDA initially accorded the drug standard review; but in a May 7, 1996, letter, the FDA's Center for Drug Evaluation and Research notified the Population Council that mifepristone would receive priority review.[45]

129. On September 18, 1996, the FDA issued a letter stating that the application was "approvable" and requested more information from the Population Council.[46]

130. On February 18, 2000, the FDA issued a second "approvable" letter, setting forth the remaining prerequisites for approval. This letter announced that the FDA had "considered this application under the restricted distribution regulations contained in 21 C.F.R. § 314.500 (Subpart H) and [had] concluded that restrictions as per [21] CFR § 314.520 on the distribution and use of mifepristone are needed to assure safe use of this product."[47]

131. The FDA told the Population Council that the agency would proceed under Subpart H because the FDA "concluded that adequate information has not been presented to demonstrate that the drug, when marketed in accordance with the terms of distribution proposed, is safe and effective for use as recommended."[48]

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[44] *Id.* at 10.
[45] *Id.*
[46] *Id.* at 10–11.
[47] Ex. 23, FDA Letter to Population Council re: NDA (Feb. 18, 2000) at 5.
[48] *Id.*

132. Given the known dangers of chemical abortion drugs, the FDA needed to approve the Population Council's application under Subpart H because this regulatory authority provided the FDA with the *only* means to restrict the drugs' distribution and use "to assure safe use." 21 C.F.R. 314.520.

133. In response to the proposed Subpart H consideration, the Population Council objected and explained that its application for mifepristone did not fall within the scope of Subpart H.[49]

134. The Population Council thus wrote a letter to the FDA just three weeks before the final approval of mifepristone, arguing that "it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable. We ask FDA to reconsider."[50]

135. The Population Council stated that "[n]either pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable for that reason alone."[51]

136. Moreover, as the Population Council observed, "[n]either is pregnancy nor unwanted pregnancy a 'serious' or 'life-threatening' situation as that term is defined in Subpart H."[52]

137. And after quoting the preamble to the FDA's Subpart H Final Rule, the Population Council's letter stated that "[t]he plain meaning of these terms does

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[49] Ex. 13, 2002 Citizen Petition at 20.
[50] *Id.*
[51] *Id.*
[52] *Id.*

not comprehend normal, everyday occurrences such as pregnancy and unwanted pregnancy."[53]

138. The letter added that unlike HIV infection, pulmonary tuberculosis, cancer, and other illnesses, "pregnancy and unwanted pregnancy do not affect survival or day-to-day functioning as those terms are used in Subpart H."[54]

139. The Population Council explained that "although a pregnancy 'progresses,'" the development of a pregnancy "is hardly the same as the worsening of a disease that physicians call progression."[55]

140. Despite these last-minute objections, the Population Council ultimately ceased its opposition to the FDA's intention to approve chemical abortion drugs under Subpart H on September 15, 2000.[56]

VI. The FDA's Approval of the Population Council's Application to Market Chemical Abortion Drugs in the United States.

141. On September 28, 2000, the FDA approved chemical abortion drugs under Subpart H "for the medical termination of intrauterine pregnancies through 49 days' pregnancy."[57]

142. The FDA informed the Population Council that Subpart H "applies when FDA concludes that a drug product shown to be effective can be safely used

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[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] Ex. 24, 2000 FDA Approval Memo. to Population Council re: NDA 20-687 Mifeprex (mifepristone) at 6 (Sept. 28, 2000).

[57] Ex. 25, 2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets at 1 (Sept. 28, 2000).

only if distribution or use is restricted, such as to certain physicians with certain skills or experience."[58]

143. The FDA would not have been able to approve the chemical abortion drugs without invoking Subpart H, as it was the only authority available to the agency to allow it to apply postmarketing restrictions on the drugs.[59]

144. To defend its use of Subpart H, the FDA agency declared that "the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H" and asserted that "[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[60]

145. The FDA stated that the chemical abortion drugs' "labeling is now part of a total risk management program." In particular, "[t]he professional labeling, Medication Guide, Patient Agreement, and Prescriber's Agreement will together constitute the approved product labeling to ensure any future generic drug manufacturers will have the same risk management program."[61]

146. The 2000 approval required the Population Council to include on the drugs' label a "black box warning for special problems, particularly those that may lead to death or serious injury."[62]

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[58] Ex. 24, 2000 FDA Approval Memo. at 6.

[59] Ex. 26, 2003 Citizen Petitioners' Response to Opposition Comments filed by The Population Council, Inc. and Danco Laboratories, LLC to Comments at 2–4 (Oct. 10, 2003) https://www.aaplog.org/wp-content/uploads/2002/08/ResponseToDanco10-03reRU-486.pdf (2003 Response).

[60] Ex. 24, 2000 Approval Memo. at 6.

[61] *Id.* at 2.

[62] *Id.*

147. The approved regimen in 2000 contained measures to assure safe use, including requiring at least three office visits: (1) the Day 1 in-person dispensing and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 return to the doctor's office to confirm no fetal parts or tissue remain.[63]

148. The FDA explained that "[r]eturning to the health care provider on Day 3 for misoprostol . . . assures that the misoprostol is correctly administered," and it "has the additional advantage of contact between the patient and health care provider to provide ongoing care, and to reinforce the need to return on Day 14 to confirm that expulsion has occurred."[64]

149. The FDA's Subpart H restrictions included the following requirements for abortionists: the ability to assess the duration of pregnancy accurately and to diagnose ectopic pregnancies (chemical abortion drugs cannot end an ectopic pregnancy, but the symptoms of these drugs resemble hemorrhaging from a life-threatening ectopic pregnancy[65]); the requirement to report any hospitalization, transfusion, or other serious events; and the ability to provide surgical intervention or to ensure that the patient has access to other qualified physicians or medical facilities.[66]

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[63] *Id.* at 2–3.

[64] *Id.* at 3.

[65] Ex. 8, Skop Decl. ¶ 29; *AAPLOG Statement on FDA removing Mifepristone safety protocols (REMS)*, at 2, https://aaplog.org/wp-content/uploads/2021/04/AAPLOG-Statement-on-FDA-removing-mifepristone-REMS-April-2021-1.pdf.

[66] Ex. 24, 2000 Approval Memo. at 6.

150. The FDA's restrictions on the distribution of mifepristone included:

- In-person dispensing from the doctor to the woman or girl;
- Secure shipping procedures;
- Tracking system ability;
- Use of authorized distributors and agents; and
- Provision of the drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing.[67]

151. The FDA did not include prohibitions on the upstream distribution of the chemical abortion drugs—from the manufacturer or importer to the abortionist—by mail, express company, or common carrier as proscribed by federal laws, nor did the FDA acknowledge and address these laws.[68]

152. The FDA also outlined the Population Council's two post-approval study commitments.[69] The Population Council was to conduct "a monitoring study to ensure providers who did not have surgical-intervention skills and referred patients for surgery had similar patient outcomes as those patients under the care of physicians who possessed surgical skills (such as those in the clinical trial)."[70]

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[67] *Id.*

[68] *Id.*

[69] Ex. 25, 2000 Approval Letter at 2–3.

[70] Ex. 24, 2000 Approval Memo. at 7.

The Population Council also agreed "to study ongoing pregnancies and their outcomes through a surveillance, reporting, and tracking system."[71]

153. In the 2000 Approval, the FDA informed the Population Council that the agency was "waiving the pediatric study requirement for this action on this application."[72] Without explanation of the effects of chemical abortion drugs on puberty or substantiation of its decision, the FDA asserted that "there is no biological reason to expect menstruating females under age 18 to have a different physiological outcome with the regimen." [73]

154. The FDA nonetheless highlighted the findings of one limited study that included 51 subjects under 20 years of age. The agency explained that the approved labeling states that the safety and efficacy for girls under 18 years of age "have not been studied" because the raw data from this limited study had not been submitted for review, the pediatric population was not part of the NDA indication, the data on safety and effectiveness were only reviewed for the indication's age group (18–35 years of age), and the clinical trials excluded patients younger than 18 years old.[74]

155. The FDA believed it would eventually overcome this data deficiency because the Population Council would "collect outcomes in their [post-approval]

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[71] *Id.*
[72] Ex. 25, 2000 Approval Letter at 3.
[73] Ex. 24, 2000 Approval Memo. at 7.
[74] *Id.*

studies of women of all ages to further study this issue"[75]—even though those studies were not designed to evaluate the safety and effectiveness of mifepristone on girls under the age of 18 years.

156. But the FDA released the Population Council from its obligation to conduct these studies in 2008.[76]

157. Therefore, since the 2000 Approval, the FDA has continued to allow pregnant girls of *any age* to take chemical abortion drugs—despite never requiring a study specifically designed to determine the safety and effectiveness of these drugs.

158. With the FDA approval in hand, the Population Council then granted Danco Laboratories, LLC ("Danco"), which was incorporated in the Cayman Islands in 1995, an exclusive license to manufacture, market, and distribute Mifeprex in the United States.[77]

VII. 2002 Citizen Petition

159. The FDA's regulations prohibit a litigant from going straight to court to challenge the agency's approval of a new drug. Instead, the FDA's regulations require the submission of a "citizen petition" requesting the agency take or refrain from taking any form of administration action before filing a lawsuit. 21 C.F.R. §§ 10.30, 10.45(b). These regulations allow the FDA to indefinitely delay a final response to a citizen petition. 21 C.F.R. § 10.30(e)(2)(iv). The FDA's eventual

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[75] *Id.*

[76] Ex. 27, 2016 FDA Letter to AAPLOG, Christian Medical & Dental Associations, and Concerned Women for America denying 2002 Citizen Petition, Docket No. FDA-2002-P-0364, at 31 (Mar. 29, 2016) (2016 Petition Denial).

[77] Ex. 13, 2002 Citizen Petition at 9.

decision on a citizen petition constitutes a final agency action for the underlying FDA action and the related citizen petition, and both are reviewable in the courts under the APA. 21 C.F.R. § 10.45(c).

160. In August 2002, Plaintiffs AAPLOG and Christian Medical & Dental Associations, along with the Concerned Women for America, (collectively, 2002 Petitioners), submitted a citizen petition (2002 Citizen Petition) with the FDA pursuant to 21 C.F.R. §§ 10.30 and 10.35; 21 C.F.R. Part 314, Subpart H (§§ 314.500–314.560); and Section 505 of the FFDCA (21 U.S.C. § 355).[78]

161. The 2002 Petitioners requested that the FDA impose an immediate stay of the approval of mifepristone and ultimately revoke the approval, in addition to requesting a full FDA audit of the underlying clinical studies.[79]

162. The 2002 Petitioners stated that the FDA's approval of mifepristone in 2000 violated the APA for many reasons, including because it was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law, given that (1) the FDA lacked the authority to approve mifepristone under Subpart H and (2) the FDA incorporated misoprostol as part of the chemical abortion regimen despite not receiving an sNDA for this new use of the drug.[80]

163. The 2002 Petitioners explained how the 2000 Approval violated Subpart H because pregnancy, without major complications, is not a "serious or life-threatening illness" for purposes of this accelerated approval authority. "Thus,

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[78] *Id.* at 1.

[79] *Id.*

[80] *Id.* at 18–23, 41–48.

pregnancy is not the kind of exceptional circumstance that falls within the scope of Subpart H. The fact that the Mifeprex Regimen is intended for healthy women provides further evidence of this point."[81]

164. Moreover, "there is a less dangerous, more effective alternative to Mifeprex available for the termination of pregnancies: namely, surgical abortions." Nor does mifepristone "treat a subset of the female population that is unresponsive to, or intolerant of surgical abortion." Indeed, as the 2000 Mifeprex label acknowledged, because "medical abortion failures should be managed with surgical termination," the option for surgical abortion must be available for any woman or girl who undergoes chemical abortion.[82]

165. Nor did the clinical trials compare chemical abortion with the existing "therapy," surgical abortion, to support a finding of a "meaningful therapeutic benefit over existing treatments."[83]

166. The 2002 Petitioners also pointed out that the clinical trials that the Population Council submitted to support its NDA failed to present "substantial evidence" that the mifepristone regimen is safe and effective.[84]

167. In fact, as the 2002 Citizen Petition demonstrated, the FDA's 2000 Approval has endangered women's lives because it lacked the necessary safeguards for this dangerous regimen. For instance, the FDA failed to require an ultrasound,

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[81] *Id.* at 19.
[82] *Id.* at 21–22.
[83] *Id.* at 37.
[84] *Id.* at 24–41.

which is necessary both to determine an accurate gestational age of the baby and to rule out an ectopic pregnancy. The FDA also did not restrict the regimen to physicians who have received proper training and possess admitting privileges to emergency facilities. In light of the FDA's subsequent acknowledgment that women had serious adverse events since the 2000 Approval, the 2002 Citizen Petition urged the FDA to "react to these sentinel events because the clinical trials underlying the approval of the Mifeprex Regimen did not adhere to FDA's endorsed scientific methodology for such trials."[85]

168. What is more, the 2002 Petitioners challenged the 2000 Approval because the U.S. clinical trial for mifepristone did not mirror the anticipated conditions of use under the approved label despite the FFDCA's requirements under 21 U.S.C. § 355(d). Under the conditions of the U.S. clinical trial:

(a) the investigators relied on transvaginal ultrasonography (along with menstrual history and pelvic examination) to confirm the gestational age of each pregnancy and exclude women with ectopic pregnancies;

(b) the physicians had experience in performing surgical abortions, were trained in the administration of the mifepristone-misoprostol procedure, and had admitting privileges at medical facilities that could provide emergency care and hospitalization; and

[85] *Id.* at 49–71.

(c) all patients needed to be within one hour of emergency facilities or the facilities of the principal investigator; and

(d) women were monitored for four hours for adverse events after taking misoprostol.[86]

169. Because the FDA's 2000 Approval did not require these safeguards for women and girls using chemical abortion drugs, the 2002 Petitioners reasoned that the agency should not have extrapolated conclusions about the safety and effectiveness of chemical abortion drugs under the approved label.[87]

170. The 2002 Citizen Petition also requested that the FDA withdraw the 2000 Approval of the chemical abortion drugs because the sponsor had not been enforcing the limited restrictions on the use of the drug regimen. Among the deviations from the approved regimen, physicians were offering chemical abortion drugs to women with pregnancies beyond the maximum seven weeks and eliminating the second of the three prescribed visits (i.e., in-facility administration of misoprostol).[88]

171. Subpart H authorizes the FDA to withdraw approval of a drug approved under Section 514.520 if "[t]he applicant fails to adhere to the postmarketing restrictions agreed upon." 21 C.F.R. § 314.530(a)(4). Because "the burden is on the applicant to ensure that the conditions of use under which the

[86] *Id.* at 75–76.
[87] *Id.* at 76.
[88] *Id.* at 71–75.

applicant's product was approved are being followed," the 2002 Petitioners asked the FDA to exercise its authority to withdraw its approval for mifepristone.[89]

172. The 2002 Petitioners also challenged the FDA's decision to waive the agency's regulatory requirement to conduct a pediatric study—the failure of which endangered the health and safety of girls—because it did not meet the requirements for such a waiver.[90]

173. The 2002 Citizen Petition next pointed out that the FDA impermissibly reduced the Population Councils' post-approval studies during the final stages of the FDA's review in 2000. "Not only did FDA approve the NDA on the basis of clinical trials so defective with respect to their design and execution as to render them insufficient to establish short-term safety and effectiveness, but FDA also permitted the Population Council to substantially pare down the [post-approval] trials that it would perform."[91]

174. Finally, the FDA then "compounded its failure to require the Population Council and Danco to comply with the strictures of the Pediatric Rule when it permitted them to consider the effect of the Mifeprex Regimen on patients under 18 as part of another study rather than as a separate [post-approval] study."[92] Because chemical abortion drugs "could conceivably interfere with

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[89] Ex. 13, 2002 Citizen Petition at 75.
[90] *Id.* at 76–83.
[91] *Id.* at 84–85.
[92] *Id.* at 86.

pubertal development," girls under 18 years of age deserve separate consideration in studies with significant numbers of participants.[93]

175. On October 10, 2003, the 2002 Petitioners filed a response ("2003 Response") to opposition comments by the Population Council and Danco. The 2003 Response not only responded to these comments, but it also provided the FDA with additional evidence that the safety and effectiveness of chemical abortion drugs have not been established in accordance with the requirements of the FFDCA or the FDA's own regulations.[94]

VIII. Implementation of a REMS for Mifepristone

176. After receiving the 2002 Citizen Petition, the FDA's next significant regulatory action on chemical abortion drugs involved incorporating Congress's mandate to convert Subpart H postmarketing restrictions for previously approved drugs into a REMS.

177. As previously discussed, Section 909(b)(1) of the FDAAA specified that a "drug that was approved before the effective date of this Act is . . . deemed to have in effect an approved [REMS] . . . if there are in effect on the effective date of this Act elements to assure safe use [pursuant to 21 C.F.R. § 514.520]."

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[93] *Id.* at 86, n. 377.

[94] Ex. 26, 2003 Response.

178. In a March 27, 2008, Federal Register notice, the FDA identified chemical abortion drugs as one of "those drugs that FDA has determined will be deemed to have in effect an approved REMS."[95]

179. In 2011, pursuant to the 2008 notice, the FDA approved a REMS for chemical abortion drugs in accordance with section 909(b)(1) of the FDAAA.[96]

180. The FDA "determined that a REMS is necessary for MIFEPREX (mifepristone) to ensure the benefits of the drug outweigh the risks of serious complications."[97]

181. The REMS incorporated the previous Subpart H restrictions and consisted of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.[98]

182. The REMS required "prescribers to certify that they are qualified to prescribe MIFEPREX (mifepristone) and are able to assure patient access to appropriate medical facilities to manage any complications."[99]

183. The FDA also instructed Danco that, "[a]s part of the approval under Subpart H, as required by 21 CFR § 314.550, you must submit all promotional

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[95] Ex. 28, Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008).

[96] Ex. 29, 2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC at 1 (June 6, 2011) (2011 Approval Letter).

[97] *Id.* at 1.

[98] *Id.* at 1; Ex. 30, 2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011) (2011 REMS).

[99] Ex. 29, 2011 Approval Letter at 1; Ex. 30, 2011 REMS.

materials, including promotional labeling as well as advertisements, at least 30 days before the intended time of initial distribution of the labeling or initial publication of the advertisement."[100]

IX. The FDA's Denial of the 2002 Citizen Petition

184. Almost *fourteen years* after receiving the 2002 Citizen Petition—on March 29, 2016—the FDA denied the 2002 Citizen Petition ("2016 Denial").[101]

185. The FDA abused its regulatory authority under 21 C.F.R. § 10.30(e)(2)(iv) to delay a final response to the 2002 Citizen Petition.

186. In the 2016 Denial, the FDA asserted that it appropriately approved chemical abortion drugs under Subpart H because "[a]s 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."[102]

187. The FDA further asserted that the Subpart H premable "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."[103]

188. The FDA asserted that "[u]nwanted pregnancy falls within the scope of subpart H under § 314.500 because unwanted pregnancy, like a number of illnesses

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[100] Ex. 29, 2011 Approval Letter at 2–3.
[101] Ex. 27, 2016 Petition Denial.
[102] *Id.* at 4 (emphasis added).
[103] *Id.*

or conditions, can be serious for certain populations or under certain circumstances."[104]

189. The FDA also asserted that chemical abortion "provides a meaningful therapeutic benefit to some patients over surgical abortion" because chemical abortion "provides an alternative to surgical abortion," which itself can lead to complications such as "a severe allergic reaction, a sudden drop in blood pressure with cardiorespiratory arrest, death, and a longer recovery time following the procedure."[105]

190. The FDA also asserted that the clinical trials constituted "substantial evidence" of effectiveness, while contending that the "FDA regulations do not require that a study be blinded, randomized, and/or concurrently controlled."[106]

191. The FDA then asserted that its decision not to require studies of pediatric patients "was consistent with FDA's implementation of the regulations in effect at that time." The agency also asserted that its 2000 Approval "determined that there were sufficient data from studies of mifepristone." Even though the 2000 Approval said the FDA was waiving the requirement for a pediatric assessment, the 2016 Petition Denial stated that the 2000 Approval "should have stated our conclusion that the pediatric study requirements were waived for pre-menarchal patients and that the pediatric study requirements were met for post-menarchal

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[104] *Id.*

[105] *Id.* at 5.

[106] *Id.* at 9.

pediatric patients, rather than stating that we were waiving the requirements for all pediatric groups."[107]

192. In response to the 2002 Citizen Petition's argument that the FDA's inclusion of misoprostol as part of the mifepristone regimen was illegal because the sponsor of that drug had not submitted an sNDA, the FDA asserted that "[n]either the FD&C Act nor FDA regulations require the submission of a supplemental NDA by the sponsor of the misoprostol NDA for the use of misoprostol as part of the approved treatment regimen for Mifeprex."[108]

193. The FDA provided "[e]xamples of approved drug labeling that refer to the concomitant use of another drug without there being a specific reference to the combined therapy in the previously approved labeling for the reference drug."[109] But the FDA did not purport to provide an example of drug labeling where that second drug was not approved for the use of the new indication.

X. The FDA's 2016 Major Changes to the Mifepristone Regimen

194. On the *same day* that the FDA denied the 2002 Citizen Petition—March 29, 2016—the FDA also approved major changes to the mifepristone regimen (2016 Major Changes) in response to an sNDA that Danco had submitted to the FDA on May 28, 2015.[110]

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[107] *Id.* at 29.

[108] *Id.* at 15.

[109] *Id.*

[110] Ex. 31, 2016 FDA Letter to Danco Laboratories re: NDA 020687, Supp 20 (Mar. 29, 2016).

195. The FDA acknowledged that the 2000 Approval hinged on necessary safeguards to protect women and girls from the dangers of chemical abortion drugs. The FDA's "Summary Review" of the 2016 Major Changes recalled that "[a]t the time of the September, 2000 approval, FDA restricted distribution of Mifeprex under 21 CFR 314.520." After summarizing the history and provisions of the REMS for mifepristone, the FDA noted that "[t]he REMS for Mifeprex incorporated the restrictions under which the drug was originally approved."[111] But the FDA decided to remove these crucial protections after reconsidering and reopening the 2000 Approval.

196. The FDA acknowledged that "these major changes are interrelated," demonstrating the agency's awareness that each change impacted the others.[112]

197. The 2016 Major Changes included the following revisions to the 2000 Approval's safeguards for women and girls:

(a) extending the maximum gestational age at which a woman or a girl can abort her baby from 49 days to 70 days;

(b) altering the mifepristone dosage from 600 mg to 200 mg, the misoprostol dosage from 400 mcg to 800 mcg, and misoprostol administration from oral to buccal (cheek pouch);

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[111] Ex. 32, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020, at 4 (Mar. 29, 2016) (2016 Summary Review).

[112] *Id.* at 6.

(c) eliminating the requirement that administration of misoprostol occur in-clinic;

(d) broadening the window for misoprostol administration to include a range of 24-48 hours after taking mifepristone, instead of 48 hours afterwards;

(e) adding a repeat 800 mcg buccal dose of misoprostol in the event of an incomplete chemical abortion;

(f) removing the requirement for an in-person follow-up examination after an abortion; and

(g) allowing "healthcare providers" other than physicians to dispense and administer the chemical abortion drugs.[113]

198. Despite these major changes to the regimen, the FDA eliminated the requirement for prescribers to report all nonfatal serious adverse events from chemical abortion drugs. Rather than require future adverse event reports from abortionists about whether revising the dosages and removing the initial safeguards harmed women and girls, the FDA simply asserted that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged." The FDA at least conceded that "[i]t is important that the Agency be informed of any deaths with Mifeprex to monitor new safety signals or trends."[114]

[113] *Id.* at 6–10.

[114] *Id.* at 27.

199. As with the 2000 Approval, the 2016 Major Changes did not include prohibitions on the upstream distribution of chemical abortion drugs by mail, express company, or common carrier as proscribed by federal laws, nor did the FDA acknowledge and address these laws.

A. The FDA's Evidence for the Safety and Effectiveness of the 2016 Major Changes

200. The FDA lacked substantial evidence that the 2016 Major Changes would have the effect it purported or was represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

201. The FDA's review and approval did not include a single adequate and well-controlled investigation that evaluated the safety and effectiveness of mifepristone and misoprostol under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

202. Instead, the FDA relied on studies that evaluated only one or just a few of the major changes that the FDA enacted in 2016; as the FDA acknowledged, "in some cases data from a given study were relied on to provide evidence to support multiple changes"[115]—but no study supported all the changes.

203. For example, the FDA relied on a study lead by a former longtime employee of the Population Council to support extending the maximum gestational age to 70 days, changing the dosing regimen, and authorizing a repeat dose of

[115] Ex. 32, 2016 Summary Review at 6.

misoprostol if the first dose fails.[116] In this study, the abortionists (1) confirmed gestational age (and presumably screened for ectopic pregnancies) "based on routine ultrasound practices," (2) required the study participants to return to the study site 7 to 14 days after using mifepristone "for clinical assessment, which included ultrasonography," and (3) "intervened surgically if they deemed it medically necessary or at the patient's request."[117] But the labeling that the FDA approved with the 2016 Major Changes did not require (1) an ultrasound to confirm gestational age or screen for an ectopic pregnancy, (2) an in-person follow-up exam using ultrasonography, and (3) an ability of abortionists to personally perform surgical abortion if necessary. Such variations between the study conditions and the approved labeling fail to comply with the requirements of the FFDCA.

204. Moreover, the studies on which the FDA relied for each individual major change all contained at least one fatal flaw, including the following substantial weaknesses: significant loss to follow-up; safeguards not required under the labeling; small sample size lacking statistical significance; not powered to evaluate safety; and bias.

205. In fact, many of these studies showed that the new chemical abortion regimen was *unsafe* for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, or they failed to show that chemical abortion was safe under such conditions.

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[116] Ex. 33, Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 Obstetrics & Gynecology 1070 (2012).
[117] *Id.* at 1071.

B. The FDA's Lack of Research on Pediatric Populations for the 2016 Major Changes

206. The FDA's 2016 Major Changes continued to allow pregnant girls of any age to use chemical abortion drugs—despite not knowing whether these dangerous drugs could have an adverse impact on the health, safety, and welfare of developing girls.

207. The FDA did not require Danco to submit an assessment on the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, nor did the FDA require Danco to submit an assessment that supported the dosing and administration for each pediatric subpopulation for which the drug is safe and effective.[118]

208. The FDA "granted a partial PREA waiver for pre-menarcheal females ages birth to 12 years because it would be impossible to conduct studies in this pediatric population, as pregnancy does not exist in premenarchal females." The FDA then concluded that Danco "fulfilled the remaining PREA requirement in postmenarcheal females by submitting published studies of Mifeprex for pregnancy termination in postmenarcheal females less than 17 years old." The FDA cited three published studies in support of this conclusion.[119]

209. The primary study on which the FDA relied, *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, by Mary Gatter and Deborah Nucatola of Planned Parenthood of Los Angeles and

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[118] Ex. 32, 2016 Summary Review at 18–20.

[119] *Id.* at 18–19.

Kelly Cleland of Princeton University's Office of Population Research, evaluated the proposed dosing regimen followed by home administration of misoprostol through 63 days' gestation. The study also included postmenarcheal girls in the study population, from which the FDA extrapolated its conclusion.[120]

210. For the pediatric population under 18 years of age, the Planned Parenthood study stated that it had a loss to follow-up of twenty percent (20%). Therefore, the authors lacked any knowledge of whether these girls died, were hospitalized, or experienced other serious adverse events.[121] The authors also recognized that "[l]oss to follow-up was significantly higher among the *youngest* age group."[122]

211. The FDA minimized this significant data gap by asserting that "loss to follow-up was *slightly higher* in those less than 18 years old."[123] Despite this significant data gap, the FDA went on to conclude that "age did not adversely impact efficacy outcomes."[124]

212. Furthermore, in this study, Planned Parenthood also performed an ultrasound examination on *all* females prior to the chemical abortions, in addition to giving them "routine antibiotic coverage" at the beginning of the chemical

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[120] *Id.* at 19 (citing Ex. 34, Mary Gatter et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269 (2015).

[121] Ex. 34, Gatter at 4–5.

[122] *Id.* (emphasis added).

[123] Ex. 32, 2016 Summary Review at 19 (emphasis added).

[124] *Id.*

abortion regimen.[125] But the FDA did not require any of these safeguards for women and girls under the 2016 Major Changes.

213. The FDA did not address or discount any potential conflict of interest or bias in the study—despite the study disclosing that Planned Parenthood Federation of America provided funding for the study. Nor did the FDA address or discount any potential conflict of interest or bias in the study even though its authors, Mary Gatter[126] and Deborah Nucatola,[127] had significant incentives to increase their income and Planned Parenthood's profits through abortion-related actions outside of performing surgical abortion.[128]

214. A second study that the FDA cited in support of its PREA conclusion was based on a nationwide registry of induced abortions and hospital register data in Finland.[129] For the adolescent cohort who had chemical abortions, the study

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[125] Ex. 34, Gatter at 2.

[126] *See, e.g.*, The Center for Medical Progress, *Second Planned Parenthood Senior Executive Haggles Over Body Parts Prices, Changes Abortion Methods*, YouTube (July 21, 2015), https://www.youtube.com/watch?v=MjCs_gvImyw (video capturing Gatter saying she "want[s] a Lamborghini" when discussing the price that she would charge for selling intact aborted fetal body parts).

[127] *See, e.g.,* The Center for Medical Progress, *Planned Parenthood Uses Partial-Birth Abortions to Sell Baby Parts*, YouTube (July 14, 2015), https://www.youtube.com/watch?v=jjxwVuozMnU (video capturing Nucatola stating that Planned Parenthood affiliates would be "happy" selling intact aborted fetal body parts for a "reasonable" price that is "a little better than break even").

[128] The Fifth Circuit has recognized the overall authenticity and veracity of the undercover videos capturing Planned Parenthood's desire to profit from the trafficking of aborted fetal body parts. *See Planned Parenthood of Greater Tex. Family Planning & Preventative Health Servs., Inc. v. Smith*, 913 F.3d 551, 559 n. 6 (5th Cir. 2019), *on reh'g en banc sub nom. Planned Parenthood of Greater Tex. Fam. Plan. & Preventative Health Servs., Inc. v. Kauffman*, 981 F.3d 347 (5th Cir. 2020).

[129] Ex. 32 2016 Summary Review at 19–20 (citing Ex. 18, Niinimaki, *supra* note 14).

found that 12.8% experienced hemorrhaging, 7.0% had incomplete abortions, and 11.0% needed surgical evacuation of "retained products of conception."[130] Because these statistics were similar to those of the adult cohort, the FDA found these statistics "reassuring" to support the safety profile of chemical abortion drugs for a pediatric population.[131]

215. The third and final study that the FDA cited in support of its PREA conclusion was a study of 28 adolescents, ages 14 to 17 years old, with pregnancies under 57 days' gestation.[132] Even though the authors of this study cautioned that a larger study was needed to make any generalizable conclusions for pediatric populations, the FDA likewise found this small study "reassuring."[133]

216. The FDA did not require any studies on the long-term effects of chemical abortion drugs in pediatric populations with developing reproductive systems.

XI. 2019 Citizen Petition

217. In response to the 2016 Major Changes, on March 29, 2019, Plaintiffs AAPLOG and American College of Pediatricians (2019 Petitioners) submitted to the FDA a citizen petition (2019 Citizen Petition) pursuant to 21 C.F.R. §§ 10.30 and 10.35; 21 C.F.R. Part 314, Subpart H (§§ 314.500–314.560); and Section 505 of the FFDCA (21 U.S.C. § 355). The 2019 Petitioners asked the FDA to (1) "restore and

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[130] Ex. 18, Niinimaki, *supra* note 14 at 3–4.
[131] Ex. 32, 2016 Summary Review at 20.
[132] *Id.* at 19.
[133] *Id.* at 20.

strengthen elements of the Mifeprex regimen and prescriber requirements approved in 2000" and, in the event that the FDA denied that request, (2) "retain the Mifeprex Risk Evaluation and Mitigation Strategy (REMS), and continue limiting the dispensing of Mifeprex to patients in clinics, medical offices, and hospitals, by or under the supervision of a certified prescribers."[134]

218. The 2019 Citizen Petition asked the FDA to take the following actions to restore and strengthen elements of the chemical abortion drug regimen and prescriber requirements approved in 2000 to protect the health, safety, and welfare of women and girls:

- Reduce the maximum gestational age from 70 days to 49 days;
- Limit the ability to prescribe and dispense chemical abortion drugs to qualified, licensed physicians—not other "healthcare providers";
- Mandate certified abortionists to be physically present when dispensing chemical abortion drugs;
- Require that the prescriber perform an ultrasound to assess gestational age, identify ectopic pregnancies, ensure compliance with FDA restrictions, and adequately inform the woman of gestational age-specific risks, which rise with increasing gestational age;
- Restore the requirement for in-person administration of misoprostol;

[134] Ex. 35, 2019 Citizen Petition of AAPLOG to FDA (Mar. 29, 2019).

- Restore the requirement for an in-person follow-up visit to confirm abortion and rule out life-threatening infection through clinical examination or ultrasonographic scan;
- Restore the 2000 label language that stated that chemical abortion drugs are contraindicated if a woman lacks adequate access to emergency medical care; and
- Restore the prescriber reporting requirements for all serious adverse events, including any deaths, hospitalizations, blood transfusions, emergency room visits, failures requiring surgical completion, ongoing pregnancy, or other major complications following the chemical abortion regimen.[135]

219. The 2019 Petitioners also asked the FDA to require a formal study of outcomes for at-risk populations, including the pediatric female population, patients with repeat chemical abortions, patients who have limited access to emergency room services, and patients who self-administer misoprostol.[136]

220. The 2019 Citizen Petition explained that "[t]he developmental stage of puberty involves a complex interplay of both progesterone and estrogen effects on the developing female reproductive system." Therefore, "[t]he use, and especially the potential multiple use, of Mifeprex, which is a powerful progesterone blocker, is

[135] *Id.*

[136] *Id.* at 13–14.

likely to significantly impact the developing reproductive system of the adolescent female."[137]

221. If the FDA refused to restore and strengthen the chemical abortion regimen and prescriber requirements approved in 2000, the 2019 Citizen Petition requested that the FDA retain the mifepristone REMS and continue limiting the dispensing of mifepristone to clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. In other words, the FDA should do no further harm to the few remaining safeguards for women and girls who undergo the chemical abortion drug regimen.[138]

222. In particular, the 2019 Petitioners explained that eliminating or relaxing the REMS to facilitate internet or telephone prescriptions would be dangerous to women and girls.[139] The 2019 Citizen Petition also raised concerns about dispensing from a pharmacy instead of a clinical facility.[140]

223. The 2019 Citizen Petition provided the FDA with detailed analysis and data to support these requests.

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[137] *Id.*
[138] *Id.* at 14–25.
[139] *Id.* at 18–20.
[140] *Id.* at 20–23.

XII. The FDA's Approval of a Generic Version of Mifeprex and a Single, Shared System REMS

224. On April 11, 2019, the FDA approved GenBioPro, Inc.'s[141] generic version of Mifeprex, "Mifepristone Tablets, 200 mg" (2019 ANDA Approval). The FDA determined GenBioPro's Mifepristone Tablets, 200 mg, "to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Mifeprex Tablets, 200 mg, of Danco Laboratories, LLC." GenBioPro's generic version of mifepristone has the same labeling and REMS as does Danco's Mifeprex.[142]

225. On the same day, the FDA approved modifications to the existing REMS for chemical abortion drugs to establish a single, shared system REMS for mifepristone products for the "medical termination of intrauterine pregnancy," thus allowing the FDA to have a uniform REMS for the chemical abortion drugs that two companies were now marketing. The FDA did not make any substantive modifications to the REMS approved in 2016.[143]

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[141] GenBioPro, Inc. is located at 3651 Lindell Road, Suite D1041, Las Vegas, Nevada. https://www.dnb.com/business-directory/company-profiles.genbiopro_inc.f925af03300887aacd053afe151fefb2.html.

[142] Ex. 36, 2019 FDA ANDA Approval Letter to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

[143] Ex. 37, 2019 FDA Supplemental Approval Letter to Danco Laboratories, LLC (Apr. 11, 2019), Supplement Approval, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020687Orig1s022ltr.pdf.

XIII. 2020 ACOG-SMFM Letter to the FDA

226. On April 20, 2020, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) sent a joint letter (2020 ACOG-SMFM Letter), rather than a citizen petition, to the FDA asking the agency to remove in-person dispensing requirement for mifepristone during the COVID-19 pandemic and instead allow dispensing by mail or mail-order pharmacy.[144]

227. Following the letter, in May 2020, ACOG and others filed suit to enjoin the FDA's in-person dispensing requirement for mifepristone during the pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

228. The district court granted a nationwide preliminary injunction and lifted the in-person dispensing requirement for the pandemic. *Id.* at 233, order clarified, 2020 WL 8167535 (D. Md. Aug. 19, 2020). The Fourth Circuit refused to stay the injunction. Court Order Denying Motion for Stay Pending Appeal, *Am. Coll. of Obstetricians & Gynecologists v. FDA,* Nos. 20-1824 (4th Cir. Aug. 13, 2020), ECF No. 30.

229. The FDA then filed for an emergency stay of the injunction with the U.S. Supreme Court. On January 12, 2021, the U.S. Supreme Court granted the FDA an emergency stay of the district court's injunction.[145]

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[144] Ex. 38, 2020 Letter from ACOG and SMFM, to FDA about Mifepristone REMS (Apr. 20, 2020) (2020 ACOG-SMFM Letter).

[145] *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

XIV. 2021 FDA Letter in Response to 2020 ACOG-SMFM Letter

230. President Joe Biden took office just eight days later. Acting under new management, the FDA responded to the 2020 ACOG-SMFM letter on April 12, 2021, and stated that the agency "intends to exercise enforcement discretion" during the COVID pandemic with respect to the in-person dispensing requirement of the REMS for mifepristone (2021 Non-Enforcement Decision).[146]

231. The FDA's 2021 Non-Enforcement Decision relied, in part, on the supposed lack of reported adverse events caused by chemical abortion drugs occurring between January 2020 and January 2021—despite the agency's elimination of non-fatal reporting requirements for abortionists in 2016. Nevertheless, in 2021, the FDA still "found that the small number of adverse events reported to FDA during the COVID-19 public health emergency (PHE) provide no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to the reported adverse events."[147]

232. The FDA's 2021 Non-Enforcement Decision neither acknowledged nor addressed the federal laws expressly prohibiting the distribution of mifepristone by mail, express company, or common carrier—despite explicitly recognizing that this action would allow "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy."[148]

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[146] Ex. 39, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS, at 2 (Apr. 12, 2021) (2021 Non-Enforcement Decision).

[147] *Id.*

[148] *Id.*

XV. 2021 "Minor" Changes

233. On May 14, 2021, the FDA approved "minor" changes to the Patient Agreement Form to use "gender neutral language," replacing the pronouns "she" and "her" with "the patient." The FDA made similar revisions to the REMS document to reflect the removal of the gender-specific pronouns in the Patient Agreement Form.[149]

234. Despite these changes, the FDA did not require Danco to submit studies showing the safety and effectiveness of chemical abortion on women and girls who may be taking puberty blockers, testosterone injections, or other hormones in addition to the chemical abortion drugs.

235. Currently, the May 14, 2021, "minor" changes are the last updates to the REMS for chemical abortion drugs that the FDA has approved.[150] As discussed below, the FDA is requiring additional changes to the REMS.

XVI. The FDA's December 2021 Announcement of Further Reductions in Safeguards

236. On December 16, 2021, Defendant Cavazonni, Director of the FDA's Center for Drug Evaluation and Research, wrote a letter to Graham Chelius, M.D., of the Society of Family Planning and the California Academy of Family Physicians

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[149] Ex. 40, FDA Supplemental Approval Letter to Danco Laboratories, LLC (May 14, 2021), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/020687Orig1s024ltr.pdf.

[150] Ex. 41, 2021 Updated REMS for Mifepristone Tablets, 200mg (May 14, 2021), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390.

to inform him that the FDA had completed its review of the REMS for mifepristone.[151]

237. Although the FDA "determined that the Mifepristone REMS Program continues to be necessary to ensure that the benefits of the drug outweigh the risks," the agency "determined that it must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks."[152]

238. The letter identified specific new modifications to the REMS: "(1) removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals (i.e., the 'in-person dispensing requirement'); and (2) adding a requirement that pharmacies that dispense the drug be specially certified," signaling that the FDA will soon allow pharmacies to dispense chemical abortion drugs.[153]

239. Defendant Cavazzoni also noted that the FDA had answered the "related" 2019 Citizen Petition and would post the agency's response in the public docket.[154]

XVII. The FDA's Denial and Granting of the 2019 Citizen Petition

240. Accordingly, on December 16, 2021—the *same day* that Defendant Cavazzoni sent the letter to Dr. Chelius and *over 2.5 years* after receiving the 2019

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[151] Ex. 42, 2021 FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021).

[152] *Id.*

[153] *Id.*

[154] *Id.*

Citizen Petition—the FDA denied in part and granted in part the 2019 Citizen Petition (2021 FDA Response).[155]

241. The FDA granted the 2019 Citizen Petition only to the extent that the agency agreed that a REMS is necessary to ensure that the "benefits" of mifepristone in a regimen with misoprostol outweigh the risks. But the FDA retained only the Prescriber Agreement Form and the Patient Agreement Form as the remaining elements of the REMS.[156]

242. Aside from retaining these two remaining requirements, the FDA denied the 2019 Citizen Petition's requests (1) to restore and strengthen the mifepristone and prescriber requirements approved in 2000 and (2) to continue limiting the dispensing of mifepristone to women in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.[157]

243. Before addressing the merits of the 2019 Citizen Petition, the FDA discussed how chemical abortion drugs came to be regulated, starting with the 2000 Approval under Subpart H and the associated restrictions "needed to assure the safe use of the drug product." The FDA noted that it restricted the distribution of chemical abortion drugs under Subpart H, 21 C.F.R. § 314.520. The agency also

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[155] Ex. 43, 2021 FDA Letter to AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) (2021 FDA Response).

[156] *Id.* at 21–23.

[157] Ex. 43, 2021 FDA Response.

explained how and why chemical abortion drugs have an associated REMS to "assure safe use" due to the drug's approval under Subpart H.[158]

244. After providing this regulatory background, the FDA defended its decision in the 2016 Major Changes to reconsider and revise the safeguards codified in the original 2000 Approval and the subsequent REMS. The agency also disregarded the analyses and data set forth in the 2019 Citizen Petition.

245. The FDA repeated its previous justifications not to require studies in the pertinent pediatric population in the underlying 2000 Approval and the 2016 Major Changes, and it again asserted—without evidence—that "the safety and efficacy were expected to be the same for postpubertal (i.e., post-menarchal) adolescents."[159]

246. In response to the 2019 Citizen Petition's request to preserve the few safeguards after the 2016 Major Changes, the FDA stated that the REMS for mifepristone "must be modified to remove the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals, because this requirement is no longer necessary to ensure that the benefits of the drug outweigh the risks."[160]

247. In support of its claim that in-person dispensing is unnecessary, the FDA relied on the "small" number of adverse events voluntarily reported in the FDA Adverse Event Reporting System (FAERS) database to justify the elimination

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[158] *Id.* at 2–3.
[159] *Id.* at 38.
[160] *Id.* at 25

of this safeguard, even though the FDA had years ago removed the requirement for abortionists to report nonfatal adverse events.[161]

248. The FDA relied on the FAERS database despite conceding these facts: "FAERS data does have limitations"; the "FDA does not receive reports for every adverse event"; and thus "FAERS data cannot be used to calculate the incidence of an adverse event . . . in the U.S."[162]

249. The FDA likewise admitted that FAERS "is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events" and the adverse events reported to the FDA "represent a fraction of the actual adverse events occurring in American women."[163] The FDA also agreed that there are reporting "discrepancies [that] render the FAERS inadequate to evaluate the safety of mifepristone abortions."[164]

250. The complicated FAERS electronic submission process further hinders the reporting of adverse events and exacerbates the unreliability of the number of

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[161] *Id.* at 25–36.

[162] Ex. 44, Questions and Answers on FDA's Adverse Event Reporting System (FAERS), https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

[163] Ex. 45, Kathi A. Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 26 Law & Medicine 3, 25–26 (2021).

[164] Ex. 46, Christiana A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Rsch & managerial Epidemiology 1 (2021).

adverse event reports. Doctors or other interested individuals seeking to submit an adverse event report must navigate a confusing webpage.[165] Recognizing this difficulty in submitting adverse event reports, the FDA provides a 48-page manual as guidance on the technical specifications for submitting an adverse event form.[166]

251. The FDA also relied on some published studies in making its 2021 decision to deny the 2019 Citizen Petition. The agency, however, noted that "the ability to generalize the results of these studies to the United States population is hampered," "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," and the FDA "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States."[167]

252. Despite these limitations, the FDA concluded that mifepristone would "remain safe and efficacy [would] be maintained" if it removed the in-person dispensing requirement from the REMS program.[168]

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[165] Ex. 47, FDA, *FDA Adverse Event Reporting System (FAERS) Electronic Submissions*, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions.

[166] Ex. 48, *Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments* (April 2021), https://www.fda.gov/media/132096/download.

[167] Ex. 43, 2021 FDA Response at 28.

[168] *Id.*

253. The FDA's 2021 Petition Response neither acknowledged nor addressed the federal laws expressly prohibiting the distribution of mifepristone by mail, express company, or common carrier.

254. In summary, the following chart illustrates the changes to the mifepristone regimen over the years:

Regulation	**2000 Approval**	**2016 Major Changes**	**2021 Non-Enforcement Decision and Petition Denial**
Maximum Gestational Age	49 days	70 days	70 days
Dosage	• 600 mg of mifepristone • 400 mcg of misoprostol	• 200 mg of mifepristone • 800 mcg of misoprostol	• 200 mg of mifepristone • 800 mcg of misoprostol
Route of misoprostol administration	Vaginal	Buccal	Buccal
Timing of misoprostol administration	48 hours after mifepristone	24-48 hours after mifepristone	24-48 hours after mifepristone
Repeat dose of 800 mcg misoprostol	No	Yes	Yes
Dispensed only by or under the supervision of a physician	Yes	No	No
In-person *administration* of drug regimen	Yes	No	No
In-person *dispensing* of drug regimen	Yes	Yes	No
Follow-up in-person evaluation post-abortion	Yes	No	No
Requiring prescribers to report all non-fatal serious adverse events	Yes	No	No

XVIII. Injuries to Plaintiffs and Their Patients

255. The Alliance for Hippocratic Medicine, the AAPLOG, the American College of Pediatricians, and the Christian Medical & Dental Associations have members in Texas and around the country who have treated and will continue to treat women and girls who have suffered complications from the FDA's unlawful approval of chemical abortion drugs and subsequent elimination of the safeguards necessary to protect women and girls.

256. These medical associations sue on their own behalf and on behalf of their members and their members' patients—all of whom have been harmed and will continue to be harmed by the FDA's actions.

257. Dr. Jester practices medicine in Texas and has treated a woman who suffered complications from the FDA's unlawful approval of chemical abortion drugs and elimination of the safeguards necessary to protect women and girls. Dr. Frost-Clark, Dr. Johnson, and Dr. Delgado have also treated women and girls who have suffered complications from the FDA's unlawful approval of chemical abortion drugs and elimination of the safeguards necessary to protect women and girls.

258. These doctors sue on behalf of themselves and their patients—both of whom have been harmed and will continue to be harmed by the FDA's actions.[169]

[169] *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118–20 (2020) (holding that doctors and medical providers had third-party standing on behalf of their patients because the Court has "long permitted" them "to invoke the rights of their actual or potential patients").

259. The sworn declarations attached to the Complaint detail how each Plaintiff has been, is, and/or will be personally and professionally injured by the FDA's actions. As many of their injuries overlap, the injuries discussed below cite the specific Plaintiff declaration(s) associated with those injuries. The Complaint incorporates by reference each of the allegations in these declarations.

A. Injuries to Patients

260. The FDA's 2000 Approval legalized an unsafe drug regimen.[170]

261. Chemical abortion drugs cause women and girls to suffer many intense side effects, including cramping, heavy bleeding, and severe pain.[171]

262. Women and girls who take chemical abortion drugs experience significantly more complications than those who have surgical abortions.[172]

263. The FDA's 2000 Approval has caused women and girls to suffer complications from chemical abortion.[173]

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[170] *See* Compl. ¶¶ 141–158.

[171] Ex. 4, Harrison Decl. ¶ 23; Ex. 9, Wozniak Decl. ¶ 17; Ex. 8, Skop Decl. ¶ 13; Ex. 49, Johnson Decl. ¶ 8; Ex. 50, Frost-Clark Decl. ¶ 9; Ex. 51, Delgado Decl. ¶ 11.

[172] Ex. 4, Harrison Decl. ¶ 22; Ex. 9, Wozniak Decl. ¶ 15; Ex. 8, Skop Decl. ¶ 19; Ex. 10, Foley Decl. ¶ 8; Ex. 51, Delgado Decl. ¶ 11.

[173] Ex. 4, Harrison Decl. ¶ 24; Ex. 7, Francis Decl. ¶ 10; Ex. 9, Wozniak Decl. ¶ 8; Ex. 8, Skop Decl. ¶¶11–13, 16–19, 22–23; Ex. 52, Jester Decl. ¶ 16; Ex. 49, Johnson Decl. ¶¶ 9–11; Ex. 10, Foley Decl. ¶ 3; Ex. 50, Frost-Clark Decl. ¶ 7; Ex. 3, Dickerson Decl. ¶ 11.

264. Since the 2016 Major Changes, the rate of women and girls who have suffered complications from chemical abortion and required critical medical treatment has increased and will continue to increase.[174]

265. The FDA's decision to expand the gestational age for approved mifepristone use to 70 days (10 weeks) harms women.[175]

266. This expansion of the permissible gestational age is especially dangerous for women and girls when combined with the FDA's elimination of the in-person dispensing and follow-up visit requirements.[176]

267. The FDA's failure to require an ultrasound, its subsequent elimination of in-person drug administration, physician supervision, and patient follow-up, and, finally, its removal of the requirement of in-person dispensing in specified health care settings, exposes women and girls to increased risk of suffering complications from chemical abortion and requiring further medical attention following the drug regimen.[177]

268. Because the FDA does not require it, many abortionists do not remain physically near women and girls during the most painful and excruciating periods of

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[174] Ex. 4, Harrison Decl. ¶ 26; Ex. 7, Francis Decl. ¶ 11; Ex. 9, Wozniak Decl. ¶ 18; Ex. 52, Jester Decl. ¶ 23; Ex. 49, Johnson Decl. ¶ 9; Ex. 10, Foley Decl. ¶ 10; Ex. 51, Delgado Decl. ¶¶ 16, 18; Ex. 3, Dickerson Decl. ¶ 11.

[175] Ex. 9, Wozniak Decl. ¶ 10; Ex. 52, Jester Decl. ¶ 17.

[176] Ex. 52, Jester Decl. ¶ 13.

[177] Ex. 4, Harrison Decl. ¶¶ 24–31; Ex. 7, Francis Decl. ¶ 11; Ex. 9, Wozniak Decl. ¶¶ 8–10, 14; Ex. 8, Skop Decl. ¶¶ 20, 25–29; Ex. 5, Barrows Decl. ¶¶ 15–18; Ex. 52, Jester Decl. ¶¶ 15–18, 22–23, 25; Ex. 10, Foley Decl. ¶ 9; Ex. 50, Frost-Clark Decl. ¶¶ 12–15.

the chemical abortion drug regimen, often sending them home with the drugs. Given their lack of admitting privileges and treatment capabilities, abortionists usually instruct women to go to the emergency department of the closest hospital for treatment of any severe adverse events.[178]

269. The FDA has eliminated all procedural safeguards that would rule out ectopic pregnancies, verify gestational age, identify any contraindications to prescribing mifepristone, or identify potential complications like sepsis and hemorrhage, remaining fetal parts, and others until the patient is at a critical time or it is too late to help the patient. As a result, women and girls often suffer unexpected episodes of heavy bleeding or severe pain and must rush to the emergency department of the nearest hospital.[179]

270. As more women and girls require treatment in emergency departments, the other patients of the treating doctors are adversely affected. With the increase in women and girls suffering emergency complications from chemical abortion or seeking to reverse the effects of the chemical abortion regimen, there is a direct correlation in the decrease in time, attention, and resources that emergency department doctors have to treat their other patients.[180]

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[178] Ex. 4, Harrison Decl. ¶ 19; Ex. 10, Foley Decl. ¶ 11.

[179] Ex. 8, Skop Decl. ¶¶ 13, 17–18, 22–23, 28–29; Ex. 5, Barrows Decl. ¶¶ 17–18; Ex. 52, Jester Decl. ¶¶ 13, 15–16, 23; Ex. 10, Foley Decl. ¶ 9; Ex. 50, Frost-Clark Decl. ¶¶ 12–15.

[180] Ex. 9, Wozniak Decl. ¶¶ 17–18, 27; Ex. 7, Francis Decl. ¶ 12; Ex. 49, Johnson Decl. ¶¶ 14, 16; Ex. 8, Skop Decl. ¶ 32; Ex. 10, Foley Decl. ¶ 10; Ex. 51, Delgado Decl. ¶ 18; Ex. 3, Dickerson Decl. ¶ 14.

271. Abortionists commonly violate the remaining safeguards and the FDA-approved label for chemical abortion drugs by giving the drugs to women who are contraindicated for chemical abortion (i.e., could experience deadly adverse events if they take the drugs) and then subsequently harmed by these drugs, demonstrating that the FDA's remaining safeguards for women and girls are ineffective in protecting them.[181]

272. The FDA's decision not to require abortionists to report all adverse events for chemical abortion drugs harms women and girls because it creates an inaccurate and false safety profile for the use of chemical abortion drugs.[182]

273. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain undercounted and therefore are unknown. Because abortion providers cannot know the accurate risk levels that their patients face when ingesting these drugs, these providers cannot properly inform their patients about the risks associated with chemical abortion. This prevents women and girls from giving informed consent to these providers.[183]

274. Many women and girls do not fully understand the nature of chemical abortion drugs and the risks that these drugs present to them.[184]

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[181] Ex. 9, Wozniak Decl. ¶ 24.

[182] Ex. 4, Harrison Decl. ¶ 35; Ex. 52, Jester Decl. ¶ 24.

[183] Ex. 4, Harrison Decl. ¶¶ 36–38; Ex. 9, Wozniak Decl. ¶¶ 19–20; Ex. 49, Johnson Decl. ¶ 17.

[184] Ex. 4, Harrison Decl. ¶ 31; Ex. 8, Skop Decl. ¶¶ 13, 27; Ex. 52, Jester Decl. ¶ 24; Ex. 49, Johnson Decl. ¶ 12; Ex. 10, Foley Decl. ¶¶ 12, 15; Ex. 51, Delgado Decl. ¶ 15.

275. Abortionists who prescribe or dispense chemical abortion drugs are not providing women with an adequate, accurate assessment of the known risks and effects associated with chemical abortion. Therefore, women and girls are unable to give informed consent to the drugs they are receiving, and thus they are not consenting at all to taking the chemical abortion drugs—resulting in physical and mental injuries.[185]

276. Women and girls often suffer distress and regret after undergoing chemical abortion, sometimes seeking to reverse the effects of mifepristone.[186]

277. A woman or girl can experience these emotions and feelings upon viewing the body of her lifeless baby after taking chemical abortion drugs.[187]

278. Even with medical oversight, abortionists can sometimes coerce women into taking chemical abortion drugs—without their true informed consent.[188]

279. The FDA's actions to eliminate in-person dispensing and administration also harm women because the lack of oversight will likely exacerbate human trafficking. Many trafficked women experience abortions and doctors potentially serve as an important resource to intervene on behalf of these trafficked women and girls.[189]

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[185] Ex. 4, Harrison Decl. ¶ 37; Ex. 8, Skop Decl. ¶¶ 14, 16, 27; Ex. 49, Johnson Decl. ¶ 12; Ex. 10, Foley Decl. ¶ 15; Ex. 50, Frost-Clark Decl. ¶ 20; Ex. 51, Delgado Decl. ¶ 15.

[186] Ex. 8, Skop Decl. ¶¶ 15–16; Ex. 10, Foley Decl. ¶¶ 12, 16; Ex. 51, Delgado Decl. ¶ 14.

[187] Ex. 8, Skop Decl. ¶ 15.

[188] Ex. 51, Delgado Decl. ¶ 15.

[189] Ex. 8, Skop Decl. ¶ 31.

280. Women and girls will continue to suffer complications from chemical abortion drugs.[190]

B. Injuries to Plaintiff Doctors

281. Because the FDA's 2000 Approval of chemical abortion drugs legalized an unsafe drug regimen, women and girls have suffered many intense side effects and increasing complications—requiring crucial medical attention and treatment.[191]

282. The FDA's 2000 Approval has caused medical professionals, including Plaintiff doctors and the members of Plaintiff medical associations, to treat women and girls who have suffered complications from mifepristone and misoprostol.[192]

283. Since the 2016 Major Changes and the associated elimination of necessary safeguards for women and girls, medical professionals, including Plaintiff doctors and the members of Plaintiff medical associations, have seen and will continue to see an additional increase in the rate of women and girls who have suffered complications from chemical abortion—complications requiring critical treatment from these doctors.[193]

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[190] Ex. 4, Harrison Decl. ¶ 26; Ex. 7, Francis Decl. ¶ 11; Ex. 9, Wozniak Decl. ¶ 29; Ex. 8, Skop Decl. ¶ 21; Ex. 52, Jester Decl. ¶ 20; Ex. 49, Johnson Decl. ¶ 18.

[191] Ex. 4, Harrison Decl. ¶ 23; Ex. 9, Wozniak Decl. ¶¶ 15, 17; Ex. 8, Skop Decl. ¶¶ 13, 18; 23; Ex. 5, Barrows Decl. ¶ 17; Ex. 49, Johnson Decl. ¶ 8; Ex. 50, Frost-Clark Decl. ¶ 9; Ex. 51, Delgado Decl. ¶ 11; Ex. 10, Foley Decl. ¶ 8; Ex. 3, Dickerson Decl. ¶ 11.

[192] Ex. 4, Harrison Decl. ¶ 24; Ex. 7, Francis Decl. ¶ 10; Ex. 8, Skop Decl. ¶¶ 12–21; Ex. 52, Jester Decl. ¶ 17; Ex. 49, Johnson Decl. ¶ 9; Ex. 10, Foley Decl. ¶ 3; Ex. 50, Frost-Clark Decl. ¶ 7; Ex. 3, Dickerson Decl. ¶¶ 11, 13.

[193] Ex. 4, Harrison Decl. ¶ 26; Ex. 7, Francis Decl. ¶ 11; Ex. 9, Wozniak Decl. ¶ 18; Ex. 52, Jester Decl. ¶¶ 18, 23, 25; Ex. 49, Johnson Decl. ¶ 9; Ex. 10, Foley Decl. ¶ 9; Ex. 50, Frost-Clark Decl. ¶¶ 12–15; Ex. 51, Delgado Decl. ¶¶ 13, 16; Ex. 3, Dickerson Decl. ¶ 12.

284. The FDA's approved regimen for chemical abortion drugs harms not only women and girls but also medical professionals, including Plaintiff doctors and the members of Plaintiff medical associations, who respond and treat these complications and other effects from chemical abortion drugs.[194]

285. The FDA's elimination of most of the safeguards protecting women and girls from the dangers of mifepristone has made chemical abortion more widely available and with less medical supervision—causing more women and girls to experience complications from chemical abortion and, therefore, increasing emergency situations. An increase in complications only compounds the harm to doctors, including Plaintiff doctors and the members of Plaintiff medical associations.[195]

286. When women and girls suffer complications from chemical abortion drugs, these adverse events can overwhelm the medical system and consume crucial limited medical resources, including blood for transfusions, physician time and attention, space in hospitals and medical centers, and other equipment and

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[194] Ex. 4, Harrison Decl. ¶¶ 26–30; Ex. 7, Francis Decl. ¶¶ 12–13; Ex. 9, Wozniak Decl. ¶ 17; Ex. 8, Skop Decl. ¶¶ 25, 32; Ex. 52, Jester Decl. ¶¶ 17, 18; Ex. 49, Johnson Decl. ¶ 14; Ex. 51, Delgado Decl. ¶ 13; Ex. 3, Dickerson Decl. ¶ 12.

[195] Ex. 52, Jester Decl. ¶¶ 20, 25; Ex. 50, Frost-Clark Decl. ¶ 8; Ex. 4, Harrison Decl. ¶¶ 26–30, 28; Ex. 7, Francis Decl. ¶ 14; Ex. 8, Skop Decl. ¶¶ 20, 28, 32; Ex. 49, Johnson Decl. ¶ 14; Ex. 10, Foley Decl. ¶ 10.

medicines.[196] This need for blood transfusions exacerbates the current critical national blood shortage.[197]

287. The increased occurrence of complications related to chemical abortion drugs multiplies the workload of health care providers, including Plaintiff doctors and the members of Plaintiff medical associations, in some cases by astronomical amounts. This is especially true in maternity care "deserts" (i.e., geographic areas where there are not a large number of OB/Gyn providers for patients).[198]

288. When there is a complication from chemical abortion drugs, the typical care doctors provide patients moves from simple patient management to complicated patient management. Accordingly, a patient who suffers complications from chemical abortion drugs requires significantly more time and attention from providers than most patients require.[199]

289. For example, Plaintiff Dr. Jester needed to treat a woman who had traveled from Texas to New Mexico to obtain chemical abortion drugs from Planned Parenthood. The woman returned to Texas, suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection. At the hospital, Dr. Jester provided her with intravenous antibiotics and performed a dilation and curettage

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[196] Ex. 4, Harrison Decl. ¶ 28; Ex. 7, Francis Decl. ¶ 17; Ex. 9, Wozniak Decl. ¶ 17.

[197] Ex. 4, Harrison Decl. ¶ 19; *see also* Current National Blood Supply, https://americasblood.org/for-donors/americas-blood-supply/ (last visited Nov. 16, 2022); Catherine Garcia, *The urgent American blood shortage, explained*, The Week (Oct. 26, 2022), https://theweek.com/health-and-wellness/1017643/the-urgent-american-blood-shortage-explained.

[198] Ex. 4, Harrison Decl. ¶ 29; Ex. 7, Francis Decl. ¶ 14; Ex. 9, Wozniak ¶¶ 17–18.

[199] Ex. 4, Harrison Decl. ¶ 30.

(i.e., the surgical procedure to remove a dead baby and pregnancy tissue from inside the uterus). If she had waited a few more days before receiving care from Dr. Jester, she could have been septic and died.[200]

290. Dr. Nancy Wozniak, a member of Plaintiff AAPLOG, needed to treat a woman who had contraindications to chemical abortion drugs (due to her taking anti-coagulants) but still received chemical abortion drugs from Planned Parenthood in Indiana. The woman consumed the first chemical abortion drug, mifepristone, at Planned Parenthood and took an Uber for a ride home. During her Uber ride, she began to experience bleeding and other adverse side effects from the mifepristone. Instead of taking her home, the Uber driver took her to the emergency department of Dr. Wozniak's hospital. Dr. Wozniak treated the woman and advised her not to take the second chemical abortion drug, misoprostol, because of the grave risk that she could bleed out and die.[201]

291. The FDA's elimination of the in-person dispensing requirement for chemical abortion drugs—allowing mail-order abortion—further harms the practice of medicine. The increasing number of chemical abortions through mail-order or telemedicine methods means that more women and girls will suffer complications and require medical attention from doctors, including Plaintiff doctors and the

[200] Ex. 52, Jester Decl. ¶ 17.

[201] Ex. 9, Wozniak Decl. ¶¶ 24–25.

members of Plaintiff medical associations, especially given that remote abortionists often cannot or do not treat such complications.[202]

292. To circumvent state laws that regulate abortions and protect the health and safety of women and girls, abortionists are relying on access to chemical abortion drugs through mail-order schemes or telemedicine, further increasing the use of these drugs and the complications associated with them.[203]

293. As more emergency situations arise, emergency room doctors, such as Plaintiff doctors and the members of Plaintiff medical associations, are having to treat more patients, including performing hysterectomies or removing fetal parts remains. The more patients suffering emergency complications from chemical abortion or seeking to reverse the chemical abortion process, the less time and attention these doctors have to treat their other patients.[204]

294. Because abortionists do not adequately describe what happens during a chemical abortion and give these drugs to women and girls to take outside of the abortion facility, doctors have needed to treat and care for many women who have come to the emergency department for their intense bleeding and other effects of

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[202] Ex. 9, Wozniak Decl. ¶ 14; Ex. 5, Barrows Decl. ¶ 17; Ex. 52, Jester Decl. ¶¶ 22–23; Ex. 50, Frost-Clark Decl. ¶ 12–15; Ex. 10, Foley Decl. ¶ 10.

[203] Ex. 9, Wozniak Decl. ¶ 13; Ex. 10, Foley Decl. ¶ 10; *see also* Ruth Reader, *State abortion bans prove easy to evade*, Politico (Nov. 11, 2022, 2:24 PM), https://www.politico.com/news/2022/11/01/state-abortion-bans-medication-00064407; Emily Bazelon, *Risking Everything to Offer Abortions Across State Lines*, New York Times (Oct. 4, 2022), https://www.nytimes.com/2022/10/04/magazine/abortion-interstate-travel-post-roe.html.

[204] Ex. 9, Wozniak Decl. ¶¶ 17–18, 27; Ex. 7, Francis Decl. ¶ 14; Ex. 49, Johnson Decl. ¶¶ 14, 16; Ex. 8, Skop Decl. ¶ 32; Ex. 51, Delgado Decl. ¶ 18.

the chemical abortion drugs—although not considered complications from the regimen.[205]

295. Doctors, including Plaintiff doctors and the members of Plaintiff medical associations, experience enormous pressure, stress, and chaos in these emergency situations that the FDA created through its approval of chemical abortion drugs and elimination of necessary safeguards.[206]

296. Some of these emergency situations force pro-life doctors, including Plaintiff doctors and the members of Plaintiff medical associations, into situations in which they feel complicit in an elective chemical abortion by needing to remove a baby with a beating heart or pregnancy tissue as the only means to save the life of the woman or girl. This feeling of complicity in the act of an elective chemical abortion causes great emotional suffering, mental anguish, and spiritual distress among these doctors.[207]

297. For example, Dr. Ingrid Skop, a member of Plaintiff AAPLOG, needed to treat a young woman who had been bleeding for six weeks after she took chemical abortion drugs at a Planned Parenthood facility. After two follow-up appointments, Planned Parenthood had given her an additional dose of the second chemical abortion drug, misoprostol, which failed to resolve her complications. When Dr. Skop treated the young woman, Dr. Skop performed a sonogram,

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[205] Ex. 10, Foley Decl. ¶ 15; Ex. 49, Johnson Decl. ¶ 11.

[206] Ex. 9, Wozniak Decl. ¶ 17; Ex. 5, Barrows Decl. ¶ 19; Ex. 52, Jester ¶ 20; Ex. 49, Johnson ¶ 15; Ex. 3, Dickerson Decl. ¶ 14.

[207] Ex. 8, Skop Decl. ¶ 34; Ex. 7, Francis Decl. ¶ 13; Ex. 5, Barrows Decl. ¶ 26; Ex. 3, Dickerson Decl. ¶ 16.

identified a significant amount of pregnancy tissue remaining in the woman's uterus, and had to perform a suction aspiration to resolve her complication.[208]

298. The members of Plaintiff medical associations oppose being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. Accordingly, Plaintiff medical associations and their members are harmed by the FDA's repeated removal of necessary safeguards, which may force them to treat women and girls seeking the completion of an elective chemical abortion. This concern is real and imminent, especially in light of the Biden HHS's impermissible actions to compel doctors to complete elective chemical abortions under the Emergency Medical Treatment and Active Labor Act (EMTALA).[209]

299. The FDA's loosening of chemical abortion regulations impacts the standard of care for chemical abortion drugs and the demands and expectations that hospitals will put on their physicians.[210]

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[208] Ex. 8, Skop Decl. ¶ 23.

[209] Ex. 4, Harrison Decl. ¶ 44; Ex. 5, Barrows Decl. ¶ 26; Ex. 3, Dickerson Decl. ¶ 16; *see also Reinforcement of EMTALA Obligations specific to Patients who are Pregnant or are Experiencing Pregnancy Loss (QSO-21-22-Hospitals- UPDATED JULY 2022)*, https://www.cms.gov/files/document/qso-22-22-hospitals.pdf.

[210] Ex. 5, Barrows Decl. ¶ 25.

300. It grieves Plaintiff doctors and members of Plaintiff medical associations to treat women and girls harmed by chemical abortion drugs, including those who regret their decision to have a chemical abortion.[211]

301. When their patients have chemical abortions, doctors lose the opportunity to provide professional services and care for the woman and child through pregnancy, which causes harms to providers who no longer can care for their patients and bring about a successful delivery of a new life.[212]

302. The FDA's elimination of the requirement for abortionists to report all adverse events related to chemical abortion drugs leads to unreliable reporting. Without an accurate understanding of the adverse effects of widespread chemical abortion drug use, Plaintiff doctors and members of Plaintiff medical associations cannot effectively practice evidence-based medicine. Health care providers cannot assess the risks of a particular course of treatment if the FDA is not collecting and tracking the risks. And, therefore, they cannot accurately advise their patients and the public about these risks.[213]

303. Many doctors likely do not know about the importance of reporting adverse events related to chemical abortion drugs to the FDA. Similarly, many doctors likely do not know how to report adverse events.[214]

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[211] Ex. 52, Jester Decl. ¶ 27; Ex. 8, Skop Decl. ¶ 33; Ex. 51, Delgado ¶ 14.

[212] Ex. 51, Delgado Decl. ¶ 17; Ex. 52, Jester Decl. ¶ 19.

[213] Ex. 9, Wozniak Decl. ¶¶ 19–20; Ex. 5, Barrows Decl. ¶ 19; Ex. 8, Skop Decl. ¶ 30; Ex. 4, Harrison Decl. ¶¶ 36–39; Ex. 52, Jester Decl. ¶¶ 24, 26; Ex. 49, Johnson Decl. ¶ 17; Ex. 10, Foley Decl. ¶ 17; Ex. 50, Frost-Clark Decl. ¶ 22.

[214] Ex. 4, Harrison Decl. ¶ 33.

304. Even when Plaintiff doctors and members of Plaintiff medical associations want to voluntarily report adverse events associated with chemical abortion to the FDA, they must go through the complicated, cumbersome, and time-consuming FAERS submission process. The adverse event reporting requirements and the FAERS submission process harm medical practices by taking away significant time from a doctor to treat and meet with patients.[215]

305. In addition, even when doctors want to voluntarily report adverse events to the manufacturer, Danco, the doctor must print, fill out by hand, and then either mail or email back the form to Danco. Much of the information required by this form is impossible to obtain by the physician seeing the patient if they were not the one who dispensed the medication (such as lot number and dosage)—forcing the doctor to leave several fields blank. There is no confirmation whether the reported complications were recorded by Danco or reported to the FDA. Regardless, this submission process harms medical practices by taking away significant time from a doctor to treat and meet with patients.[216]

306. Even when doctors want to report adverse events to their state regulators, their reports can be rejected for improper reasons (e.g., asserting that there was no adverse event because the doctor saved and treated the woman injured by chemical abortion drugs).[217]

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[215] Ex. 7, Francis Decl. ¶¶ 16–18; Ex. 4, Harrison Decl. ¶ 33–34; Ex. 50, Frost-Clark Decl. ¶ 23.

[216] Ex. 7, Francis Decl. ¶¶ 16–18.

[217] Ex. 9, Wozniak Decl. ¶ 26.

307. Because many women and girls suffering complications from chemical abortion drugs tell emergency department doctors that they are experiencing miscarriages, these doctors might not report these incidences as adverse events and so these complications are significantly underreported or not fully known.[218]

308. The inability or refusal of a patient to disclose why she is presenting herself in the emergency department or what drugs she has received also impedes the ability of doctors, including Plaintiff doctors and the members of Plaintiff medical associations, to practice medicine and provide proper treatment to these patients.[219]

309. The lack of accurate information on adverse events also harms the doctor-patient relationship with all medical care providers because the patients no longer trust that their health care providers are telling them the truth. This harms even doctors who do not support or practice chemical abortions, such as the members of the AAPLOG.[220]

310. The FDA's removal of necessary safeguards for women and girls who use chemical abortion drugs increases physicians' exposure to potential liability. Emergency department physicians often have no prior relationship with the patient, lack access to the patient's medical history, and encounter patients who do not know what drugs they consumed or conceal the fact that they attempted a

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[218] Ex. 9, Wozniak Decl. ¶ 28; Ex. 10, Foley Decl. ¶ 14.

[219] Ex. 9, Wozniak Decl. ¶ 28; Ex. 49, Johnson Decl. ¶¶ 13, 15; Ex. 10, Foley Decl. ¶ 14; Ex. 50, Frost-Clark Decl. ¶¶ 16–17, 19.

[220] Ex. 4, Harrison Decl. ¶ 37.

chemical abortion. These factors place physicians in higher-risk situations with less critical information about patients, thus increasing their exposure to allegations of malpractice and potential liability.[221]

311. As this exposure increases, so does the cost to practice medicine, including insurance costs.[222]

312. Doctors, such as Dr. Jester and Dr. Delgado, serve patients as professional health care providers. They provide care to all women and unborn children, and they give them the best professional services possible. Just like all other health care providers, a hospital or practice will bill for the costs of medical services rendered. When their patients have chemical abortions, they lose the opportunity to provide professional medical care for the woman and child through pregnancy and bring about a successful delivery of a new life.[223]

313. Plaintiffs expect to continue to treat women and girls who suffer complications from chemical abortion drugs.[224]

C. Injuries to Plaintiff Medical Associations

314. Plaintiffs medical associations have also suffered organizational harms from the FDA's approval and deregulation of chemical abortion drugs.

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[221] Ex. 9, Wozniak Decl. ¶¶ 21–22; Ex. 5, Barrows Decl. ¶¶ 22–24; Ex. 52, Jester Decl. ¶ 21; Ex. 49, Johnson Decl. ¶ 15; Ex. 10, Foley Decl. ¶ 14; Ex. 50, Frost-Clark Decl. ¶¶ 16–18; Ex. 3, Dickerson Decl. ¶ 15.

[222] Ex. 5, Barrows Decl. ¶ 24.

[223] Ex. 52, Jester Decl. ¶ 19; Ex. 51, Delgado ¶ 17.

[224] Ex. 4, Harrison Decl. ¶ 26; Ex. 7, Francis Decl. ¶ 11; Ex. 9, Wozniak Decl. ¶ 29; Ex. 8, Skop Decl. ¶ 21; Ex. 52, Jester Decl. ¶¶ 12, 20; Ex. 49, Johnson Decl. ¶ 18.

315. For example, the inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates Plaintiff medical associations' purpose to support women's health and to educate doctors, their patients, and the public about these dangers.[225]

316. In addition, Plaintiff AAPLOG has needed to divert limited time, energy, and resources to compensate for this lack of information by conducting their own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of Plaintiff AAPLOG, including their efforts about the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.[226]

317. Plaintiffs AAPLOG and Christian Medical & Dental Associations submitted a citizen petition in 2002 challenging the FDA's 2000 Approval of chemical abortion drugs and requesting an audit of the clinical studies. Both associations were concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving chemical abortion drugs put the lives and health of women and girls at risk. It took considerable time, energy, and resources to draft their 92-page petition and the 30-page response to comments letter, in addition to compiling and analyzing supporting sources and

[225] Ex. 4, Harrison Decl. ¶¶ 38–39; Ex. 7, Francis Decl. ¶¶ 19–20; Ex. 5, Barrows Decl. ¶¶ 20–21; Ex. 6, Van Meter Decl. ¶¶ 19–20; Ex. 3, Dickerson Decl. ¶¶ 21–22.
[226] Ex. 4, Harrison Decl. ¶ 40; Ex. 7, Francis Decl. ¶ 21.

studies. This effort caused both associations to divert limited time, energy, and resources from its other priorities and routine functions.[227]

318. Similarly, Plaintiffs AAPLOG and American College of Pediatricians submitted another citizen petition in 2019 challenging the FDA's 2016 Major Changes to the chemical abortion drug regimen. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting sources and studies. This effort caused both associations to divert limited time, energy, and resources from its other priorities and routine functions.[228]

319. The Catholic Medical Association, a member of the Alliance for Hippocratic Medicine, has also taken actions to challenge the FDA's approval and deregulation of chemical abortion drugs—at the expense of other priorities.[229]

320. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, Plaintiff medical associations continue to expend considerable time, energy, and resources on its public advocacy and educational activities about chemical abortion drugs—to the detriment of their other priorities and functions.

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[227] Ex. 4, Harrison Decl. ¶ 41; Ex. 7, Francis Decl. ¶ 22; Ex. 5, Barrows Decl. ¶ 27.
[228] Ex. 4, Harrison Decl. ¶ 42; Ex. 7, Francis Decl. ¶ 23; Ex. 6, Van Meter Decl. ¶ 21.
[229] Ex. 3, Dickerson Decl. ¶¶ 17–20.

This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs cease.[230]

XIX. The Need for Judicial Relief

321. Injunctive relief is necessary to prevent these harms, and judicial relief is appropriate to vacate, set aside, enjoin, and declare these acts unlawful.

322. All of the agency actions at issue—the 2000 Approval, the 2016 Petition Denial, the 2016 Major Changes, the 2019 ANDA Approval, the 2021 Non-Enforcement Decision, and the 2021 Petition Response, as well as the agency's failure to act and prohibit or restrict chemical abortion drugs—are final agency actions subject to judicial review under the APA.

323. All the acts of Defendants described above, and their officers, agents, employees, and servants, were executed and are continuing to be executed by Defendants under the color and pretense of the policies, statutes, ordinances, regulations, customs, and usages of the United States.

324. Under 5 U.S.C. § 701(a), no statute precludes judicial review of the agency's actions, and the actions are not committed to agency discretion by law.

325. Under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions" if they are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

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[230] Ex. 4, Harrison Decl. ¶ 43; Ex. 7, Francis Decl. ¶ 24; Ex. 5, Barrows Decl. ¶ 27; Ex. 6, Van Meter Decl. ¶ 22; Ex. 3, Dickerson Decl. ¶ 20.

326. Under the APA, a reviewing court must "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

327. Likewise, a court must "compel agency action unlawfully withheld." 5 U.S.C. § 706(1).

328. Plaintiffs have no adequate remedy available at law.

329. Plaintiffs have no adequate or available administrative remedy. In the alternative, any administrative remedy would be futile or unnecessary.

330. Defendants would suffer no harm from the relief requested, and the relief requested would serve the public interest.

CLAIMS FOR RELIEF

CLAIM ONE

2000 APPROVAL

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706) IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

331. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

332. Defendants lacked legal authority in 2000 to approve mifepristone under the FDA's Subpart H regulations.

I. Subpart H

333. The FDA's Subpart H regulations apply only 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 (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 C.F.R. § 314.500.

334. Pregnancy is not an illness.

335. Pregnancy is neither "serious" nor "life-threatening," as those terms are understood in Subpart H.

336. Chemical abortion does not provide a "meaningful therapeutic benefit to patients over existing treatments."

337. Defendants lacked the authority to approve mifepristone for chemical abortion under Subpart H in 2000.

338. Because the French and American trials did not compare the Mifeprex regimen with the then-existing method for ending pregnancies (i.e., surgical abortion), the trials did not demonstrate a "meaningful therapeutic benefit over existing therapy."

339. Thus, the FDA's 2000 Approval of mifepristone for chemical abortion was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with Subpart H's provision for the accelerated approval of certain new drugs.

II. FFDCA

340. Defendants lacked legal authority in 2000 to approve mifepristone under the FFDCA.

341. The FDA's 2000 Approval violated the FFDCA because the clinical trials on which the agency relied did not use the full set of design features the

agency typically requires to produce unbiased investigations of drug safety and effectiveness.

342. Because these trials were not blinded, randomized, or concurrently controlled, they did not establish the safety and effectiveness of the Mifeprex regimen.

343. The FDA also failed to perform a statistical analysis of the data from the U.S. Clinical Trial.

344. The FDA impermissibly extrapolated conclusions about the safety and effectiveness of mifepristone from the U.S. Clinical Trial even though the agency did not retain the requirements governing physician training, ultrasound, the post-misoprostol waiting period, or physician privileges at facilities that provide emergency care. The U.S. Clinical Trial failed to meet the requirements of the FFDCA that the trial demonstrates safety and effectiveness under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. Instead, the FDA had insufficient information on whether mifepristone was safe under such conditions.

345. Finally, the FDA violated the FFDCA and the agency's implementing regulations because the agency mandated the use of misoprostol for chemical abortion as part of the 2000 Approval—despite the requirement that the sponsor submit an sNDA for a new use of a previously approved drug.

346. Therefore, Defendants lacked the authority to approve mifepristone for chemical abortion under the FFDCA. Given these infirmities, the 2000 Approval

was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the FFDCA.

III. PREA

347. Defendants lacked legal authority in 2000 to approve mifepristone under PREA.

348. In the 2000 Approval, the FDA stated that it was "waiving the pediatric study requirement for this action on this application."[231]

349. Because the 2000 Approval failed to meet any of the qualifications for a waiver, *see* 21 U.S.C. § 355c(a)(5)(A), (B), the FDA lacked authority when waiving the pediatric study requirement without explanation, and the 2000 Approval was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right when the FDA waived the pediatric study requirement without explanation. For the same reason, the 2000 Approval was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law when the FDA waived the pediatric study requirement without explanation.

350. In 2016, despite contrary evidence in the administrative record, the FDA sought to provide an impermissible post-hoc rationalization that it inaccurately stated in the 2000 Approval that it was "waiving" the pediatric study requirements and, instead, should have said it had found that the requirements

[231] Ex. 25, 2000 Approval Letter at 3.

were met for post-menarchal pediatric patients by extrapolating from studies of adult populations.[232]

351. In addition to such a post-hoc rationalization being impermissible and an inaccurate representation of the agency's decision-making at the time, the FDA lacked authority under PREA. The 2000 Approval was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and the 2000 Approval was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. Because the agency was allowed to extrapolate from studies of adult populations *only if* the course of a "disease" is substantially similar in adults and the pediatric population. Because pregnancy is not a disease, PREA did not permit the FDA to make such an extrapolation.

352. In addition to such a rationalization being impermissible and an inaccurate representation of the agency's decision-making at the time, the FDA lacked authority under PREA. The 2000 Approval was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and the 2000 Approval was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law because the FDA failed to satisfy the requirement for documentation of the scientific data that supports its extrapolation that the course of the "disease" and the effects of the drug are sufficiently similar in adult women and pediatric girls.

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[232] Ex. 27, 2016 Petition Denial at 29.

353. In addition to such a rationalization being impermissible and an inaccurate representation of the agency's decision-making at the time, the FDA lacked authority under PREA, the 2000 Approval was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and the 2000 Approval was arbitrary, capricious, an abuse of discretion, and not in accordance with law because PREA allows the agency to extrapolate from adequate and well-controlled studies in adults and, as discussed above, the U.S. Clinical Trial did not include adequate and well-controlled studies in adults.

354. In addition to such a rationalization being impermissible and an inaccurate representation of the agency's decision-making at the time, the 2000 Approval was arbitrary, capricious, and an abuse of discretion because the FDA's explanation that it expected girls—under the age of 18 years and going through reproductive development—to have the same physiological outcome with the drug regimen as adult women was unreasonable and not supported by the administrative record.

355. In addition to such a rationalization being impermissible and an inaccurate representation of the agency's decision-making at the time, the 2000 Approval was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law because the FDA did not require an assessment that evaluated the safety and effectiveness of the drug for girls under 18 years of age.

356. Therefore, Defendants lacked the authority to approve mifepristone for chemical abortion under PREA, and the 2000 Approval was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with PREA.

IV. Pretext

357. The FDA's illegal and unreasonable rationales for the 2000 Approval—in light of the political context of the agency's actions—indicate that the stated reasons for the 2000 Approval are pretext. Therefore, the FDA's 2000 Approval is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

V. Reopener and Request

358. "The reopening doctrine . . . create[s] 'an exception to statutory limits on the time for seeking review of an agency decision.'" *Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 141 (D.C. Cir. 1998). "Under the reopening doctrine, the time for seeking review starts anew where the agency reopens an issue." *Sierra Club v. EPA*, 551 F.3d 1019, 1024 (D.C. Cir. 2008). The U.S. Court of Appeals for the Fifth Circuit has adopted the "reopening doctrine." *See Texas v. Biden*, 20 F.4th 928, 951–55 (5th Cir. 2021), *rev'd on other grounds*, *Biden v. Texas*, 142 S. Ct. 2528 (2022).

359. The FDA's 2016 Major Changes decision and the 2021 Petition Response reopened the FDA's underlying 2000 Approval of chemical abortion drugs for chemical abortion. When issuing these decisions, the FDA undertook a serious, substantive reconsideration of the safeguards required in the 2000 Approval decision and affirmed in the 2016 Petition Denial. Ultimately, by removing these

safeguards, the FDA completely changed the regulatory context and created a different regulatory construct for chemical abortion drugs.

360. For the reasons stated above, the FDA's 2000 Approval of chemical abortion drugs must be held unlawful, set aside, and preliminarily and permanently enjoined.

CLAIM TWO

2016 PETITION DENIAL

**ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)
IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT;
ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW**

361. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

362. The 2002 Citizen Petition provided the FDA with substantial legal arguments that the 2000 Approval exceeded the agency's authority and was not in accordance with law under Subpart H, the FFDCA, and the Pediatric Rule.

363. The 2002 Citizen Petition also provided the FDA with significant scientific and factual reasons to withdraw the 2000 Approval.

364. By disregarding the arguments, facts, and reasons set forth in the 2002 Citizen Petition, the FDA's 2016 Petition Denial was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; and it was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. The FDA's 2016 Petition Denial was unreasonable and not supported by the administrative record.

365. The FDA's illegal and unreasonable rationales for the 2016 Petition Denial—in light of the political context of the agency's actions—indicate that the stated reasons for the 2016 Petition Denial are pretext. Therefore, the FDA's 2016 Petition Denial is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

366. "The reopening doctrine . . . create[s] 'an exception to statutory limits on the time for seeking review [of an agency decision].'" *Surface Transp. Bd.*, 158 F.3d at 141. "Under the reopening doctrine, the time for seeking review starts anew where the agency reopens an issue." *Sierra Club*, 551 F.3d at 1024. The U.S. Court of Appeals for the Fifth Circuit has adopted the "reopening doctrine." *See Texas v. Biden*, 20 F.4th at 951–55.

367. The FDA's 2016 Major Changes decision and the 2021 Petition Response have reopened the FDA's 2016 Petition Denial. When issuing these decisions, the FDA undertook a serious, substantive reconsideration of the safeguards enshrined in the 2000 Approval decision. Ultimately, by removing the safeguards in the 2000 Approval, the FDA created a different regulatory construct and completely changed the regulatory context for the chemical abortion drug regimen.

368. Therefore, the FDA's 2016 Petition Denial must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

CLAIM THREE

2016 MAJOR CHANGES

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706) IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

369. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

370. Defendants lacked legal authority to make the 2016 Major Changes.

I. FFDCA

371. The FDA's 2016 Major Changes violated the FFDCA because they did not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

372. The 2016 Major Changes violated the FFDCA because the results of the tests on which the FDA relied for its 2016 Major Changes showed that chemical abortion is unsafe for use under such conditions, or they did not show that such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

373. The 2016 Major Changes violated the FFDCA because the FDA had insufficient information to determine whether mifepristone is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

374. The FDA's 2016 Major Changes lacked substantial evidence that the new drug will have the effect it purports or is represented to have under the

conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

375. In violation of the FFDCA, none of the studies on which the FDA relied for its 2016 Major Changes evaluated the safety and effectiveness of the chemical abortion regimen under the conditions of the label approved in 2016, or they failed to satisfy the substantial evidence requirement for showing the safety and effectiveness of the regimen under the conditions of the label approved in 2016.

376. Therefore, Defendants lacked legal authority to make the 2016 Major Changes. The FDA's 2016 Major Changes were in excess of statutory jurisdiction, authority, or limitations, or short of statutory right under the FFDCA. The FDA's 2016 Major Changes were unreasonable and not supported by the administrative record.

II. PREA

377. The FDA lacked legal authority under PREA to make the 2016 Major Changes, and the 2016 Major Changes were in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and were arbitrary, capricious, an abuse of discretion, and not in accordance with law, because PREA allows the FDA to extrapolate from studies of adult populations only if the course of a "disease" is substantially similar in adults and the pediatric population. Because pregnancy is not a disease, PREA did not permit the FDA to make such an extrapolation.

378. Defendants lacked legal authority under PREA to make the 2016 Major Changes and the 2016 Major Changes were in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and were arbitrary, capricious,

an abuse of discretion, and not in accordance with law, because the FDA failed to satisfy the requirement for documentation of the scientific data that supports its extrapolation that the course of the "disease" and the effects of the drug are sufficiently similar in adult women and pediatric girls.

379. Defendants lacked legal authority under PREA to make the 2016 Major Changes and the 2016 Major Changes were in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and were arbitrary, capricious, an abuse of discretion, and not in accordance with law, because the FDA did not require an assessment that evaluated the safety and effectiveness of mifepristone for girls under 18 years of age.

III. Pretext

380. The FDA's illegal and unreasonable rationales for the 2016 Major Changes—in light of the political context of the agency's actions—indicate that the stated reasons for the 2016 Major Changes are pretext. Therefore, the FDA's 2016 Major Changes is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

IV. Request

381. For the reasons stated above, the FDA's 2016 Major Changes must be held unlawful, set aside, and preliminarily and permanently enjoined.

CLAIM FOUR

2019 ABBREVIATED NEW DRUG APPROVAL

**ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)
IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT;
ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW**

382. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

383. Defendants lacked legal authority to issue the 2019 ANDA Approval.

384. Because the FDA relied on the unlawful 2000 Approval of Mifeprex as a means to approve GenBioPro's generic drug, Mifepristone Tablets, 200 mg, if the Court finds that the 2000 Approval was unlawful, as set forth above, then the 2019 ANDA Approval needed independently to satisfy the requirements of the FFDCA and PREA.

385. Unable to rely on an unlawful approval, the FDA's approval of the 2019 ANDA Approval violated the FFDCA because it lacked the clinical investigations, adequate testing, sufficient information, and substantial evidence to show the safety and effectiveness of mifepristone under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof as required by 21 U.S.C. § 355(d).

386. Unable to rely on an unlawful approval, the FDA's approval of the 2019 ANDA also violated PREA because the submission lacked the necessary assessment on the safety and effectiveness of mifepristone on the pediatric population as required by 21 U.S.C. § 355c(a).

387. For these reasons, the 2019 ANDA Approval was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right, and the 2019 ANDA Approval was arbitrary, capricious, an abuse of discretion, and not in accordance with law.

388. The FDA's illegal and unreasonable rationales for the 2019 ANDA Approval—in light of the political context of the agency's actions—indicate that the stated reasons for the 2019 ANDA Approval are pretext. Therefore, the FDA's 2019 ANDA Approval is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

389. Therefore, the 2019 ANDA Approval must be held unlawful, set aside, and preliminarily and permanently enjoined.

CLAIM FIVE

2000 APPROVAL, 2016 MAJOR CHANGES, 2019 ANDA APPROVAL, 2021 NON-ENFORCEMENT DECISION, AND 2021 PETITION RESPONSE

ULTRA VIRES; ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706) IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

390. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

391. The FDA lacked legal authority when issuing its 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response.

392. None of these FDA actions comply with the federal laws that expressly prohibit the mailing or delivery by any letter carrier, express company, or other

common carrier of any substance or drug intended for producing abortion. 18 U.S.C. §§ 1461–62.

393. Since the 2000 Approval, the FDA has failed to restrict the upstream distribution of chemical abortion drugs from manufacturer or importer to abortionists in violation of these federal laws.

394. The FDA's 2021 Non-Enforcement Decision and 2021 Petition Response also violated these federal laws because they impermissibly removed the in-person dispensing requirement for chemical abortion drugs and, accordingly, authorized the downstream distribution of chemical abortion drugs by mail, express company, and other common carriers.

395. Because a federal agency cannot permit what federal law expressly prohibits, the FDA lacked legal authority when issuing its 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response.

396. Therefore, the FDA's 2000 Approval, 2016 Major Changes, 2021 Non-Enforcement Decision, and 2021 Petition Response must be held unlawful, set aside, and preliminarily and permanently enjoined under the Court's inherent equitable power to enjoin *ultra vires* actions, *Larson*, 337 U.S. at 689–91.

CLAIM SIX

2021 PETITION RESPONSE

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706) IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

397. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1–330 of this complaint.

398. The 2019 Citizen Petition provided the FDA with significant data and reasons to justify restoring the pre-2016 REMS.

399. The 2019 Citizen Petition also provided the FDA with significant data and reasons to justify strengthening the REMS for chemical abortion drugs, including the requirement that the abortionist uses an ultrasound to assess gestational age and diagnose ectopic pregnancies.

400. Finally, the 2019 Citizen Petition asked the FDA to require a formal study of outcomes for at-risk populations, including girls under the age of 18 years, as the agency has never studied these outcomes.

401. By disregarding the data and reasons set forth in the 2019 Citizen Petition, the FDA's 2021 Petition Response was unreasonable and not supported by the administrative record.

402. The FDA's 2021 Petition Response was in excess of statutory jurisdiction, authority, or limitations, or short of statutory right and arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

403. The FDA's illegal and unreasonable rationales for the 2021 Petition Denial—in light of the political context of the agency's actions—indicate that the stated reasons for the 2021 Petition Denial are pretext. Therefore, the FDA's 2021 Petition Denial is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the APA. 5 U.S.C. § 706(2)(A).

404. Therefore, the FDA's 2021 Petition Response must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

PRAYERS FOR RELIEF

For these reasons, Plaintiffs respectfully request that the Court enter an order as to Defendants, including their employees, agents, successors, and all persons in active concert or participation with them.

A. Issue a preliminary and permanent injunction ordering Defendants to withdraw mifepristone and misoprostol as FDA-approved chemical abortion drugs and to withdraw Defendants' actions to deregulate these chemical abortion drugs.

B. Hold unlawful, set aside, and vacate the 2000 Approval.

C. Hold unlawful, set aside, and vacate the 2016 Petition Denial.

D. Hold unlawful, set aside, and vacate the 2016 Major Changes.

E. Hold unlawful, set aside, and vacate the 2019 ANDA Approval.

F. Hold unlawful, set aside, and vacate the 2021 Non-Enforcement Decision.

G. Hold unlawful, set aside, and vacate the 2021 Petition Response.

H. Declare that the chemical abortion drugs mifepristone and misoprostol fall outside the scope of the FDA's regulation entitled "Subpart H–Accelerated

Approval of New Drugs for Serious or Life-Threatening Illnesses" (codified at 21 C.F.R. §§ 314.500, et seq.) because pregnancy is not an "illness" and these drugs do not "provide meaningful therapeutic benefit to patients over existing treatments."

I. Declare that the Federal Food, Drug, and Cosmetic Act requires the FDA to rely on clinical investigations and studies that show a drug is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof when reviewing and approving a new drug application or a supplemental new drug application.

J. Declare that the Federal Food, Drug, and Cosmetic Act prohibits the FDA from relying on studies that incorporate safeguards and protections not included under the conditions prescribed, recommended, or suggested in the proposed labeling when reviewing and approving a new drug application or a supplemental new drug application.

K. Declare that the Federal Food, Drug, and Cosmetic Act prohibits the FDA from relying exclusively on studies that fail to evaluate all the requested changes in the proposed labeling thereof when reviewing and approving a new drug application or a supplemental new drug application.

L. Declare that 18 U.S.C. § 1461 and 18 U.S.C. § 1462 prohibit the FDA from approving a new drug application or a supplemental new drug application that fails to limit distribution of chemical abortion drugs in accordance with these laws.

M. Retain jurisdiction of this matter for the purpose of enforcing this Court's order.

N. Award Plaintiffs' costs, attorneys' fees, and other disbursements for this action.

O. Grant any other relief this Court deems equitable, just, and appropriate.

Respectfully submitted this November 18, 2022.

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**Pro Hac Vice Application forthcoming*

TABLE OF EXHIBITS

Exhibit	Description
1	Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, Annals of Health Law, Winter 2014 at 61.
2	Bill Analysis, C.S.H.B. 3446, Committee Report.
3	Declaration of Mario R. Dickerson
4	Declaration of Dr. Donna Harrison
5	Declaration of Dr. Jeffrey Barrows
6	Declaration of Dr. Quentin Van Meter
7	Declaration of Dr. Christina Francis
8	Declaration of Dr. Ingrid Skop
9	Declaration of Dr. Nancy Wozniak
10	Declaration of Dr. Steven A. Foley
11	Byron Calhoun, *The maternal mortality myth in the context of legalized abortion,* 80 The Linacre Quarterly 264 (2013).
12	*The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform*, 109th Cong. 4 (2006).
13	2002 Citizen Petition of Am. Ass'n of Pro-Life Obstetricians & Gynecologists to U.S. Food & Drug Admin. (FDA) (Aug. 20, 2002).
14	FDA-Approved Label for Misoprostol (Cytotec) (Jan. 2017).
15	Maarit J. Mentula et al., *Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study*, 26 Hum. Reprod. 927 (2011).
16	Marrit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795 (2009).
17	James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015*, Health Servs. Rsch. & Managerial Epidemiology, Nov. 9, 2021.

18	Maarit Niinimaki, et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BJM, April 20, 2011.
19	James Studnicki et al., *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, Health Servs. Rsch. & Managerial Epidemiology, May 20, 2022.
20	Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*. 36 Health Commc'n 1485 (2021).
21	Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients, 63 Fed. Reg. 66,632 (Dec. 2, 1998).
22	New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942 (Dec. 11, 1992).
23	FDA Letter to Population Council re: NDA (Feb. 18, 2000).
24	2000 FDA Approval Memorandum to Population Council re: NDA 20-687 Mifeprex (mifepristone) (Sept. 28, 2000).
25	2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets (Sept. 28, 2000).
26	2003 Citizen Petitioners' Response to Opposition Comments filed by The Population Council, Inc. and Danco Laboratories, LLC (Oct. 10, 2003).
27	2016 FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists, Christian Medical & Dental Associations, and Concerned Women for America denying 2002 Citizen Petition, Docket No. FDA-2002-P-0364 (Mar. 29, 2016) (2016 Petition Denial).
28	Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16,313, 16,314 (Mar. 27, 2008).
29	2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC (June 6, 2011).
30	2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011).
31	2016 FDA Letter to Danco Laboratories re: NDA 020687, Supp 20 (Mar. 28, 2016).

32	FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020 (March 29, 2016) (2016 Summary Review).
33	Beverly Winikoff, et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 Obstetrics & Gynecology 1070 (2012).
34	Mary Gatter, et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269 (2015).
35	2019 Citizen Petition of Am. Ass'n of Pro-Life Obstetricians & Gynecologists to FDA (Mar. 29, 2019).
36	2019 FDA Abbreviated New Drug Application (ANDA) Approval Letter to GenBioPro, Inc. (Apr. 11, 2019).
37	2019 FDA Supplemental Approval Letter to Danco Laboratories, LLC (Apr. 11, 2019).
38	2020 Letter from Am. Coll. of Obstetricians & Gynecologists and Soc'y for Maternal-Fetal Med., to FDA about Mifepristone REMS (Apr. 20, 2020).
39	2021 FDA Letter to Am. Coll. of Obstetricians & Gynecologists and Soc'y for Maternal-Fetal Med. about Mifepristone REMS (Apr. 12, 2021).
40	2021 FDA Supplemental Approval Letter to Danco Laboratories, LLC (May 14, 2021).
41	2021 Updated REMS for Mifepristone Tabets, 200mg (May 14, 2021).
42	2021 FDA Center for Drug Evaluation and Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021).
43	2021 FDA Letter to Am. Ass'n of Pro-Life Obstetricians & Gynecologists and Am. Coll. of Pediatricians denying in part and granting in part 2019 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) (2021 FDA Response).
44	Questions and Answers on FDA's Adverse Event Reporting System (FAERS), https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.
45	Kathi A. Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 26 Law & Medicine 3 (2021).
46	Christina A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Rsch. & Managerial Epidemiology 1 (2021).

47	FDA, *FDA Adverse Event Reporting System (FAERS) Electronic Submissions.*
48	*Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments* (April 2021).
49	Declaration of Dr. Tyler Johnson
50	Declaration of Dr. Regina Frost-Clark
51	Declaration of Dr. George Delgado
52	Declaration of Dr. Shaun Jester

Exhibit 1

Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, Annals of Health Law, Winter 2014 at 61

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The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities

Laura J. Lederer

Christopher A. Wetzel

The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities

Laura J. Lederer* and Christopher A. Wetzel**

INTRODUCTION

> [W]hen I turned 13 I'd had enough of the abuse in home and I ran away. I didn't know where to go so I went to the center of town and stood by the town hall. A man saw me hanging around there and he said that he was looking for a 'protégé.' I didn't know what it was but it sounded fine to me. He said that I could stay at his house if I didn't have a place to stay. . . . When we got to his house he pulled out a bottle of gin and had me drink and drink. The next thing I remember is waking up drunk in his bed all wet and hurt. He took me out on the street and told me what to do . . . During that time I saw 10 to 20 men a day. I did what he said because he got violent when I sassed him. I took all kinds of drugs—even though I didn't really like most of them . . . Over the years I had pimps and customers who hit me, punched me, kicked me, beat me, slashed me with a razor. I had forced unprotected sex and got pregnant three times and had two abortions at [a clinic]. Afterward, I was back out on the street again. I have so many scars all over my body and so many injuries and so many illnesses. I have hepatitis C and stomach and back pain and a lot of psychological issues. I tried to commit suicide several times.
>
> –Kayla, survivor[1]

Kayla's story is typical of women and girls trafficked for commercial sex

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1. All survivor names have been changed to protect their privacy.

in the United States. Experiences like the ones she describes were reported by trafficking survivors who answered questions about their trafficking experience in a series of focus groups. Her story represents not the worst that occurs in sex trafficking, but rather, the common experience of women and girls trafficked into commercial sex by a criminal industry that generates an estimated $33.9 billion per year worldwide.[2]

This paper explores the health consequences and healthcare experiences of women and girls trafficked in the United States for commercial sex. The paper is based on an original study of over one hundred domestic sex trafficking victims and survivors. It provides evidence that women and children who are trafficked into prostitution are physically, mentally, and emotionally devastated by the crime, and this devastation is lasting – with injuries, illnesses, and impairments continuing for decades. It illustrates how our healthcare system is failing trafficked women and children. It makes the case that health care providers of all kinds – in emergency wards, healthcare clinics, and private practices – are seeing trafficking victims but failing to identify them, thereby unwittingly contributing to continuing criminal activity and exacerbating both public and private physical and mental health problems for this segment of the population. It offers recommendations on ways that public policy and healthcare practice can combat sex trafficking by more readily identifying victims and catalyzing rescues. Finally, it argues that law, policy, and protocols must change in order to adequately address the health consequences of sex trafficking.

Section I briefly summarizes previous studies on health and human trafficking and puts the current study in context. Section II describes the current study, including methodology used to collect information from survivors. Section III presents the results of the study, detailing findings on survivors' physical and mental health issues. In addition, it describes victims' contact with healthcare providers during the time they were trafficked. Section IV summarizes critical issues in the provision of health care for sex trafficking victims, with particular attention to reproductive health care. Finally, Section V sets forth recommendations for legislators, policymakers, and healthcare professionals.

I. PREVIOUS LITERATURE AND CONTEXT

The current study fills a gap in the growing body of literature on health and violence in the context of sex trafficking. A majority of trafficking-

2. Patrick Belser, Forced Labor and Human Trafficking: Estimating the Profits 14 (Int'l Labour Office, Working Paper No. 42, 2005), available at http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1016&context=forcedlabor.

related studies have focused on trafficking outside of the United States. These studies have often concentrated narrowly on one or two aspects of sex trafficking, such as the prevalence of sexually transmitted diseases/infections (STDs/STIs)[3] or mental health issues,[4] though a few took a more comprehensive approach to examining the health and violence-related experiences of women in the commercial sex industry.[5] International studies established that trafficking victims are subject to a myriad of physical and psychological symptoms stemming from extensive abuse.[6]

Recently, some researchers have undertaken domestic studies on sex trafficking as well.[7] Three early studies surveyed 100 or more women and

3. See, e.g., Audrey E. Pettifor et al., Increased Risk of Chlamydial and Gonococcal Infection in Adolescent Sex Workers in Madagascar, 34 SEXUALLY TRANSMITTED DISEASES 475 (2007); Jay G. Silverman et al., HIV Prevalence and Predictors Among Rescued Sex-Trafficked Women and Girls in Mumbai, India, 43 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES 588 (2006); Jay G. Silverman et al., Syphilis and Hepatitis B Co-Infection Among HIV-Infected, Sex-Trafficked Women and Girls, Nepal, 14 EMERGING INFECTIOUS DISEASES 932 (2008); see also Arun Kumar Acharya, Sexual Violence and Proximate Risks: A Study on Trafficked Women in Mexico City, 12 GENDER, TECHNOLOGY & DEVELOPMENT 77 (2008).

4. See, e.g., Geetha Suresh et al., An Assessment of the Mental Health of Street-Based Sex Workers in Chennai, India, 25 J. CONTEMP. CRIM. JUST. 186 (2009); Hyunjung Choi et al., Posttraumatic Stress Disorder (PTSD) and Disorders of Extreme Stress (DESNOS) Symptoms Following Prostitution and Childhood Abuse, 15 VIOLENCE AGAINST WOMEN 933 (2009); See, e.g., Mazeda Hossain et al., The Relationship of Trauma to Mental Disorders Among Trafficked and Sexually Exploited Girls and Women, 100 AM. J. PUB. HEALTH 2442 (2010);

5. See, e.g., Melissa Farley et al., Prostitution and Trafficking in Nine Countries: An Update on Violence and Posttraumatic Stress Disorder, 2 J. TRAUMA PRAC. 33 (2003); See, e.g., Cathy Zimmerman et al., The Health of Trafficked Women: A Survey of Women Entering Posttrafficking Services in Europe, 98 AM. J. PUB. HEALTH 55 (2008).

6. Olga Gajic-Veljanoski & Donna E. Stewart, Women Trafficked into Prostitution: Determinants, Human Rights, and Health Needs, 44 TRANSCULTURAL PSYCHIATRY 338, 352-53 (2007).

7. See, e.g., Celia Williamson & Michael Prior, Domestic Minor Sex Trafficking: A Network of Underground Players in the Midwest, 2 J. CHILD & ADOLESCENT TRAUMA 46 (2009); KEVIN BALES & STEVEN LIZE, TRAFFICKING IN PERSONS IN THE UNITED STATES: A REPORT TO THE NATIONAL INSTITUTE OF JUSTICE 16-17 (2005), available at https://www.ncjrs.gov/pdffiles1/nij/grants/211980.pdf.; Rochelle L. Rochelle L. Dalla, Night Moves: A Qualitative Investigation of Street-Level Sex Work, 26 PSYCHOL. WOMEN Q. 63 (2002). These studies are qualitative in nature, communicating important narratives but not providing quantitative data. Other literature focuses on experiences of violence and/or substance abuse among victims but does not provide substantial data on victims' physical and mental health consequences. See, e.g., Steven P. Kurtz et al., Sex Work and "Date" Violence, 10 VIOLENCE AGAINST WOMEN 357 (2004) [hereinafter Kurtz et al., Violence]; Jody Raphael & Deborah L. Shapiro, Violence in Indoor and Outdoor Prostitution Venues, 10 VIOLENCE AGAINST WOMEN 126 (2004) [hereinafter Raphael & Shapiro, Violence]; Amy M. Young et al., Prostitution, Drug Use, and Coping with Psychological Distress, 30 J.

touched on the problems that the instant study examines, but were each limited to a single city and examined a comparatively small number of health consequences.[8] The most comprehensive early study interviewed victims in five U.S. regions and discussed violence at length while touching on both physical and mental health consequences.[9] However, it was small and somewhat narrow in focus.[10]

While other studies have been conducted,[11] two Minnesota-based studies

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DRUG ISSUES 789 (2000); Nabila El-Bassel et al., Correlates of Partner Violence Among Female Street-Based Sex Workers: Substance Abuse, History of Childhood Abuse, and HIV Risks, 15 AIDS PATIENT CARE & STDS 41 (2001).

8. See Roberto J. Valera et al., Violence and Post Traumatic Stress Disorder in a Sample of Inner City Street Prostitutes, 16 AM. J. HEALTH STUD. 149, 149 (2000) (studying violence generally and PTSD, but not physical symptoms); Roberto J. Valera et al., Perceived Health Needs of Inner-City Street Prostitutes: A Preliminary Study, 25 AM. J. HEALTH BEHAV. 50, 50 (2001) (discussing five types of violence, sixteen physical symptoms, PTSD, and substance use); JODY RAPHAEL & DEBORAH L. SHAPIRO, CTR. FOR IMPACT RESEARCH, SISTERS SPEAK OUT: THE LIVES AND NEEDS OF PROSTITUTED WOMEN IN CHICAGO 4 (2005) [hereinafter RAPHAEL & SHAPIRO, SISTERS], available at http://www.impactresearch.org/documents/sistersspeakout.pdf (interviewing 222 victims in Chicago on 39 chronic physical health problems as well as experiences of violence and substance abuse, but not mental health).

9. JANICE G. RAYMOND & DONNA M. HUGHES, COAL. AGAINST TRAFFICKING IN WOMEN, SEX TRAFFICKING OF WOMEN IN THE UNITED STATES 7 (2001), available at http://action.web.ca/home/catw/attach/sex_traff_us.pdf.

10. Id. at 29 (interviewing only ten participants).

11. In 2004-2005, researchers published a series of Miami-based studies focusing on drug use, social service needs and barriers to them, and the connections between an abusive past, mental health problems, and HIV risk. See Hilary L. Surratt et al., Sex Work and Drug Use in a Subculture of Violence, 50 CRIME & DELINQUENCY 43, 46 (2004); Steven P. Kurtz et al., Barriers to Health and Social Services for Street-Based Sex Workers, 16 J. HEALTH CARE POOR & UNDERSERVED 345, 345 (2005) [hereinafter Kurtz et al., Barriers]; Hilary L. Surratt et al., The Connections of Mental Health Problems, Violent Life Experiences, and the Milieu of the "Stroll" with the HIV Risk Behaviors of Female Street Sex Workers, 17 J. PSYCHOL. & HUM. SEXUALITY 23, 23 (2005). These studies saw high rates of participation and asked respondents about their overall health condition but did not discuss specific physical health symptoms and limited participation to victims who were current drug users and still active in the commercial sex trade. See, e.g., Surratt et al., supra, at 46; Kurtz et al., Barriers, supra, at 346. Another 2004 study made unique contributions to the literature, revealing disturbing mortality rates among women in prostitution in Colorado and concluding that "[w]omen engaged in prostitution face the most dangerous occupational environment in the United States." John J. Potterat et al., Mortality in a Long-term Open Cohort of Prostitute Women, 159 AM. J. EPIDEMIOLOGY 778, 780-82, 784 (2004). The study also found that "active prostitutes were almost eighteen times more likely to be murdered than women of similar age and race during the study interval." Id. at 782. The study did not, however, address specific physical and mental health symptoms. Another 2005 study examined the role of medical care providers, but interviewed only twenty-one victims in three cities and was primarily qualitative. FAMILY VIOLENCE PROT. FUND, TURNING PAIN INTO
POWER: TRAFFICKING SURVIVORS' PERSPECTIVES ON EARLY INTERVENTION STRATEGIES

are especially relevant. A 2010 survey of 117 Minneapolis women examined the impact of victims' age of entry into commercial sex on substance abuse and HIV risk.[12] Because of these emphases, however, it discussed physical and emotional health consequences only at a high level of generality, such as whether participants "ever had an STD" or "ever experienced emotional violence."[13] Another 2011 study of 105 Native American women engaged in commercial sex in Minnesota[14] covered a substantial range of violent experiences, physical and health symptoms, and drugs, as well as Post-Traumatic Stress Disorder (PTSD).[15] The study contains some discussion of other mental health symptoms, but primarily in the context of determining whether the victims suffered from PTSD.

These studies set the stage for our current, more expansive study, which looks at over 200 health issues in more detail and across a broader geographic and ethnic spectrum. As far can be determined, our study is the first to examine many of the reproductive health issues experienced by sex trafficking victims, including birth control usage, pregnancies, miscarriages, and forced and elective abortions. In addition, it analyzes health care access and interactions and collects data on symptoms experienced both during and after trafficking.

II. METHODS

This study collected data from female sex trafficking survivors.[16] The study used a mixed-methods approach, combining qualitative data collection from focus groups and structured interviews with quantitative analysis. An initial feasibility study using a single focus group was conducted in November of 2011. Following this initial focus group, a

(2005), available at http://www.futureswithoutviolence.org/userfiles/file/ImmigrantWomen/Turning%20Pain%20intoPower.pdf.

12. Lauren Martin et al., Meaningful Differences: Comparison of Adult Women Who First Traded Sex as a Juvenile Versus as an Adult, 16 VIOLENCE AGAINST WOMEN 1252, 1252 (2010).

13. Id. at 1262.

14. MELISSA FARLEY ET AL., PROSTITUTION RESEARCH & EDUC., GARDEN OF TRUTH: THE PROSTITUTION AND TRAFFICKING OF NATIVE WOMEN IN MINNESOTA, 22 (2011) [hereinafter FARLEY ET AL., PROSTITUTION RESEARCH], available at http://www.prostitutionresearch.com/pdfs/Garden_of_Truth_Final_Project_WEB.pdf.

15. Id. at 28-30, 35-40.

16. The terms "survivor" and "trafficking survivor" will be used throughout to refer to the individuals interviewed in this study. "Victim" and "trafficking victim" will refer generally to individuals who are victims of trafficking as defined by the Trafficking Victims Protection Act of 2000. 22 U.S.C.A. § 7102(15) (West, WestlawNext through P.L. 106-386). The statute defines "sex trafficking" as "the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act." § 7102(10).

series of eleven similar focus groups were conducted in cities across the United States from January 2012 to December 2012.[17] Local leaders in the anti-trafficking movement, often survivor-led service providers, were asked to assist in locating survivors in their cities who wished to participate in the study. The focus groups included 107 participants, all domestic survivors of sex trafficking, ranging in age from fourteen to sixty. During these focus groups, participants commented on and discussed a range of topics, including subjects such as any early childhood trauma, the age at which they were trafficked, how they were recruited, how long they were held in captivity, and the overarching health issues they experienced. Following the focus group sessions, survivors completed an extensive health survey.[18]

The health survey included three components. In the first component, survivors reported on more than one hundred discrete health conditions drawn primarily from the World Health Organization's Statistical Classification of Diseases and Related Health Problems.[19] These health problems ranged from neurological and gastrointestinal symptoms to respiratory, cardiovascular, and dermatological conditions. Survivors answered questions about conditions in categories including, general health, communicable and non-communicable diseases, dental health, substance abuse, as well as nearly thirty psychological symptoms and disorders. The first component also asked about a range of sexually transmitted infections, gynecological and urinary tract conditions, birth control usage, pregnancy, and pregnancy outcomes.

Because of the ubiquity of violence in sex trafficking,[20] the first component also sought information about violence that the trafficking victim endured. The questionnaire asked whether the victim had been

17. The cities chosen included Columbus, Ohio; Honolulu, Hawaii; San Diego, San Francisco, and Sacramento, and Los Angeles, California; Minneapolis, Minnesota; St. Paul, Minnesota; St. Louis, Missouri; Washington, D.C.; Asheville, North Carolina; Nashville, Tennessee. The initial "feasibility" group was conducted in Washington, D.C. in November of 2011, with a pilot study in Columbus, Ohio, shortly thereafter. The average focus group size was just under nine trafficking victims, with the largest group being twenty-two participants (St. Louis), and the lowest being two participants (Los Angeles). The participants came from survivor centered service providers and shelters including, but not limited to, Courtney's House; Breaking Free; Kwanzaa Northside Women's Space; Pacific Alliance to Stop Slavery; Save Our Adolescents from Prostitution (SOAP); Courage House; Magdalene; Generate Hope; Veronica's Voice; and On Eagles Wings.

18. See infra, Appendix for a sample questionnaire completed by a survivor.

19. See generally WORLD HEALTH ORG., INTERNATIONAL CLASSIFICATION OF DISEASES (2010), available at http://www.who.int/classifications/icd/en/.

20. See, e.g., RAYMOND & HUGHES, supra note 9, at 63-65, 67-68, 75-77; Raphael & Shapiro, Violence, supra note 7, at 132-36; Kurtz et al., Violence, supra note 7, at 367-78; RAPHAEL & SHAPIRO, SISTERS, supra note 8, at 18-20.

subjected to physical abuse, such as being beaten, punched, kicked, raped, penetrated with foreign objects, threatened with a weapon, burned with cigarettes, strangled, stabbed, slashed, or forced to have unprotected sex. In addition to physical violence, victims indicated whether they were violated in other ways, such as being asked to participate in pornography, recreate a scene from pornographic material, or submit to abuse by a person in authority.

The second component of the survey consisted of a series of open-ended questions about health care. It asked such questions as whether and how long the victim used birth control during the time she was trafficked, where the birth control was obtained, who escorted the victim to the facility where birth control was obtained, and the type of birth control used. Because previous studies have identified health care providers as critical potential identifiers of trafficking victims,[21] the second component also asked what types of facilities survivors had visited to receive medical treatment and whether the healthcare provider asked or knew about their situations. Each victim also answered more detailed reproductive health questions, including her history of pregnancies, miscarriages, abortions and live births, where the abortions and/or births occurred, and whether she maintained custody of any children she had. With respect to abortion, the victim indicated how many abortions she had undergone, at what stage of pregnancy, and whether the abortion was coerced.

The final component of the questionnaire asked victims about the symptoms they experienced after escaping trafficking. This component covered the same range of physical and psychological symptoms as the first component. A full copy of a completed questionnaire is included in this article's Appendix.

Answers from the questionnaires were coded and entered in a spreadsheet. For questions in the first and third components where survivors circled symptoms to indicate that they had experienced them, a binary coding system (1 if circled, 0 if not) was used. For the open-ended second component, common answers were assigned a number and for questions where survivors gave an unwieldy variety of answers, the least common answers were grouped into a single "other" category.[22] When

21. See, e.g., Helen Cole, Human Trafficking: Implications for the Role of the Advanced Practice Forensic Nurse, 14 J. AM. PSYCHIATRIC NURSES ASS'N 463, 466 (2009) (citing Jeffrey Barrows & Reginald Finger, Human Trafficking and the Healthcare Professional, 101 S. MED. J. 521 (2008)); ERIN WILLIAMSON ET AL., DEP'T HEALTH & HUMAN SERVS., NATIONAL SYMPOSIUM ON THE HEALTH NEEDS OF HUMAN TRAFFICKING VICTIMS: POST-SYMPOSIUM BRIEF 4-8 (2008).

22. Coded data came almost exclusively from the questionnaires. Survivors' focus

survivors did not answer a question, the response was coded as "N/A."

This coding system allowed the spreadsheet program to count how many survivors gave each response by counting how many cells in a column were filled with a given number. The totals were then calculated as percentages both of all survivors and of those who answered the particular question. The results section analyzes the frequency with which individual symptoms and experiences were reported by the survivors in this study as well as the percentages of victims who reported at least one symptom or experience in a given category.

III. RESULTS

A. Physical Health Symptoms

> I am telling you that you have to not be in your sober mind to run these tricks—you just can't do it straight so everyone on the street is hooked on some drug. I've done drugs so long I have really hurt my body. I have kidney disease, liver problems, hepatitis C, high blood pressure, polymyositis [an inflammatory muscular disease], and fibroid tumors.
>
> –Taylor, survivor

Survivors suffered tremendously, virtually without exception. Out of 106 survivors,[23] 105 (99.1%) reported at least one physical health problem during trafficking. The most frequently reported physical problems were neurological—91.5% of respondents[24] reported at least one neurological symptom and 82.1% specifically reporting memory problems, insomnia, or poor concentration. Headaches or migraines (53.8%) and dizziness (34.0%) were also common symptoms. The trafficking experience ravaged the general health of victims as well, with 85.7% reporting at least one symptom in the general health category. In particular, the respondents' dietary health was often poor. Severe weight loss (42.9%), malnutrition (35.2%), loss of appetite (46.7%), and eating disorders (36.2%) were especially common; 71.4% of respondents reporting at least one of these diet-related symptoms.

The toll of constant commercial sexual exploitation and physical abuse on the victims led to a range of additional conditions. Physical injuries

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group statements were consulted only in the few instances where a questionnaire answer was unambiguous and the survivor's statements clarified it.

23. One participant did not fill out the first component of the survey.

24. Because many interviewees did not answer every question, percentages given are of respondents who answered the particular question, not necessarily of all 107 interviewees.

were rampant, with nearly 70% of victims reported physical injuries, most commonly to the head or face. Symptoms not conventionally associated with sexual abuse were only slightly less common: 67.9% of respondents experienced some type of cardiovascular or respiratory difficulty and 61.3% suffered from gastrointestinal symptoms while being trafficked. More than half of the survivors (54.3%) reported dental problems, with tooth loss the most common problem (42.9%). The only major health category in which less than half of respondents reported a symptom was dermatological issues, which were nonetheless reported by 27.4% of respondents. This study's findings of widespread physical health consequences are generally consistent with the results of previous domestic studies and build on their findings by revealing a more comprehensive picture of the health issues that plague trafficking victims.[25]

Table 1. Physical Health Problems

Category	**% of respondents reporting at least one symptom**[26]
Any Physical Health Problem	99.1% (N=106)
Neurological	91.7% (N=106)
General Health	86.0% (N=105)
Injuries	69.2% (N=102)
Cardiovascular/Respiratory	68.5% (N=106)
Gastrointestinal	62.0% (N=106)
Dental	54.3% (N=105)

B. Psychological Symptoms

> "The mental health problems are the worst and most long lasting. I was diagnosed with chronic depression, have anxiety, post-traumatic stress syndrome, nightmares, flashbacks, disorientation. I've been suicidal at

25. See, e.g., FARLEY ET AL, PROSTITUTION RESEARCH, supra note 14, at 29-30, 31; RAYMOND & HUGHES, supra note 9, at 79.

26. The small differences in the number of respondents are due to some subjects electing to fill out some portions of the questionnaire but not others. Judgment occasionally had to be exercised by coders as to whether a given victim had not answered a section or had indicated not experiencing any of the symptoms. However, such judgment was required on only a small minority of surveys and was made with a presumption against selective completion of the questionnaire.

> times. I don't think anyone is out on the street without having these long lasting effects."
>
> —Amanda, survivor

Survivors were overwhelmingly traumatized not only physically, but also mentally. The brutal treatment they endured created ongoing psychological and mental conditions in many of these victims and exploited existing mental instability in others. All but two of those who responded to the survey (104/106, 98.1%) reported at least one psychological issue during their captivity and survivors noted an average of more than a dozen (12.11). The most frequently reported problems included depression (88.7%), anxiety (76.4%), nightmares (73.6%), flashbacks (68.0%), low self-esteem (81.1%), and feelings of shame or guilt (82.1%). The picture painted by these surveys and the personal interviews that accompanied many of them is one of complete mental devastation. A substantial number of survivors suffered from other psychological disorders, including acute stress (38.7%), bipolar (30.2%), depersonalization (19.8%), multiple personality (13.2%), and borderline personality (13.2%) disorders.

Two additional and particularly chilling reporting rates confirm the extent of mental trauma that survivors suffered: 41.5% had attempted suicide (one victim reported 9 such attempts) and 54.7% suffered from Post Traumatic Stress Disorder. The psychological consequences that the trafficking victims in these focus groups reported were wide-ranging, severe, and in some cases nearly universal. As with physical symptoms, the findings on the psychological consequences of trafficking are consistent with other studies.[27]

Even the escape from their trafficking circumstances was far from a remedy for the psychological suffering of survivors. When reporting on their health experiences after trafficking, 96.4% of survivors reported at least one psychological symptom and an average of 10.5. As the table below indicates, there were only minor improvements in the number of psychological problems experienced when the victims escaped from their trafficking situations. Sex trafficking took a lasting mental and emotional as well as physical toll on nearly every survivor in the study.

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27. See, e.g., FARLEY ET AL., PROSTITUTION RESEARCH, supra note 14, at 31; RAYMOND & HUGHES, supra note 9, at 83; Melissa Farley & Howard Barkan, Prostitution, Violence, and Posttraumatic Stress Disorder, 27 WOMEN & HEALTH 37, 42 (1998), available at http://www.prostitutionresearch.com/Farley%26Barkan%201998.pdf.

Table 2. Psychological Health Problems

	During Trafficking (N=106)	**After Trafficking** (N=83)[28]	**Change in % reporting**
Reported at least one psychological issue	98.1%	96.4%	-1.7%
Average number of psychological issues	12.1	10.5	-1.6
Depression	88.7%	80.7%	-8.0%
Flashbacks	68.0%	63.9%	-4.1%
Shame/guilt	82.1%	71.1%	-11.0%
PTSD	54.7%	61.5%	+6.8%
Attempted suicide	41.5%	20.5%	-21.0%

C. Reproductive Issues

> If I hadn't had my children when I was young, I wouldn't be able to have them because I have had so many STDs and gynecological problems—including pelvic inflammatory disease, cervical infections, gonorrhea, herpes, chlamydia—I can't have children now.
>
> –Megan, survivor

Not surprisingly, survivors also reported significant numbers of reproductive health problems while they were being trafficked. Most notably, more than two-thirds of these women (67.3%) contracted some form of sexually-transmitted disease or infection (STD/STI). Survivors reported significantly higher rates of chlamydia (39.4%) and gonorrhea

28. Some respondents answered only the questions about symptoms experienced during trafficking, accounting for the difference in number of respondents for during and post-trafficking questions.

(26.9%) than the next most common disease (Hepatitis C, 15.4%). Well over half of survivors (63.8%) reported at least one gynecological symptom other than STDs/STIs, with pain during sex (46.2%), urinary tract infections (43.8%), and vaginal discharge (33.3%) among the most common such symptoms. The extent of reproductive health issues that survivors reported is hardly surprising due to the extreme levels of sexual abuse these women endured. On average, the respondents reported being used for sex by approximately thirteen buyers per day,[29] with a median response of ten. Some respondents reported typical days of as many as thirty to fifty buyers.

Reporting problems complicated the data regarding pregnancies and their results, with some respondents answering related questions inconsistently.[30] While these reporting issues make precision impossible, the data merits concluding with confidence that pregnancy, miscarriage, and abortion were all common experiences for survivors in the study. Even without accounting for possible underreporting, forty-seven of the sixty-six women (71.2%) who gave an answer for the number of pregnancies they had during trafficking reported at least one pregnancy while being trafficked; fourteen of these (21.2% of respondents) reported five or more pregnancies. Of the

29. Where victims gave a range for the number of buyers per day, the answer was coded as the median of that range, using the lower median where the range contained an even number of possibilities. For example, an answer of 5-7 was coded as 6 and an answer of 10-15 was coded as 12.

30. For example, thirty-four respondents circled "pregnancy" as something they experienced during trafficking in the survey's first component, but an additional nineteen women gave a number of one or greater to the open-ended question "How many pregnancies did you have while being trafficked?" in the second component of the survey despite not having circled "pregnancy" earlier, bringing the total to fifty-three. There is reason to believe, however, that even the combined total of fifty-three women may underreport the number who experienced a pregnancy because many of the victims may have had different standards for what counted as a pregnancy. In some cases, the victims appeared not to count pregnancies that ended in abortion or miscarriage, reporting for example, two pregnancies, two live births, two miscarriages, and one abortion. Thus, women whose pregnancies all ended in miscarriage or abortion may not be reflected even in the combined total of fifty-three. Similar discrepancies occurred on a smaller scale with regard to miscarriages (thirty-two subjects circled, ten more did not circle but reported one or more, and two subjects who had circled nonetheless reported zero as the number they had) and abortions (thirty-nine subjects circled, three additional subjects did not circle but reported having one or more). There were additional inconsistent sequences of answers about pregnancies and pregnancy outcomes. Thirty-nine subjects reported numbers of births, miscarriages, and abortions that totaled a different number than the subject reported as her total number of pregnancies or gave otherwise conflicting answers. In most of these cases, there was no obvious explanation that accounted for the difference. Possible explanations include varying standards of what counts as a pregnancy, multiple-child births (twins, triplets, etc.), and answering different questions with reference to different periods of time (i.e., counting only pregnancies occurring during trafficking but counting all miscarriages, births, or abortions whether before, during, or after trafficking).

sixty-four respondents who gave an answer for the number of miscarriages they experienced, thirty-five (54.7%) had at least one miscarriage and nineteen (29.7%) had more than one.[31] Similarly, more than half (55.2%) of the sixty-seven respondents who answered reported at least one abortion, with twenty respondents (29.9%) reporting multiple abortions. Without accounting for possible underreporting, this subset of responding survivors reported a total of 114 abortions.

The prevalence of forced abortions is an especially disturbing trend in sex trafficking. Prior research noted that forced abortions were a reality for many victims of sex trafficking outside the United States[32] and at least one study noted forced abortions in domestic trafficking.[33] The survivors in this study similarly reported that they often did not freely choose the abortions they had while being trafficked. While only thirty-four respondents answered the question whether their abortions were of their own volition or forced upon them, more than half (eighteen) of that group indicated that one or more of their abortions was at least partly forced upon them.[34] One victim noted that "in most of [my six abortions,] I was under serious pressure from my pimps to abort the babies." Another survivor, whose abuse at the hands of her traffickers[35] was particularly brutal, reported

31. The interviewer notes that in some cases, survivors may have used miscarriage as a euphemism for abortion.

32. S. Abdulraheem & A.R. Oladipo, Trafficking in Women and Children: A Hidden Health and Social Problem in Nigeria, 2 INT'L J. SOC. & ANTHROPOLOGY 34, 37 (2010); Acharya, supra note 3, at 90; CATHY ZIMMERMAN ET AL., THE HEALTH RISKS AND CONSEQUENCES OF TRAFFICKING IN WOMEN AND ADOLESCENTS: FINDINGS FROM A EUROPEAN STUDY 24, 51 (2003), available at http://www.oas.org/atip/Global%20Reports/Zimmerman%20TIP%20HEALTH.pdf.

33. RAYMOND & HUGHES, supra note 9, at 18; see also U.S. v. Todd, 627 F.3d 329, 331 (9th Cir. 2009) (mentioning a forced abortion in describing how sex trafficking defendant abused his victims); U.S. v. Stokes, No. 10-00244-04 2011 WL 1585601, at *15 (W.D. Mo. 2011) (mentioning a forcible "abortion" performed by a defendant as one of the "overt acts" in furtherance of a sex trafficking conspiracy).

34. Additionally, several survivors stated in their interviews that they felt forced to choose abortion by the circumstance of being trafficked.

35. Street gangs are increasingly turning to sex trafficking as a source of income. See, e.g., Laura J. Lederer, Sold for Sex: The Link Between Street Gangs and Trafficking in Persons, 4 PROTECTION PROJECT J. HUM. RTS. & CIV. SOC'Y 1, 1 (2011); KAMALA D. HARRIS, CAL. DEP'T OF JUST., THE STATE OF HUMAN TRAFFICKING IN CALIFORNIA 63-64 (2012), available at http://oag.ca.gov/sites/all/files/pdfs/ht/human-trafficking-2012.pdf; Press Release, U. S. Att'y's Office, E. Dist. of Va., Gang Leader Sentenced to 40 Years for Leading Juvenile Sex Trafficking Ring (Sept. 14, 2012), http://www.justice.gov/usao/vae/news/2012/09/20120914stromnr.html; Press Release, U. S. Att'y's Office, E. Dist. of Va., Leader of MS-13 Gang Sentenced to 50 Years in Prison for Sex Trafficking Multiple Teens (June 1, 2012), http://www.fbi.gov/washingtondc/press-releases/2012/leader-of-ms-13-gang-sentenced-to-50-years-in-prison-for-sex-trafficking-multiple-teens. For a case study of gang

seventeen abortions and indicated that at least some of them were forced on her. Notably, the phenomenon of forced abortion as it occurs in sex trafficking transcends the political boundaries of the abortion debate, violating both the pro-life belief that abortion takes innocent life and the pro-choice ideal of women's freedom to make their own reproductive choices.

D. Violence, Abuse, and Humiliation

> I've had a hard life during this time—16 years on the street, 10 to 20 customers per day. I've been hit, punched, kicked, beaten, whipped with a belt, forced to have sex, threatened with a weapon, shot at, and had my head split open. . . . One of my regulars got together with some friends and kidnapped me. They held me against my will, put a belt around my neck, and forced me to do all kinds of horrible things. When I said I didn't want to they said they would kill my family.
>
> –Nicole, survivor

The survey asked survivors if they had experienced violence or abuse, listing twelve possible forms.[36] These included being threatened with a weapon, shot, strangled, burned, kicked, punched, beaten, stabbed, raped, or penetrated with a foreign object. The survey also asked about other kinds of abuse such as threats, intimidation, verbal abuse and humiliation. Nearly all the survivors (92.2%) reported being the victim of at least one form of physical violence. Many survivors had suffered more than half of these experiences. Respondents reported an average of 6.25 of the 12 forms of violence. Likewise, most of these abuses were the rule rather than the exception—eight of the twelve were reported by half or more of the respondents, including behaviors as extreme as strangulation. In their interviews, survivors described additional ways they were abused. One survivor was whipped and had bleach poured on her, while another was forced to eat feces and was hung by her arms in a closet. As another survivor describes, "[my pimp] had his girls out on the streets every night. It was either you made the [money] for him or you got beat." In addition to the abuses detailed below, almost all survivors reported serious verbal

involvement in sex trafficking near Washington, D.C., see Laura J. Lederer & Justin Davis, Street Gangs and Human Trafficking in the Greater Washington, D.C. Area (Aug. 1, 2013) (unpublished manuscript) (on file with authors).

36. The specific forms on the survey were being threatened with a weapon, strangulation, burning with cigarettes, being kicked, punched, beaten, or beaten with an object, stabbing/slashing, rape (vaginal, oral, or anal), penetration with foreign objects, forced unprotected sex, and abuse by a person of authority.

abuse, including repeatedly being called derogatory names, treated as less than human, and being deprived of basic physical and emotional needs such as food, sleep, and a caring environment.

Table 3. Violence and Abuse in Sex Trafficking

Common Forms of Violence/Abuse	**% Reporting** (N=103)
Some form of violence/abuse	95.1%
Forced sex	81.6%
Punched	73.8%
Beaten	68.9%
Kicked	68.0%
Forced unprotected sex	68.0%
Threatened with weapon	66.0%
Strangled	54.4%
Abused by person of authority	50.5%

In addition to physical mistreatment, some victims were subjected to other forms of degradation, such as recreating scenes from pornography (29.3%) or being forcibly recorded for pornographic purposes (17.1%). Other studies confirm the prevalence of violence against trafficking victims.[37]

E. Substance Abuse

> I started doing drugs, specifically cocaine down at the local go-go bar, and eventually I tried heroin. I was a mess, wrecked my life, wasted it on drugs because I'd been raped and I didn't think I mattered to anyone. When I was 31 years old I started dating a . . . guy who was a drug dealer. We dealt together, did crack together, and he started prostituting me to close drug deals.
>
> —Radeel, survivor

Many survivors were dependent on drugs or alcohol while they were

37. See, e.g., FARLEY ET AL., PROSTITUTION RESEARCH, supra note 14, at 28-29; RAPHAEL & SHAPIRO, SISTERS, supra note 8, at 132-35; RAYMOND & HUGHES, supra note 9, at 75; Melissa Farley, Prostitution and the Invisibility of Harm, 26 WOMEN & THERAPY 247, 251-53 (2003).

trafficked either because the substances were forced on them as a control mechanism by their traffickers[38] or because substance use was a means of coping with the immense abuse they suffered. 84.3% used alcohol, drugs, or both during their captivity and more than a quarter (27.9%) said that forced substance use was a part of their trafficking experience. More than a quarter of victims reported injected drugs and overdoses (27.2% and 26.0% respectively). As the following table indicates, alcohol, marijuana, and cocaine were the most common substances but others were prevalent as well.

Table 5. Substance Abuse in Sex Trafficking

Substance	**% Reporting Usage** (N=102)
Substance Abuse	84.3%
Alcohol	59.8%
Marijuana	53.4%
Cocaine	50.5%
Crack Cocaine	44.7%
Heroin	22.3%
Ecstasy	13.6%
PCP	9.7%

Overwhelmingly, survivors were the objects of repeated and extreme violence and were frequently driven to substance abuse either by force or by their dire circumstances.

IV. CRITICAL ISSUES IN PROVISION OF HEALTH CARE FOR VICTIMS OF SEX TRAFFICKING

> During the time I was on the street, I went to hospitals, urgent care clinics, women's health clinics, and private doctors. No one ever asked me anything anytime I ever went to a clinic. . . . I was on birth control during the 10 years I was on the streets—mostly Depo-Provera shots which I got at the Planned Parenthood and other neighborhood clinics. I also got the morning-after pill from them. I was young and so I had to

38. For instance, one survivor described how her pimp, "gave us drugs to keep us under his thumb."

> have a waiver signed in order to get these—one of the doctors (a private doctor I think) signed this waiver when my uncle took me to see him.
>
> –Lauren, survivor

Despite their abusive situations, most survivors did receive medical treatment at some point during their trafficking. Of those who answered the questions about their contact with healthcare (N=98), 87.8% had contact with a healthcare provider while they were being trafficked. By far the most frequently reported treatment site was a hospital/emergency room, with 63.3% being treated at such a facility. Survivors also had significant contact with clinical treatment facilities, most commonly Planned Parenthood clinics, which more than a quarter of survivors (29.6%) visited. More than half (57.1%) of respondents had received treatment at some type of clinic (urgent care, women's health, neighborhood, or Planned Parenthood).

Table 6. Victim Contact with Health Care Provider

Treatment Source	**% Reporting** (N=98)
Any contact with healthcare	87.8%
Any type of clinic	57.1%
Hospital/ER	63.3%
Planned Parenthood	29.6%
Regular doctor	22.5%
Urgent care clinic	21.4%
Women's health clinic	19.4%
Neighborhood clinic	19.4%
On-site doctor	5.1%
Other[39]	13.3%

Since pimps and traffickers[40] generally exercise nearly complete control of

39. Those who specified "other" treatment sources mentioned: a methadone clinic for heroin addiction, a psychiatric hospital, prisons (several mentioned treatment in prison facilities), Red Door and YouthLink (public health clinics), a therapist, a city Health Department, a pastor, the Pacific Alliance to Stop Slavery (a Hawaii anti-trafficking organization), and the grandmother of a trafficker.

40. The Oxford Dictionary defines a pimp as "a man who controls prostitutes and arranges clients for them, taking a percentage of their earnings in return." Pimp Definition,

their victims,[41] these points of contact with healthcare represent rare opportunities for victim identification and intervention.[42] In addition, because of the hearsay exception in the Federal Rules of Evidence for statements made for medical treatment (regardless of whether the declarant testifies),[43] statements by victims to healthcare professionals should usually be admissible in a trafficking prosecution.[44]

These opportunities have largely been missed as even those healthcare professionals who recognized that victims might have been "on the street" rarely understood that they had a pimp/trafficker. Just over half (51.9%) of respondents who answered (N=81) said that at least some of the time the doctor knew they were "on the street," while the remaining respondents did not believe doctors were aware of their situations. Almost half of survivors (43.1%) (N=58) said the doctor asked them something about their lives,[45] but only 19.5% of those who answered (N=41) reported that the doctor knew they had a pimp.[46] At least two prior studies have demonstrated that medical care providers are woefully unprepared to identify trafficking

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OXFORD DICTIONARIES, http://oxforddictionaries.com/definition/english/pimp?q=pimp (last visited Nov. 26, 2013). These actions fall within the TVPA's definition of sex trafficking. 22 U.S.C. § 7102(10) (West, WestlawNext through P.L. 106-386) (defining sex trafficking as "the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act."). Pimps are, therefore, one subset of traffickers.

41. See POLARIS PROJECT, DOMESTIC SEX TRAFFICKING: THE CRIMINAL OPERATIONS OF THE AMERICAN PIMP 5, available at http://www.polarisproject.org/resources/resources-by-topic/sex-trafficking (last visited Nov. 26, 2013).

42. See, e.g., Cole, supra note 21, at 466 (citing Jeffrey Barrows & Reginald Finger, Human Trafficking and the Healthcare Professional, 101 S. MED. J. 521 (2008)); WILLIAMSON, supra note 21, at 4.

43. FED. R. EVID. 803(4). The exception permits the admission of statements that are "made for—and [are] reasonably pertinent to—medical diagnosis or treatment" and describe "past or present symptoms or sensations; their inception; or their general cause." Id.

44. While such statements must be "made for . . . medical diagnosis or treatment" purposes, courts have construed this requirement in a manner favorable to sexual assault and rape victims, generally permitting the admission of statements that identify an abuser because the identity of an abuser is pertinent to diagnosis and treatment in sexually abusive contexts. See, e.g., Morgan v. Foretich, 846 F.2d 941, 948-50 (4th Cir. 1988); U.S. v. Renville, 779 F.2d 430, 435-39 (8th Cir. 1988); U.S. v. George, 960 F.2d 97, 99-100 (9th Cir. 1992); U.S. v. Tome, 61 F.3d 1446, 1450 (10th Cir. 1995); U.S. v. Chaco, 801 F. Supp. 2d 1217, 1227 (D.N.M. 2011). This rationale would logically extend to the sex trafficking context as well, especially where the victim is a minor.

45. Several survivors noted in the margins of their surveys that they were unable to answer questions about their lives or situations honestly either because their pimp/trafficker was present or because they feared reprisal from their pimp.

46. Even these numbers may overstate trafficking awareness on the part of medical personnel. One respondent indicated that the physician who treated them had an established relationship with the pimp. If other survivors said their doctors were aware they had a pimp because of similar situations, the awareness statistic would be skewed.

victims.[47]

As noted above, pregnancy, miscarriage, and abortion were all experienced by half or more of survivors who answered questions about them. Several other survivors said that they had hysterectomies or tubal ligations either during or after trafficking and another two survivors were sold specifically for sodomy in order to avoid pregnancy. Healthcare providers who specialize in these types of care are therefore particularly likely to have opportunities for identification and intervention. Clinics that perform abortions must be especially vigilant in efforts to recognize possible trafficking victims. Roughly two-thirds (67.6%) of survivors who specified a location (N=37) identified a clinic as the site of their abortion(s), far outpacing hospitals (16.2%) and other sites (13.5%). One survivor described her situation:

I got pregnant six times and had six abortions during this time. Several of them were from a doctor who was a client—he did them 'back door'—I came in the back door after hours and paid him off the books. This kept my name off any records.... I think he felt like he was helping. At least one of my abortions was from Planned Parenthood because they didn't ask any questions. But they were expensive and on the street you didn't want to pay $250, $300, or more. So you went 'back door' where the charge was more like $150. I had so much scar tissue from these abortions because there was no follow-up and in a couple of cases I had bad infections, so bad that I eventually lost my fallopian tubes [and had to have a hysterectomy].[48]

Table 7. Where Sex Trafficking Victims Sought Abortions

Where abortions were performed	**% Identifying site** (N=37)
Clinic	67.6%
Hospital	16.2%
Other[49]	13.5%
Different sites at different times	2.7%

47. See J.C. Wong et al., Human Trafficking: An Evaluation of Canadian Medical Students' Awareness and Attitudes, 24 EDUC. FOR HEALTH 1, 3-5 (2011); Makini Chisolm-Straker & Lynne Richardson, Assessment of Emergency Department (ED) Provider Knowledge About Human Trafficking Victims in the ED, 14 ACAD. EMERGENCY MED. (5 SUPPL. 1) S134 (2007), http://onlinelibrary.wiley.com/doi/10.1197/j.aem.2007.03.704/pdf.

48. The abortions were arranged by a series of sex traffickers, not by the victim herself.

49. Those who specified the "other" site of their abortion mentioned an abortionist's home, doctor's offices (including an OB/GYN), and an Arkansas back alley.

Survivors also interacted with medical professionals for purposes of obtaining birth control. A large majority (80.9%) of those who answered the question (N=73) indicated that they had used some form of birth control for some portion of their time being trafficked. Of those who specified where they obtained the birth control (N=59), approximately half (51.7%) said they had obtained it from a doctor or clinic. More than half (65.2%) of respondents said that they went alone to the doctor or other source where they obtained birth control. Together, these responses indicate that a significant number of trafficking victims see healthcare providers (especially clinics and doctors) to obtain birth control without trafficker supervision, suggesting that medical staff have a rare opportunity to communicate one-on-one with victims.[50]

Table 8. Type of Birth Control Utilized During Sex Trafficking

Birth Control Type[51]	**% Reporting Usage** (N=59)
Condoms	52.5%
Multiple Types	22.0%
Depo-Provera	11.9%
Birth Control Pill	10.2%
IUD	3.4%

VI. RECOMMENDATIONS

A. General Awareness: Common Symptoms and Warning Signs

Medical professionals must be made aware of critical signals for identifying trafficking victims. An important part of this training should be to help the health care professional understand the coercive dynamic of trafficking, especially the extreme degree of control exercised by traffickers, and the prevalence of this criminal exploitation of women and girls. Setting up internal protocols, procedures and regulations can further

50. While condoms (readily available in non-medical settings) were the most common form of birth control, nearly half of survivors (47.5%) used another type of birth control instead of or in addition to condoms. Thus, requests for birth control by noticeably young girls who also show signs of injury or abuse could be viable warning signals of a possible trafficking situation for medical professionals.

51. In addition to the contraceptive forms of birth control listed here, 25% of survivors who answered (N=60) reported use of the "morning-after pill."

these goals and assist medical care providers in their vital role as identifiers of trafficking victims.

Based on the reported symptoms of survivors, a number of particularly widespread health-related consequences of trafficking should serve as warning signs to medical professionals. The most suggestive physical symptoms are injuries from physical violence, since this was a nearly universal experience for the survivors in the study. Signs of being kicked, punched, or beaten, all of which at least two thirds of respondents reported, should be a major "red flag" along with any signs of forced sex (reported by 81.6%), and head or facial injuries (each reported by more than half of survivors). While these may also be signals of domestic violence, their presence in patients seeking multiple abortions or treatment for sexually transmitted or serious communicable diseases may help healthcare providers to distinguish possible sex trafficking situations. Indications of extreme forms of violence (such as strangulation, stabbing, cigarette burns or gunshot wounds) also may be important clues for identification since these would have far fewer alternate explanations. One researcher notes that tattoos identifying the victim as the "property" of a particular trafficker could also alert care providers,[52] though these may be difficult to recognize.

In addition, those psychological symptoms that were particularly common among trafficking victims should be useful warning signs. Depression was the most common symptom for survivors (88.7%) and anxiety, irritability, nightmares, low self-esteem, and feelings of shame/guilt were all reported by more than 70% of survivors as well. The combination of these symptoms should therefore arouse suspicion when displayed by patients who repeatedly require reproductive health services, when an older or controlling male figure is present with the patient, and when the patient also presents signs of physical abuse. The well-documented rates of PTSD in trafficking victims,[53] (54.7% of survivors in this study) make it another important clue to identifying trafficking victims. Indications of attempted or repeated self-harm would likewise be a reason for considering trafficking as a possibility in these context, since 46.2% of respondents reported suicide ideation and 41.5% had attempted suicide.

The presence of sexually transmitted diseases or infections is another major identifier because nearly two-thirds (67.3%) of survivors reported having at least one such disease. Multiple or serial cases of such diseases or

52. Reena Isaac et al., Health Care Providers' Training Needs Related to Human Trafficking: Maximizing the Opportunity to Screen and Intervene, 2 J. APPLIED RES. ON CHILD 1, 10 (2011).

53. See, e.g., Farley & Barkan, supra note 27, at 42 (reporting that 68% of victims met criteria for PTSD and 76% met criteria for partial PTSD).

infections is a particularly strong signal that should immediately raise the possibility of a trafficking situation in the minds of healthcare providers. Because of the overwhelming rate of substance abuse (84.3%) that survivors reported, signs of alcohol and/or drug abuse could also be a significant warning sign when observed in patients who require reproductive health services at a young age, appear to be controlled by another person, or also exhibit the physical and psychological symptoms detailed above.

Clinics and other abortion providers should be especially attentive to warning signs particularly with regard to younger patients. Multiple abortions and evidence of coercion (such as the presence of a significantly older or controlling "boyfriend," or the physical and psychological symptoms discussed above) in these patients should prompt the healthcare provider to seek more information about the patient's situation. More than half (52.9%) of survivors (N=34) indicated that at least one abortion was partly or wholly forced on them, making this concern especially grave.

These warning signs are not intended to be exhaustive or authoritative, but they build on and refine the suggestions of prior research.[54] To be sure, there are myriad other physical and psychological symptoms that could alert medical staff to the possibility that a patient is a victim of trafficking and many other contexts in which victims seek medical services. Nonetheless, the symptoms and service contexts most mentioned by survivors should prove particularly relevant to the problem of victim identification by medical professionals and may also lead to conversations that could later assist prosecutors because of their likely admissibility under the Federal Rules of Evidence.

B. Protocols for Identifying Victims and Catalyzing Rescues

Interaction between medical care providers and victims is an extraordinarily delicate situation. Because some victims may come alone, the health provider has an opportunity, if trust level and other considerations allow, to ask questions about the possible victim's situation and to provide her with resources like contact information for rescue and other services. Existing literature and this study both provide some guidance for carefully making the most of these opportunities.

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54. See, e.g., Isaac et al., supra note 52, at 9-10; T.K. Logan et al., Understanding Human Trafficking in the United States, 10 VIOLENCE, TRAUMA, & ABUSE 3, 19-20 (2009); Jeffrey Barrows & Reginald Finger, Human Trafficking and the Healthcare Professional, 101 S. MED. J., 521, 522-23 (2008); Cole, supra note 21, at 468; Patricia A. Crane & Melissa Moreno, Human Trafficking: What is the Role of Health Care Provider?, 2 J. APPLIED RES. ON CHILD 1, 6-7 (2011).

Building trust with possible victims is a critical first step and requires patience and cultural sensitivity on the part of medical professionals:

> Building trust with trafficking victims may be a slow process and requires patience and determination. Taking the time to build rapport is critical. . . . The [health care provider] must have the humility to accept and acknowledge that there may be much about the victim's culture they do not understand, and that the impact of such taboos may be significant in that culture. Many small steps are needed to build trust, such as open-ended questions, few interruptions, and a private area to talk. Often more than one visit is needed, and the victim may need to be told to return to the clinic to reevaluate a health care issue when the HCP strongly suspects trafficking and further assessment and questioning is desired to get a patient to open up. Messages for the HCP to convey in private with a suspected victim include a focus on safety, getting healthy, and that the victim's welfare is the highest priority.[55]

Because traffickers often accompany victims to treatment and their presence may prevent truthful answers, victims should be interviewed in private if at all possible.[56] Separation should be done discreetly,[57] perhaps by requesting that the male figure assist with paperwork or remain in the waiting room while staff obtain specimens.[58]

Asking directly whether the patient is a victim of trafficking may be meaningless and directly asking about the most traumatic aspects of trafficking is also "ill-advised."[59] Rather, a serious of "sensitive probing questions" can help uncover or unpack the underlying trafficking situation. For example, the health care sector can borrow from the law profession. Legal aid attorneys working on custody cases noted that when gathering the facts about an abusive husband or boyfriend to help a client gain custody of her child, facts patterns emerged that made it clear that the client was a victim of sex trafficking. The victim did not come through the door self-identifying as a trafficking victim, but slowly over the course of conversation, understood her victimization and was able to seek help from law enforcement to emerge from the trafficking situation. Gradually working with the victim's identifiable health problems to elicit important facts about their over-arching situation is likely to be most effective and

55. Crane & Moreno, supra note 54, at 7-8.
56. Id. at 9.
57. Cole, supra note 21, at 467.
58. Crane & Moreno, supra note 54, at 9.
59. Id.

least intrusive.[60]

Additionally, where a translator is needed, care needs to be taken to identify someone the right translator to avoid the possibility of complicity with a trafficker.[61] Especially in tight-knit communities, that someone unconnected translates is critical. In addition, other language considerations are key to creating trust and communication. Using informal language (sometimes even slang) rather than formal or clinical terminology may improve communication with victims, bridging conceptual or definitional gaps about trafficking generally, as well as with specific issues like violence and rape. Specific suggested questions include asking about the patient's freedom to contact family and friends, her eating and sleeping conditions (whether basic needs are being met), her ability to come and go freely, who lives with her, and whether she feels happy and cared for.[62] Sometimes it is possible for the provider to ask direct and specific questions about whether the patient has been drugged, raped, coerced, or hurt and get honest answers.

Regardless of the patient's comfort level and degree of cooperation, if a provider strongly suspects the patient is a victim of sex trafficking, he (or she) should call the National Trafficking Hotline.[63] Calls can be made anonymously if necessary. Providers need to have strategies and preparation for how to address potential sex trafficking cases, including coordination with law enforcement and with local NGO service providers.[64] Healthcare providers can play a crucial role in the trafficking rescue process by identifying possible victims and following up on those suspicions with careful, strategic questions, and actions that catalyze rescues or help create exit strategies.

B. Regulations: Training for Healthcare Professionals and Hotline Posting Requirements

Legislators and policymakers also have an important role to play in increasing health care providers' recognition and identification of trafficking victims. State legislators should draft and pass laws that require healthcare providers to undergo training on trafficking generally, including the basic warning signs and indicators for victim identification, techniques

60. Id.
61. Id.; see also Barrows & Finger, supra note 54, at 522.
62. Barrows & Finger, supra note 54, at 522; Crane & Moreno, supra note 54, at 10; and Logan et al., supra note 54, at 20. Each of these sources provides a more complete list of suggested questions.
63. Cole, supra note 21, at 467; Barrows & Finger, supra note 54, at 522.
64. Cole, supra note 21, at 467.

for communicating effectively with possible victims to assess their situations and determine victim status, and appropriate actions to take when a victim is identified. The Obama administration has recognized the need for additional trafficking-related training for federal social service employees and law enforcement.[65] Likewise, medical professionals need training to recognize and appropriately respond to trafficking victims.

New Jersey recently adopted a statute that may serve as a baseline model for such training requirements. Under the new law, the New Jersey Department of Health will "develop, approve, and provide for a one-time training course on the handling and response procedures of suspected human trafficking activities for employees of every licensed health care facility."[66] In order to maintain their licenses, health care facilities must verify completion of the course by a subset of its employees to be defined by regulation.[67] Other states should follow New Jersey's lead by making trafficking-related training a requirement for licensing with a comprehensive definition of the facilities affected.[68] Additionally, other states can build on the New Jersey statute by providing for ongoing trainings,[69] expanding the scope of training to include recognition of victims as well as protocols for handling and response of potential victims, and by requiring that all employees participate in the training course.

Another measure that can be instituted is to require that medical facilities post information about the National Human Trafficking Resource Center

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65. PRESIDENT'S INTERAGENCY TASK FORCE TO MONITOR AND COMBAT TRAFFICKING IN PERSONS, COORDINATION, COLLABORATION, CAPACITY: FEDERAL STRATEGIC ACTION PLAN ON SERVICES FOR VICTIMS OF HUMAN TRAFFICKING IN THE UNITED STATES 25-26 (2013), available at http://www.ncdsv.org/images/HHS-DHS-DOJ_FederalStrategicActionPlanOnServiceForVictimsOfHumanTrafficking_4-2013.pdf.

66. N.J. STAT. ANN. § 2C:13-12(c)(1) (West, WestlawNext through L.2013, c. 169 and J.R. No. 13). Alternatively, the statute permits the state to approve an existing training course provided by a statewide nonprofit group with experience administering similar trainings. Id.

67. Id.

68. See id. (defining "health care facility" as a "facility or institution whether public or private, engaged principally in providing services for health maintenance organizations, diagnosis, or treatment of human disease, pain, injury, deformity, or physical condition," including, inter alia, hospitals, mental hospitals, maternity hospitals, outpatient clinics, diagnostic centers, and treatment centers).

69. One option in states that require Continuing Medical Education (CME) courses would be to institute a trafficking-related CME requirement. For example, the Florida Medical Association offers a CME course comparing domestic violence with human trafficking and training employees to recognize and respond to both. See Fla. Med. Ass'n, Domestic Violence with a Special Focus on Human Trafficking, http://flmedical.inreachce.com/ (follow "public health" hyperlink; then follow "Domestic Violence with a Special Focus on Human Trafficking" hyperlink) (last visited Nov. 26, 2013).

Hotline, a toll-free phone number that connects callers to law enforcement as well as other services[70] An earlier proposed version of the 2013 TVPRA would have required the Secretary of Health and Human Services and the Attorney General to "make reasonable efforts to encourage [s]tates to adopt legislation" that requires posting of information about the hotline at a variety of establishments, including hospitals and urgent care centers.[71] Measures like this in future federal legislation could be a catalyst to state-level posting requirements. Posting laws improve victim access to the hotline and could even spur otherwise hesitant victims to share their situation with medical staff. In fact, California[72] and Georgia[73] have already adopted posting laws. Other states should follow suit and expand the range of medical facilities covered by the statutes to include abortion and women's health clinics.[74] Some survivors have that while posting laws and brochures are important, even better (or in addition) is a small business card with the hotline number as well as shelter and rescue information on it. A business card can be slipped into a handbag or even a shoe and concealed for use later on.

Finally, both federal and state governments must commit to providing resources to aid survivors of sex trafficking regardless of age. Although the Violence Against Women Reauthorization Act of 2013 provided significant resources for the care of trafficking victims, it only targeted these resources at victims who are minors.[75] These resources need to be extended to cover adult trafficking victims and adult survivors, as their physical and mental health needs are just as great as those of minor sex trafficking victims. Federal and state funding of medical care and other related survivor needs should recognize this reality by eliminating age-based restrictions on funding.

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70. Posting the National Human Trafficking Resource Center Hotline, POLARIS PROJECT, http://www.polarisproject.org/what-we-do/policy-advocacy/capacity-building/posting-the-national-human-trafficking-resource-center-hotline (last visited Nov. 26, 2013). This page of the Polaris Project website also provides model language for state-level posting legislation.

71. H.R. 898, 113th Cong. § 224(c)(1)-(3) (2013).

72. CAL. CIV. CODE § 52.6 (West, WestlawNext through Ch. 800 of 2013 Reg. Sess., 2013-2014 1st Ex. Sess. Laws, and Res. Ch 123).

73. GA. CODE ANN. § 16-5-47 (West, WestlawNext through the end of the 2013 Regular Session).

74. For additional public policy recommendations and more detail on state training and posting requirements, see Laura J. Lederer & Ashley Johnson, Healthcare Professionals' Role in Combating Human Trafficking (Aug. 2, 2013) (unpublished manuscript) (on file with authors).

75. Violence Against Women Reauthorization Act of 2013, Pub. L. 113-4, 127 Stat. 136, 136-160 (2013) (codified in various sections of the U.S.C.).

VII. CONCLUSION

Victims of sex trafficking suffer severe physical and psychological health consequences as a result of their trafficking. Victims frequently have contact with medical professionals in a variety of health care settings, including hospital emergency wards, neighborhood clinics, women's health clinics, and Planned Parenthood clinics, as well as private practices. Violence-related injuries, serious illness or disease, pregnancy, birth control, and abortion, substance abuse, addiction and overdose, as well as serious psychological problems, are all reasons why substantial numbers of victims seek treatment.

Because they are "first responders" health care providers have unique opportunities to intervene on behalf of trafficking victims. Health care institutions must develop protocols for training, identifying, and treating sex trafficking victims. Medical personnel must increase efforts to understand the nature and scope of the problem of sex trafficking in the United States in order to improve their capacity to identify victims. This is especially true when they have the ability to speak privately with victims in a context where their statements may be admissible in a later prosecution of their traffickers. To this end, medical staff, particularly in hospital emergency rooms and local clinics should be alert for the most common physical and psychological conditions and symptoms these victims experience, especially in the context of reproductive health. By doing so, the medical community can play a vital role in the ongoing fight to eliminate modern-day slavery.

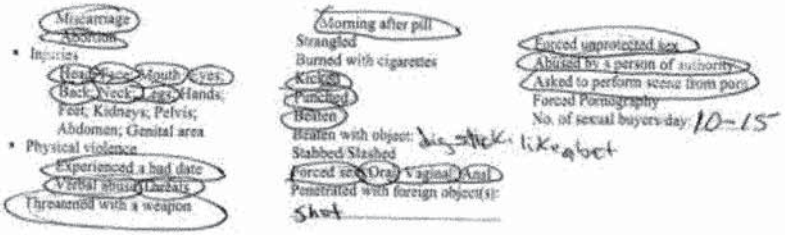
Appendix – Sample Completed Survey

Health Questionnaire

Health Issues While Trafficked: (Please circle all that apply to you)

- Neurological symptoms
  - Headaches or migraines
  - Dizziness
  - Fainting
  - Hearing problems
  - Memory problems
  - Insomnia
  - Poor concentration
  - Nerve damage
- Gastrointestinal symptoms
  - Stomach/Abdominal pain
  - Indigestion
  - Ulcers
  - Nausea/Vomiting
  - Diarrheal disease
- Respiratory symptoms
  - Shortness of breath
  - Bronchitis
  - Pneumonia
  - Cold/flu symptoms
  - Asthma
  - Tuberculosis
- Cardiovascular symptoms
  - Rapid or irregular heartbeat
  - Chest pain
  - Breathing difficulty
- Dermatological
  - Rashes
  - Lice
  - Scabies
  - Chicken pox
  - Impetigo
  - Shingles
- Psychological symptoms
  - Depression
  - Anxiety
  - Panic attacks
  - Nightmares
  - Hostility
  - Irritability
  - Flashbacks
  - Nightmares
  - Hyper-alertness
  - Withdrawal/Isolation
  - Frequent crying
  - Low self-esteem
  - Shame/Guilt
  - Acute stress disorder
  - Bipolar
  - Delusions of Parasitosis (Believe infected with parasites)
  - Physical hyper-alertness
  - Depersonalization disorder
  - Multiple personality disorder
  - Borderline personality disorder
  - Somatization
  - Paranoid ideation
  - Dissociation
  - Identity problems
  - Relational problems
  - Suicide ideation
  - Attempted suicide
  - PTSD
- Oral health
  - Gingival disease
  - Decayed teeth
  - Abscesses
  - Throat trauma
  - Tooth loss
- General health symptoms
  - Sore throat
  - Body chills
  - Night sweats
  - Hearing loss
  - Vision problems
  - Severe weight loss
  - Malnutrition
  - Loss of appetite
  - Eating disorders
  - Poor hygiene
  - Anemia
  - Chronic fatigue
- General body pains
  - Joint pain
  - Back pain
  - Neck pain
  - Arthritis
  - Swelling of limbs
  - Pain/numbness in hands/feet
- Diseases
  - Diabetes
  - Heart disease
  - Cancer
- Sexual diseases
  - STD/STI: T. vaginalis;
  - N. gonorrhea; Syphilis;
  - Chlamydial trachomatis;
  - Genital herpes;
  - Candidiasis;
  - Other: _____
  - HPV
  - Hepatitis C
  - HIV/AIDS
- Substance abuse
  - Alcohol
  - Drugs: Marijuana, Cocaine;
  - Crack Cocaine;
  - Heroine; PCP; Ecstasy;
  - Other: _____
  - Injecting drug use
  - Overdose
  - Forced substance use
- Gynecological/Reproductive
  - Vaginal discharge
  - Vaginal bleeding
  - Cervical/vaginal infection
  - Urinary tract infection
  - Bladder inflammation
  - Pelvic inflammatory disease
  - Pelvic pain
  - Vaginal pain
  - Pain during sex
  - Infertility
  - Birth control
  - Pregnancy

Please be aware of cultural and religious differences when administering the questionnaire



For the above listed health issues, where did you receive treatment?

Hospital/ER;
Urgent Care Clinic
Neighborhood Clinic
Planned Parenthood
Women's Health Clinic
General Doctor
On-site Doctor
Other: Dr. my pimp knew

Did the doctor, nurse, health provider know you were "on the street"?
yes

If yes, did the doctor, nurse, health provider ask you anything about your life?
no

If yes, and if you had a pimp, did the health care provider know you had a pimp?
yes - only the one Private Dr.
Not the health clinic's - but they never asked.

Please be aware of cultural and religious differences when administering the questionnaire

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If you circled birth control, pregnancy, miscarriage, morning after pill or abortion, please answer the following questions:

How long were you on birth control while being trafficked?
Never

What kind of birth control did you use? (Condom, Depo-Provera, Diaphragm, BCP)
Sponge

Who gave you the birth control? (Trafficker, doctor, clinic worker)
I bought-

Who took you to the clinic, doctor, or hospital where you received birth control?

How many pregnancies did you have while being trafficked?
9 in the life / but 8 pregnancies

Who fathered the child children? (Male sexual buyer, boyfriend, pimp, trafficker)

How many children did you give birth to?
two

Where was each child delivered? (Hospital, clinic, on-site)

Do you have custody of your child?
yes

How many miscarriages did you have?
1

Were you given the morning after pill? Who supplied the drug?
Dr. two times - not for sure if I was pregnant.

How many abortions did you have?
6

At what term in your pregnancy did you have an abortion?
1st term - everytime

Was the abortion of your own volition or forced upon you?
experienced both - lack of options to raise a baby

If you had an abortion, where was the abortion performed? (Hospital, clinic, on-site)
Dr. office - clinics

Please be aware of cultural and religious differences when administering the questionnaire.

Health Issues Post-Trafficking: (Please circle all that apply to you)

- Neurological symptoms
  - Headaches or migraines
  - Dizziness
  - Fainting
  - Hearing problems
  - Memory problems
  - Insomnia
  - Poor concentration
  - Nerve damage
- Gastrointestinal symptoms
  - Stomach/Abdominal pain
  - Indigestion
  - Ulcers
  - Nausea/Vomiting
  - Diarrheal disease
- Respiratory symptoms
  - Shortness of breath
  - Bronchitis
  - Pneumonia
  - Cold/flu symptoms
  - Asthma
  - Tuberculosis
- Cardiovascular symptoms
  - Rapid or irregular heartbeat
  - Chest pain
  - Breathing difficulty
- Dermatological
  - Rashes
  - Lice
  - Scabies
  - Chicken pox
  - Impetigo
  - Shingles
- Psychological symptoms
  - Depression
  - Anxiety
  - Panic attacks
  - Helplessness
  - Hostility
  - Irritability
  - Flashbacks
  - Nightmares
  - Hyper-alertness
  - Withdrawal/Isolation
  - Frequent crying
  - Low self-esteem
  - Shame/Guilt
  - Acute stress disorder
  - Bipolar
  - Delusions of Parasitosis (believe infected with parasites)
  - Physical hyper-alertness
  - Depersonalization disorder
  - Multiple personality disorder
  - Borderline personality disorder
  - Somatization
  - Paranoid ideation
  - Dissociation
  - Identity problems
  - Relational problems
  - Suicide ideation
  - Attempted suicide
  - PTSD
  - Phobias: people/crowds
- Oral health
  - Gingival disease
  - Decayed teeth
  - Abscesses
  - Throat trauma
  - Tooth loss
- General health symptoms
  - Sore throat
  - Body chills
  - Night sweats
  - Hearing loss
  - Vision problems
  - Severe weight loss
  - Malnutrition
  - Loss of appetite
  - Eating disorders
  - Poor hygiene
  - Anemia
  - Chronic fatigue
- General body pains
  - Joint pain
  - Back pain
  - Neck pain
  - Arthritis
  - Swelling of limbs
  - Pain/numbness in hands/feet
- Diseases
  - Diabetes
  - Heart disease
  - Cancer
- Sexual diseases
  - STD/STI: T. vaginalis; N. gonorrhea; Syphilis; Chlamydia trachomatis; Genital herpes; Candidiasis; Other: _____
  - HPV
  - Hepatitis C
  - HIV/AIDS
- Substance abuse
  - Alcohol
  - Drugs: Marijuana; Cocaine; Crack Cocaine; Heroine; PCP; Ecstasy; Other: _____
  - Injecting drug use
  - Overdose
- Gynecological/Reproductive
  - Vaginal discharge
  - Vaginal bleeding
  - Cervical/vaginal infection
  - Urinary tract infection
  - Bladder inflammation
  - Pelvic inflammatory disease
  - Pelvic pain
  - Vaginal pain
  - Pain during sex
  - Infertility
  - Birth control
  - Pregnancy
  - Miscarriage
  - Morning after pill
  - Abortion

Please be aware of cultural and religious differences when administering the questionnaire

Exhibit 2

Bill Analysis, C.S.H.B. 3446,

Committee Report

BILL ANALYSIS

C.S.H.B. 3446
By: Laubenberg
State Affairs
Committee Report (Substituted)

BACKGROUND AND PURPOSE

Human trafficking, child pornography, and international sex tourism reportedly generate billions of dollars a year worldwide and there are indications that a significant number of U.S. citizens and foreign nationals are trafficked within the borders of the United States. Texas law already requires certain places of business to post signs that are visible to employees and patrons that provide a toll-free phone number for a national human trafficking helpline. It has been noted, however, that there is no law requiring these postings at an abortion facility despite the fact that many of the women who undergo abortions may be victims of human trafficking, especially sex trafficking. Due to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking. C.S.H.B. 3446 seeks to require signs relating to human trafficking to be displayed at certain abortion facilities.

CRIMINAL JUSTICE IMPACT

It is the committee's opinion that this bill does not expressly create a criminal offense, increase the punishment for an existing criminal offense or category of offenses, or change the eligibility of a person for community supervision, parole, or mandatory supervision.

RULEMAKING AUTHORITY

It is the committee's opinion that rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 of this bill.

ANALYSIS

C.S.H.B. 3446 amends the Health and Safety Code to require a licensed ambulatory surgical center that performs more than 50 abortions in any 12-month period or a licensed abortion facility to conspicuously display in each patient admission area, waiting room, restroom, and patient consulting room signs that contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking, as well as the following information: a woman cannot be forced to have an abortion against her will, regardless of her age; if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and human trafficking, including sex trafficking, is a violation of state law. The bill prohibits the signs from containing any information other than that information and prescribes the required sign measurements. The bill requires an applicable center or facility to post a sign in English and a sign in Spanish, as well as any other language in which the political subdivision within which the facility is located is required under the Election Code to provide election materials, if applicable. The bill requires the executive commissioner of the Health and Human Services Commission, not later than December 1, 2015, to adopt rules as necessary to implement and enforce the bill's provisions and establishes that an ambulatory surgical center or abortion facility is not required to comply with the bill's provisions before January 1, 2016.

EFFECTIVE DATE

September 1, 2015.

COMPARISON OF ORIGINAL AND SUBSTITUTE

While C.S.H.B. 3446 may differ from the original in minor or nonsubstantive ways, the following comparison is organized and formatted in a manner that indicates the substantial differences between the introduced and committee substitute versions of the bill.

INTRODUCED	HOUSE COMMITTEE SUBSTITUTE
SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Sections 171.0125 and 171.0126 to read as follows:	SECTION 1. Subchapter B, Chapter 171, Health and Safety Code, is amended by adding Section 171.0125 to read as follows:
Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room.	Sec. 171.0125. REQUIRED SIGNS AT CERTAIN FACILITIES: AVAILABLE RESOURCES. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display signs that satisfy the requirements of this section in each patient admission area, waiting room, restroom, and patient consulting room.
(b) The sign required by this section must be in English and Spanish and display the following text: You can't be forced. No one can make you have an abortion against your will, even if you are a minor. In fact, forcing a minor to have an abortion is considered child abuse. If you are a minor being forced into making a particular decision, you can report it by calling the Texas Abuse Hotline at 1-800-252-5400. The call is free and the hotline operates 24 hours per day, 365 days per year. You and the father. The father of your child must provide support for the child, even if he has offered to pay for an abortion. The Child Support Division of the Office of the Attorney General can help you locate your child's father and determine that he is the father. The Child Support Division can also help establish and enforce child support orders and collect money owed, as well as distribute child support payments. To learn more about child support services, call the Child Support Division at (512) 460-6000. You and adoption. The law allows adoptive parents to pay costs of prenatal care, childbirth, and newborn care. To learn more about adoption services and the organizations available to assist you, call Woman's Right to Know at (512) 776-6917. You are not alone. Many agencies are willing to help you carry your child to term and to assist you after your child's birth. This includes providing access to health care services for mother and baby, supplies, healthy food items, nutrition education, and in-home support.	(b) The signs required by this section must contain the following information: (1) a woman cannot be forced to have an abortion against her will, regardless of her age; (2) if a woman is being forced to have an abortion or being abused, the state is able to help the woman; and (3) human trafficking, including sex trafficking, is a violation of state law.
	(c) The signs required by this section must also contain a phone number for the Department of Public Safety and a toll-free phone number of a nationally recognized information and referral hotline for victims of human trafficking. (d) The signs required by this section may not contain any information other than the information described by Subsections (b) and (c).

INTRODUCED

(See subsection (b) above.)

(c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.

Sec. 171.0126. REQUIRED SIGNS AT CERTAIN FACILITIES: HUMAN TRAFFICKING. (a) An ambulatory surgical center licensed under Chapter 243 that performs more than 50 abortions in any 12-month period or an abortion facility licensed under Chapter 245 shall conspicuously display a sign that satisfies the requirements of this section in each patient admission area, waiting room, and patient consulting room.

(b) The sign required by this section must be in English and Spanish and display the following text:

WARNING: Being forced to engage in sexual activity or forced to obtain an abortion is illegal under Texas law. Call the national human trafficking hotline: 1-888-373-7888.

(c) The executive commissioner of the Health and Human Services Commission shall adopt rules as necessary to implement and enforce this section.

SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act.

SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Sections 171.0125 and 171.0126, Health and Safety Code, as added by this Act, before January 1, 2016.

SECTION 4. This Act takes effect September 1, 2015.

(e) The signs required by this section must each be at least 11 inches in width and 17 inches in length.

(f) A facility described by Subsection (a) shall post a sign required by this section in English and a sign in Spanish. If the facility is located in a political subdivision that is required to provide election materials in a language other than English or Spanish under Section 272.011, Election Code, the facility shall also post a sign in that language.

(g) The executive commissioner shall adopt rules as necessary to implement and enforce this section.

SECTION 2. Not later than December 1, 2015, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement Section 171.0125, Health and Safety Code, as added by this Act.

SECTION 3. An ambulatory surgical center or abortion facility is not required to comply with Section 171.0125, Health and Safety Code, as added by this Act, before January 1, 2016.

SECTION 4. Same as introduced version.

Exhibit 3

Declaration of Mario R. Dickerson

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF MARIO R. DICKERSON

I, Mario R. Dickerson, a citizen of the United States and a resident of Willow Grove, Pennsylvania, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I serve as the Executive Director of the Catholic Medical Association ("CMA"). Given my involvement in CMA, I am familiar with the organization's history, the issues confronting it, and the views of the organization and its members concerning various emerging issues, including the deregulated use of mifepristone, or RU-486, to accomplish chemical abortions. I am also familiar with CMA members and their practices.
3. CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2700 physicians and healthcare professionals nationwide.
4. CMA is a nonprofit organization incorporated in Virginia, and its registered agent is in Virginia.
5. CMA's mission is to inform, organize, and inspire its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the principles of the Catholic faith in the science and practice of medicine.
6. CMA seeks to pursue its mission in conformity to Christ the Divine Physician. Its members are challenged to be a voice of truth spoken in charity, to show

how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

7. CMA is a member of the Alliance for Hippocratic Medicine (AHM).

8. CMA is committed to taking a Catholic and Hippocratic approach to medicine.

9. Consistent with Catholic teaching, CMA and its members are morally and ethically opposed to all forms of abortion—chemical or surgical.

10. I have spoken with CMA members who have treated women harmed by chemical abortion drugs.

11. The FDA's unauthorized approval of mifepristone (also known as "Mifeprex" and "RU-486") and subsequent elimination of certain safeguards for the use of the dangerous chemical abortion drug regimen, including those found in the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, has led to an increasing risk that women and girls may suffer adverse events from chemical abortion.

12. The FDA has continued to eliminate safeguards such that the chemical abortion drugs can now be administered and dispensed with no in-person examination or oversight by a physician. This leaves physicians, including CMA members, to treat the complications that women and girls suffer due to the actions of the FDA and abortionists.

13. CMA's member physicians include OB/GYNs and emergency department physicians who have treated women suffering complications from chemical abortion.

14. The FDA's actions harm CMA and its member physicians who are called away from other patients to render emergency treatment to women and/or girls who present to emergency departments with symptoms, such as heavy bleeding and severe pain, and more serious complications, including hemorrhage and sepsis caused by chemical abortion drugs. This causes CMA's member physicians much stress and grief, while impeding their ability to perform their practice of medicine in the manner that they desire.

15. Often, emergency department doctors do not have a prior relationship with these patients and lack access to the patient's medical history. Sometimes these patients were underinformed about the effects of the chemical abortion drug regimen, they may not even know what drugs they consumed, or they are told to say they are suffering a miscarriage if there is a need for them to seek emergency help following a chemical abortion. This leaves doctors at increased risk of liability and could impact their ability to render the best care possible to the patient—all because of the FDA's elimination of necessary safeguards.

16. Moreover, the FDA's removal of necessary safeguards could force CMA members to treat women and girls who present to emergency departments following an elective chemical abortion requiring those doctors to complete an

unfinished elective abortion—terminating the life of an unborn child—in violation of their conscience rights.

17. Since 2005, CMA has called upon the FDA to respond to citizens petitions calling for removal of RU-486 from the market in an urgent action. CMA renewed this resolution in 2015.

18. In 2016, CMA enacted a resolution that called for the FDA to require a central registry for all those having a chemical abortion, with mandatory reporting from every state and territory of complications and mortalities from chemical abortions; that the drug be administered only by a physician with surgical privileges at a hospital within 30 minutes of the facility where the drug is dispensed; that the dispensing physician be responsible for follow-up and handling of complications; and that the patient be informed that the process could be stopped without harm to her or the baby.

19. These resolutions are vital to ensure the safety of women and girls, and to protect doctors, including CMA members.

20. CMA has spent considerable time, effort and resources challenging the FDA's actions—at the expense of other CMA priorities. For example, to implement these resolutions, committees have had to review them, it has taken time during General Assembly meetings to discuss them, which takes our members away from their other business, and it has taken time for our Executive Director and Board to review, taking them away from other priorities such as fundraising and membership recruitment and retention.

21. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This prevents CMA from providing the public, their members, and their members' patients with accurate statistics and complete information regarding the risks associated with the use of chemical abortion drugs.

22. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. CMA creates and organizes educational resources and events; advocates for members, the Church, and the medical profession in public forums; and provides guidance for bishops and other national leaders on healthcare ethics and policy. The inability to share accurate information on the risks of chemical abortion frustrates and complicates CMA's purpose to educate doctors, their patients, and the public about these dangers.

Executed this November 12, 2022.

By: Mario R. Dickerson
Mario R. Dickerson

Exhibit 4

Declaration of Dr. Donna Harrison

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. DONNA HARRISON

I, Donna Harrison, a citizen of the United States of America and a resident of Berrien Center, Michigan, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist.
3. I received my medical degree from the University of Michigan and completed my residency at a University of Michigan affiliate hospital, St. Joseph Mercy Hospital.
4. I am a diplomate of the American Board of Obstetrics and Gynecology.
5. I serve as the Chief Executive Officer of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).
6. I also serve as the President of Plaintiff Alliance for Hippocratic Medicine (AHM).
7. I am familiar with AAPLOG, its members, their fields of practice, and AAPLOG's policies and positions, including as set forth in the complaint, which I have reviewed.
8. AAPLOG is the largest organization of pro-life obstetricians and gynecologists ("OB/Gyns") in the world and is headquartered in Indiana. AAPLOG includes OB/Gyns and other physicians, with more than 7,000 medical professionals nationwide and more than 300 members in Texas.

AAPLOG members oppose elective abortion and are committed to the care and well-being of their patients including both pregnant women and their unborn children. AAPLOG members are concerned about the adverse impacts of chemical abortion on their practice of medicine.

9. AAPLOG's mission includes advocating on behalf of its members, including in litigation.

10. AAPLOG sues in this case on behalf of itself and its members.

11. I am also familiar with AHM, its members, their members' fields of practice, and AHM's policies and positions, including as set forth in the complaint, which I have reviewed.

12. AHM is a nonprofit organization that upholds and promotes the fundamental principles of Hippocratic medicine. AHM is incorporated in the State of Texas and has its registered agent in Amarillo, Texas.

13. AHM's members include the membership of the American Association of Pro-Life Obstetricians and Gynecologists, American College of Pediatricians, Catholic Medical Association, Christian Medical and Dental Associations, and Coptic Medical Association of North America. In opposing chemical abortion, AHM's members are concerned about the safety and well-being of pregnant women and girls, their preborn children, and chemical abortion's adverse impacts on the practice of medicine.

14. AHM sues in this case on behalf of itself and its members.

15. I am familiar with chemical abortion drugs, their use, and the complications that accompany chemical abortion.

16. As part of my duties and responsibilities at AAPLOG, I have authored several studies on the approval of mifepristone as an abortifacient. Among these, I co-authored two studies with other physicians and scholars examining the adverse events associated with the use of mifepristone. Our studies of the real-world use of mifepristone concluded that significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient. We recommended that a pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm the gestational age of the unborn child. We concluded that the FDA's adverse event reporting system is grossly inadequate to evaluate real-world complications and significantly underestimates adverse events from mifepristone. One major reason that the FAERS database does not reflect real world complications is that FDA only required the manufacturer to report complications, and the manufacturer in turn obtains data from the abortionists. However, as our studies of the FAERs database indicate, most complications are not handled by the abortion provider, but rather by the Emergency Department, and the Emergency Department physician has no knowledge of the reporting process or obligation to report those complications to the manufacturer or to the FDA. *See* Kathi Aultman, et al., *Deaths and Severe Adverse Events After the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36

Issues L. Med. 3 (2021), https://pubmed.ncbi.nlm.nih.gov/33939340/; Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 Ann. Pharmacother. 171 (2006), https://pubmed.ncbi.nlm.nih.gov/16380436/.

17. In addition, as part of my duties and responsibilities at AAPLOG, I co-authored a paper comparing the published complications after use of mifepristone from Planned Parenthood in 2009 and 2010 and compared those numbers to the complications in the FDA Adverse Event Reporting System for the same time period. We found that Cleland identified 1,530 Planned Parenthood mifepristone cases with specific adverse events (AEs) for 2009 and 2010. For this period, FAERS online dashboard includes a total (from all providers) of only 664, and the FDA released only 330 adverse event reports (AERs) through Freedom of Information Act (FOIA) requests. Cleland identified 1,158 ongoing pregnancies in 2009 and 2010. FAERS dashboard contains only 95, and only 39 were released via FOIA requests. We concluded that there are significant discrepancies in the total number of AERs and specific AEs for 2009 and 2010 mifepristone abortions reported in 1) Cleland's documentation of Planned Parenthood AEs, 2) FAERS dashboard, and 3) AERs provided through FOIA. These discrepancies render FAERS inadequate to evaluate the safety of mifepristone abortions. *See* Christina A Cirucci, et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting*

System and Those Obtained Through the Freedom of Information Act, 8 Health Servs. Rsch. & Managerial Epidemiol. 23333928211068919 (2021), https://pubmed.ncbi.nlm.nih.gov/34993274/.

18. I also co-authored a study looking at the real-world effects of the FDA Approval of Mifeprex on Emergency Room utilization after Mifeprex abortions. The massive increased utilization of Emergency Departments to manage abortion complications is a predictable consequence of the FDA's failure to require the same qualifications of Mifeprex abortion providers as were mirrored in the clinical trial for Mifeprex approval.

19. Because the FDA abandoned the post marketing requirement that abortion providers have admitting privileges to handle their own complications and allowed abortion providers who lack the ability to handle complications to dispense Mifeprex, the predictable consequence is the explosion of Mifeprex complications including hemorrhage, adding to the current shortage of blood and blood products across the United States. *See* James Studnicki, et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015*, 8 Health Servs. Rsch. & Managerial Epidemiol. 23333928211053965 (2021), https://pubmed.ncbi.nlm.nih.gov/34778493/.

20. I am familiar with the FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol. As part of my duties and responsibilities at AAPLOG, I co-authored the original 2002 Citizen Petition and the 2019

Citizen Petition filed by AAPLOG and others to challenge the FDA's actions on chemical abortion drugs. As part of my duties and responsibilities at AAPLOG, I also co-authored a study detailing the aberrancies of the FDA Approval process as it affects real-world patients. *See* Byron C. Calhoun & Donna J. Harrison, *Challenges to the FDA Approval of Mifepristone*, 38 Ann. Pharmacother. 163 (2004), https://pubmed.ncbi.nlm.nih.gov/14742814/.

21. In a chemical abortion, women take mifepristone to terminate the pregnancy by killing the preborn child. Women then take misoprostol to expel all pregnancy tissues, including the preborn child, through contractions and cramping.

22. Women who take chemical abortion drugs experience more complications than those who have surgical abortions.

23. There are many intense side effects for women who take chemical abortion drugs, including cramping and heavy bleeding.

24. Since the FDA's 2000 Approval of Mifeprex (the chemical abortion drug regimen consisting of mifepristone and misoprostol), medical professionals have needed to treat women and girls who have suffered from chemical abortion and experienced complications.

25. Mifepristone and misoprostol are serious drugs that should not be administered without medical supervision. The FDA's actions to eliminate the necessary supervision of these drugs harm women and obstetrics professionals, including AHM, AAPLOG, and their members.

26. Since the FDA's 2016 Major Changes to eliminate safeguards for the use of Mifeprex, AAPLOG members have needed to treat an increasing rate of women and girls who suffer complications from chemical abortion.

27. The increase in the frequency of complications harms medical providers—including AHM and AAPLOG members—because they end up managing the increase in complications.

28. When women suffer complications from chemical abortions, it can overwhelm the medical system and consume crucial limited medical resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines.

29. The increased occurrence of complications related to chemical abortions also multiplies the workload of healthcare providers, including AHM and AAPLOG members, in some cases by astronomical amounts. This is especially true in maternity care "deserts" (i.e., geographic areas where there are not a large number of OB/Gyn providers for patients).

30. For OB/Gyn professionals, the increase in complications due to increased use of chemical abortion drugs means that the typical care given to patients goes from simple patient management to complicated patient management. Patients who suffer complications from chemical abortions require significantly more time and attention from providers than the typical OB/Gyn patient requires.

31. In my experience, many patients do not fully understand the nature of chemical abortion or the risks that these drugs present to them. This results in an increase in the frequency of women seeking emergency medical care for side effects such as cramping, heavy bleeding, and severe pain even if they are not suffering an adverse event.

32. I understand that the FDA has removed the requirement for abortionists to report all adverse events for mifepristone.

33. Many doctors likely do not know about the need to report adverse events related to chemical abortion to the FDA. Similarly, many doctors likely do not know how to report adverse events. This means that complications handled by practitioners other than the abortionist are rarely reported to the FDA or the manufacturer.

34. I personally know of practitioners, including AAPLOG members, who have tried to report adverse events related to chemical abortion drugs to the FDA. The process is complicated, cumbersome, and time-consuming. The adverse event reporting requirements and the FAERS submission process harm medical practices by taking away significant time from a doctor to treat and meet with patients.

35. The FDA's decision not to require abortionists to report all adverse events for mifepristone harms women and girls because this deregulatory action creates an inaccurate and false safety profile for the use of mifepristone and misoprostol.

36. Without an accurate picture of the adverse effects of widespread chemical abortion drug use, physicians cannot effectively practice evidence-based medicine. If the FDA is not collecting the vast majority of adverse events to understand the true risk, healthcare providers cannot assess the risks of a particular course of treatment and inform their patients accordingly.

37. The inability of providers to adequately inform women of the known risks associated with chemical abortion drugs precludes women and girls from giving informed consent to taking these drugs. The lack of information also harms the patient-doctor relationship with all medical care providers because the patients no longer trust that their healthcare providers are telling the truth. This even harms organizations and practitioners who do not support or practice chemical abortion, including AHM, AAPLOG, and their members.

38. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This prevents AHM and AAPLOG from providing the public, their members, and their members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

39. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates AHM's and AAPLOG's purpose to support women's health and to educate doctors, their patients, and the public about these dangers.

40. AHM and AAPLOG need to divert limited time, energy, and resources to compensate for this lack of information by conducting their own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of AHM and AAPLOG, including their efforts regarding the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.

41. On behalf of AAPLOG and serving as the chairperson for AAPLOG's Subcommittee on Mifeprex, I submitted a Citizen Petition in 2002 challenging the FDA's approval of Mifeprex and requesting an audit of the Mifeprex clinical studies. AAPLOG, as an organization, is concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving Mifeprex put women's lives and health at risk. It took considerable time, energy, and resources to draft the 92-page petition and the 30-page response to comments letter, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

42. Similarly, AAPLOG submitted another Citizen Petition in 2019 challenging the FDA's 2016 major changes to the chemical abortion drug regimen, which I also co-authored. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting

sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

43. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, AHM and AAPLOG continue to expend considerable time, energy, and resources on its public advocacy and educational activities regarding chemical abortion drugs—to the detriment of other AHM and AAPLOG priorities and functions. This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs ceases.

44. AHM and AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. The FDA's removal of REMS for safe use—which eliminates in-person evaluations and follow-up care—places our member doctors at increased risk of being forced to violate their conscience rights. The FDA's actions could force our members into a situation where they must render treatment to a woman in the emergency department suffering complications from chemical

abortion while she is still carrying a living fetus, and they must perform a D&C to treat her complications—ending the life of a human being.

Executed this November 11, 2022.

By: Donna Harrison MD
Donna Harrison, M.D.

Exhibit 5

Declaration of Dr. Jeffrey Barrows

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. JEFFREY BARROWS

I, Jeffrey Barrows, D.O. M.A. (Ethics), a citizen of the United States and a resident of Blountville, Tennessee, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist and am the Senior Vice President of Bioethics and Public Policy for Plaintiff Christian Medical & Dental Associations (CMDA).
3. I practiced obstetrics and gynecology for approximately 18 years. I practiced gynecology in an office setting for an additional ten years.
4. I am familiar with CMDA, its members, their fields of practice, and CMDA's policies and positions.
5. CMDA is a national nonprofit organization headquartered in Tennessee. Its members are more than 13,000 Christian physicians, dentists, and allied healthcare professionals. CMDA has more than 1,200 members in Texas, including more than 600 physicians and approximately 35 OBGYNs.
6. CMDA is opposed to elective abortions as contrary to sacred scripture, respect for the sanctity of human life, and traditional, historical Judeo-Christian medical ethics.
7. CMDA's mission includes advocating on behalf of its members, including in litigation.

8. CMDA brings this suit on behalf of itself and its members.

9. CMDA has members in Texas and around the country who care for pregnant women in hospitals and clinics. CMDA's members care for women who suffer complications from chemical abortions.

10. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

11. I am familiar with the FDA's approval of chemical abortion drugs in 2000.

12. I am familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.

13. I understand that the FDA's 2016 changes expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks), that it eliminated the in-person administration requirements for chemical abortion drugs, that it eliminated the requirement for a follow-up appointment after those drugs have been taken, and that it eliminated the prescriber reporting requirement for all adverse events except for death.

14. I also understand that the FDA subsequently eliminated the in-person dispensing requirements in 2021.

15. The FDA's actions harm women, practitioners, CMDA members, CMDA as an organization, and the medical profession generally.

16. Mifepristone and misoprostol are dangerous drugs that can potentially harm women. Relaxing the required medical supervision and oversight for patients taking these drugs puts women's health at risk.

17. By eliminating the in-person dispensing requirement and the requirement for a post-abortion follow-up, the FDA has exposed women to a higher likelihood of undetected serious complications. Specifically, the expanded use of telemedicine for chemical abortions means that some women who are beyond 70 days' gestation because they are mistaken or wrong about the gestational age of their unborn child will take these drugs outside of the appropriate window.

18. Similarly, without in-person visits and sonograms, women with ectopic pregnancies may escape diagnosis, which puts them at a greater risk of serious and life-threatening complications such as rupture of the Fallopian tube and secondary hemorrhage. Undetected ectopic pregnancies are especially dangerous for women because in some cases they can result in extreme bleeding for women.

19. By eliminating the adverse event reporting requirement for all events except death, the FDA has also undermined physicians' ability to practice evidence-based medicine. By failing to collect accurate information about the complications associated with chemical abortion, the FDA leaves doctors without accurate information about the drugs' safety for women.

20. As an organization, CMDA is harmed by the FDA's failure to require reporting of all adverse events, which prevents CMDA from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

21. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates CMDA's purpose to provide professional healthcare and to educate doctors, their patients, and the public about the dangers of chemical abortion.

22. By removing the requirements for in-person visits, the FDA has increased the risk of malpractice claims against physicians. The best way to prevent malpractice is for physicians to establish relationships with patients who they can treat over time. By doing away with the necessary medical supervision, the FDA will cause more women to present in life-threatening circumstances into the care of hospitalists and emergency department physicians who have no prior history with these patients.

23. By putting more doctors into riskier, emergent medical situations, the FDA's regulatory actions expose physicians to increased claims of liability.

24. The increased risks of exposure to liability and malpractice claims also impacts physicians because it drives up their insurance costs, especially those who practice in the hospital.

25. The FDA's loosening of chemical abortion regulations impacts the standard of care and the demands and expectations that hospitals will put on their physicians. The FDA has radically altered the standard of care for mifepristone and misoprostol. The agency did this without the requisite evidence to support its actions.

26. I am also concerned that the FDA's actions will force CMDA members to complete an unfinished elective abortion in an emergency situation, causing immediate emotional and moral distress for our members who are opposed to elective abortion and do not want to feel complicit in an immoral, unnecessary procedure.

27. CMDA has been involved with challenging the FDA's approval of chemical abortion drugs for 20 years. In 2002, we submitted a Citizen Petition with other pro-life groups challenging the FDA's actions, diverting valuable time and effort from CMDA's routine functions in order to assist in filing the petition.

Executed this November 12, 2022.

By: BARROWS DO MA
Jeffrey Barrows, D.O. M.A.

Exhibit 6

Declaration of Dr. Quentin Van Meter

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. QUENTIN L. VAN METER

I, Quentin L. Van Meter, a citizen of the United States and resident of Atlanta, Georgia, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified pediatric endocrinologist.
3. I received my medical degree from the Medical College of Virginia in 1973.
4. I did my pediatric internship (1973-1974) and my pediatric residency (1974-1976) at the Naval Regional Medical Center in Oakland, through the University of California, San Francisco. I completed my pediatric endocrinology fellowship from 1978 to 1980 at The Johns Hopkins Hospital. I also worked as a staff pediatric endocrinologist at the Naval Hospital in San Diego (1980-1986) and was Chairman and Director of the residency training program at the Naval Hospital Oakland (1986-1991).
5. Following a 20-year career in the Navy Medical Corps, I moved to the Atlanta area and joined the Fayette Medical Clinic as a Pediatrician and Pediatric Endocrinologist. To better serve the ever-expanding population of pediatric patients with endocrine disorders, I developed my own full-time pediatric endocrine practice. Specifically, my practice helps children by treating them for disorders related to hormones and the endocrine glands that produce them.

6. I currently serve as the president of the American College of Pediatricians.

7. I am familiar with the American College of Pediatricians, its members, their fields of practice, and the organization's policies and positions, including as set forth in the complaint, which I have reviewed.

8. The American College of Pediatricians is a national organization of pediatricians and other healthcare professionals. Its membership includes more than 600 physicians and other healthcare professionals drawn from 47 different states across the nation. The American College of Pediatricians has members in the State of Texas.

9. The American College of Pediatricians brings this suit on behalf of itself and its members.

10. I am familiar with the FDA's approval of mifepristone and issuance of a risk evaluation and mitigation strategy (REMS) for the chemical abortion drug regimen, which includes both mifepristone and misoprostol.

11. I understand that prior to the 2000 approval of mifepristone, the FDA never required a clinical study evaluating the safety and effectiveness of chemical abortion drugs on pregnant girls under 18 years of age.

12. As a blocker of the hormone progesterone, mifepristone is an endocrine disruptor and, therefore, could interfere with pubertal development or adversely impact an adolescent girl's developing body and reproductive system. The FDA's failure to require pediatric clinical studies places girls at

risk from these drugs, which have the potential to dangerously adversely impact the health, safety, and welfare of the exposed adolescents.

13. To my knowledge, the FDA's 2000 approval of mifepristone for use in girls was unsupported by any scientific data showing that chemical abortion drugs are safe for girls under 18 years of age.

14. By failing to require studies, the FDA's 2000 approval placed young girls going through their reproductive development at risk.

15. Numerous studies have demonstrated that there is an increased risk from chemical abortion drugs to pregnant women and girls as compared to surgical abortion.

16. One recent study discovered that one-third of all post-abortion hospital emergency department visits in 2015 were after use of chemical abortion drugs. The FDA's elimination of REMS and loosening of restrictions increases the risk that girls will suffer complications from chemical abortion drugs.

17. I am also aware that, in 2016, the FDA eliminated the requirement that abortionists report non-fatal adverse events—preventing the agency, women and girls, their doctors, and the public from having an accurate understanding of the complications from chemical abortion drugs and the rate at which they occur.

18. Women, girls and their parents cannot give informed consent to chemical abortions drugs without this necessary information. And doctors cannot

accurately apprise their patients about the dangers of chemical abortion drugs without adequate studies elucidating these risks.

19. The American College of Pediatricians is also harmed by the FDA's failure to require reporting of all adverse events because it prevents us as an organization from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

20. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and compromises our organization's purpose to provide professional healthcare and to educate doctors, their patients, and the public about the dangers of chemical abortion.

21. The American College of Pediatricians has challenged the FDA's continued deregulation of chemical abortion drugs. In 2019, we submitted a Citizen Petition with another pro-life group challenging FDA's 2016 major changes. It took considerable time, energy, and resources to assist in drafting the 26-page petition and compiling and analyzing supporting sources and studies. This effort caused the American College of Pediatricians to divert limited time, energy, and resources from its other priorities and routine functions.

22. The American College of Pediatricians continues to expend considerable time, energy, and resources on its public advocacy and educational activities

exposing the risk of harm to women, including pediatric girls, from the FDA's unlawful approval and deregulation of chemical abortion drugs.

Executed this November 11, 2022.

By: _____
Quentin L. Van Meter, M.D.

Exhibit 7

Declaration of Dr. Christina Francis

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. CHRISTINA FRANCIS

I, Christina Francis, a citizen of the United States of America and a resident of Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified Obstetrician and Gynecologist (OB/Gyn) in good standing and licensed to practice in Indiana. I have been in active practice for 14 years and have worked for the last six years as an OB/Gyn Hospitalist in Fort Wayne, Indiana.
3. As an OB/Gyn Hospitalist, my practice is completely hospital-based. I manage both high- and low-risk pregnancies and deliveries, obstetric critical care, gynecological emergencies presenting to our Emergency Department, and inpatient obstetric and gynecologic consultations.
4. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). I am also the CEO-elect of AAPLOG.
5. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.
6. AAPLOG is the largest organization of pro-life obstetricians and gynecologists ("OB/Gyns") in the world and is headquartered in Indiana.

AAPLOG includes OB/Gyns and other physicians, with more than 7,000 medical professionals nationwide and more than 300 members in Texas. AAPLOG members oppose elective abortion and are committed to the care and well-being of their patients including both pregnant women and their unborn children. AAPLOG members are concerned about the adverse impacts of chemical abortion on their practice of medicine.

7. AAPLOG's mission includes advocating on behalf of its members, including in litigation.

8. AAPLOG sues in this case on behalf of itself and its members.

9. I am familiar with the FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol.

10. I have seen first-hand the complications that can result from use of these dangerous chemical abortion drugs. Although Fort Wayne does not have an abortion facility, I have seen several women present with complications after seeking chemical abortions with mifepristone and misoprostol.

11. The frequency of these complications has increased since a federal district court first enjoined and set aside the FDA's in-person dispensing requirement for mifepristone in 2020.

12. As an example of how chemical abortion harms my patients and my medical practice, one of my patients had obtained mifepristone and misoprostol from a website, without an in-person visit. She was told that the drugs would come from India. After taking the chemical abortion drugs, she began having very

heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevated creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion. I spent several hours with her the day of her surgery/hospital admission, keeping me from my primary patient responsibilities in the labor and delivery unit and requiring me to call in an additional physician to help cover those responsibilities.

13. As an additional example, a partner of mine and I cared for another patient who also suffered complications from chemical abortion. I had taken care of her when she was hospitalized for hyperemesis gravidarum at 9 weeks 5 days gestation. She was discharged home in good condition after significant improvement with medications. During that hospital stay, she had an ultrasound, which showed a healthy pregnancy with no apparent complications and a strong fetal heart rate. During her hospitalization, she expressed to me that she was considering abortion because of experiencing hyperemesis but was unsure. Approximately one week after her discharge, the patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs. One of my partners was able to detect a fetal heartbeat. Due to the

amount of bleeding that she was experiencing and evidence of hemodynamic instability, however, my partner had no choice but to perform an emergency D&C. The patient needed to be hospitalized overnight for close observation after the D&C. Not only did my partner need to provide several hours of critical care for this patient, but my partner also needed to call in a back-up physician to care for another critically ill patient. And because the preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion.

14. As we see an increasing number of complications related to chemical abortions, it will place a greater strain on our healthcare system (especially in light of the fact that we are in the midst of a nationwide blood shortage and there are several healthcare deserts where there are no OB/Gyn's), and more physicians with ethical and medical objections to abortion will be forced to participate in completing unfinished elective chemical abortions in emergency situations, just as my partner was.

15. AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. Accordingly, AAPLOG and our members are harmed by the FDA's repeated removal of

necessary safeguards, which may force them to treat women and girls seeking the completion of an elective chemical abortion.

16. AAPLOG, its members, and their patients are also harmed by the FDA's actions that require prescribers to report only deaths and no other complications associated with chemical abortion. As a physician, I know that other complications have significant impacts on my patients as well as our healthcare system. Therefore, the FDA should require reporting of these complications too. But the system for reporting adverse events is not set up to be conducive for busy physicians to report these complications and takes a significant amount of time.

17. To report complications to the manufacturer, Danco, a form must be printed, filled out by hand, and then either mailed or scanned and emailed back. Much of the information required by this form is impossible to obtain by the physician seeing the patient if they were not the one who dispensed the chemical abortion drugs (such as lot number and dosage)—forcing me to leave several fields blank. I never received confirmation from Danco whether the complications I reported were recorded or reported to the FDA.

18. In addition to reporting to the manufacturer, the process of reporting to the FDA Adverse Event Reporting System (FAERS) is also cumbersome. The actual form to be filled out is not easy to find online—requiring several steps to get to it. It once took me two hours to get the website to accept submission of the form, taking me away from the care of my other patients. The

minimum amount of time I have spent reporting a mifepristone complication to the FAERS is thirty minutes—valuable time that should be spent in patient care.

19. The FDA's failure to require reporting of all adverse events, combined with its inadequate reporting system, prevents AAPLOG from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

20. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates AAPLOG's purpose to support women's health and to educate doctors, their patients, and the public about these dangers. It forces physicians to actually provide their patients with inaccurate information, leading to the lack of fully informed consent for women.

21. AAPLOG needs to divert limited time, energy, and resources to compensate for this lack of information by conducting our own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of AAPLOG, including our efforts regarding the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.

22. In 2002, AAPLOG submitted a Citizen Petition challenging the FDA's approval of Mifeprex and requesting an audit of the Mifeprex clinical studies.

AAPLOG, as an organization, is concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving Mifeprex put women's lives and health at risk. It took considerable time, energy, and resources to draft the 92-page petition and the 30-page response to comments letter, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

23. Later, in 2019, AAPLOG submitted another Citizen Petition challenging the FDA's 2016 major changes to the chemical abortion drug regimen. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

24. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, AAPLOG continues to expend considerable time, energy, and resources on its public advocacy and educational activities regarding chemical abortion drugs—to the detriment of other AAPLOG priorities and functions. This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs ceases.

Executed this November 11, 2022.

By: _____, MD
Christina Francis, M.D.

Exhibit 8

Declaration of Dr. Ingrid Skop

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. INGRID SKOP

I, Ingrid Skop, a citizen of the United States and a resident of San Antonio, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist working for OB Hospitalist Group with privileges in the Baptist Hospital System.
3. I also serve as a Senior Fellow and Director of Medical Affairs at the Charlotte Lozier Institute.
4. I am a member of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), where I served as a member of the board from 2018-2020. I am also a member of the Christian Medical & Dental Associations.
5. I received my medical degree from Washington University School of Medicine in 1992 and completed my residency in obstetrics and gynecology at the University of Texas Health Sciences Center at San Antonio in 1996.
6. My current practice involves delivering babies and performing surgeries in a hospital setting as an obstetric hospitalist. In my prior 25-year career in a large single-specialty OB/GYN practice, I also provided clinic-based obstetric and gynecologic care to women and girls.

7. I have provided written and oral expert testimony about chemical abortion to several state legislatures and to the United States Congress.

8. I have also published the peer-reviewed articles "Chemical Abortion: Risks Posed by Changes in Supervision" and "Medical Abortion: What Physicians Need to Know" in the Journal of American Physicians and Surgeons.

9. The articles I published reflect the research I have performed on the risks associated with unsupervised chemical abortion—a practice that is becoming more common.

10. A chemical abortion includes providing patients with a combination of two drugs. One drug—mifepristone—blocks hormonal support, killing the unborn child, while the other—misoprostol—induces uterine contractions to expel the unborn child and the pregnancy tissue.

11. The drugs mifepristone and misoprostol may cause serious complications for the women and girls who take them.

12. In my practice, I often treat patients who are admitted through the hospital's emergency department with complications from chemical abortions.

13. In my practice, I have cared for several dozen women in the emergency department who were totally unprepared for the pain and bleeding they experienced due to chemical abortion.

14. In my experience caring for women who have gone through chemical abortion, the doctors who prescribed or administered chemical abortion drugs

to these women often did not adequately prepare them for the drugs' effects, so these women could not have truly achieved informed consent.

15. At least a dozen patients have expressed significant emotional distress to me when they viewed the body of their unborn child in the toilet after the chemical abortion.

16. I have treated patients who have experienced trauma and emotional distress because of complications from chemical abortion. Those women were not anticipating that complications were possible and likely did not have sufficient informed consent to proceed with chemical abortion.

17. In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled.

18. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

19. Complications from chemical abortion are not uncommon. In fact, chemical abortions involve more complications than surgical abortions.

20. The FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion.

21. Given my experience, I expect to see and treat more patients presenting with complications from chemical abortion.

22. For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (*i.e.*, the doctors had to surgically finish the abortion with a suction aspiration procedure).

23. In my office, I treated one young woman who had been bleeding for six weeks after she took the chemical abortions drugs given to her by a doctor at a Planned Parenthood clinic. After two follow-ups at Planned Parenthood, during which she was given additional misoprostol but not offered surgical completion, she presented to me for help. I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication.

24. I have also cared for minor women below the age of 18 who have obtained chemical abortion drugs. Although mifepristone has not been studied specifically in minor women, the FDA has negligently allowed their provision to this special age group, assuming their response will be the same as adult women.

25. The FDA's actions deregulating mifepristone and expanding access to unsupervised chemical abortion harm women and their doctors, including me. Concerns about "unsafe, back-alley abortions" were used to overturn all

state abortion restrictions in 1973 and they are being recycled today to allow the abortion industry to continue perpetuating dangerous abortion methods. Yet, a clear-eyed look at the FDA's actions allowing unsupervised "mail-order abortions" shows that they are now promoting illegal, unsafe "chemical coat hangers" to the women they falsely say they want to protect.

26. The FDA's actions harm women, including my patients, because without proper oversight, chemical abortions can become even more dangerous than when they are supervised.

27. The FDA's actions harm women, including my patients, because clinics and physicians prescribing or dispensing chemical abortion drugs, or websites that provide these drugs through mail order delivery without any physician involvement, often underprepare women for the severity and risks of chemical abortion, and they often provide insufficient or no follow-up care to those women. Many women are inadequately prepared for the effects of the drugs, the severity of the pain and bleeding they will experience, the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type. These patients are being abandoned because in many cases there is no doctor-patient relationship, so they often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber.

28. Unsupervised chemical abortion—authorized by the FDA—harms women because they may have underestimated the gestational age of their unborn child. Women who should not be a candidate for chemical abortion because they are past the FDA-approved cutoff of ten weeks gestation may consume chemical abortion drugs, which will increase their chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care.

29. For example, approximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death. Failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes.

30. The FDA's removal of the reporting requirement for adverse events of mifepristone harms women by creating an inaccurate safety profile, and it harms my practice because it makes it more difficult to practice evidence-based medicine. The incidence of abortion-related complications remains unknown if there is no accurate system for data collection.

31. The FDA's actions also harm women because the lack of oversight will likely exacerbate human trafficking, which happens frequently in San Antonio. In

my practice, part of my care of my patients is ensuring that they are making medical decisions free of coercion. Many trafficked women experience unintended pregnancies and alert doctors serve as an important resource to intervene on behalf of women. Removing the in-person medical interaction removes an opportunity to identify and rescue these women. It also leaves them at risk of being coerced into an abortion they may not desire.

32. Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications. When I must perform surgery to deal with complications from chemical abortions, this takes attention away from my other patients. As a hospitalist, I am often supervising multiple laboring patients on labor and delivery. When I am called to the operating room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients.

33. Unsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care.

34. The FDA's expansion of chemical abortion also harms my conscience rights because it could force me to have to surgically finish an incomplete elective chemical abortion. I object to abortion because it ends a human life. My moral and ethical obligation to my patients is to promote human life and health.

But the FDA's actions may force me to end the life of a human being in the womb for no medical reason.

Executed this November 11, 2022.

By: Ingrid Skop
Ingrid Skop, MD

Exhibit 9

Declaration of Dr. Nancy Wozniak

IN IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. NANCY WOZNIAK

I, Nancy Wozniak, M.D., a citizen of the United States and a resident of Fishers, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am a board-certified obstetrician and gynecologist practicing in the greater Indianapolis area. My practice includes obstetrics at two Indianapolis-area hospitals.
3. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and serve as AAPLOG's Secretary. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.
4. I am familiar the approval of mifepristone and misoprostol as chemical abortion drugs by the U.S. Food and Drug Administration (FDA) and with the FDA's Risk Evaluation and Mitigation Strategy (REMS) for the use of mifepristone and misoprostol for chemical abortions.
5. A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

6. Under the REMS established by the FDA in 2016 for mifepristone and misoprostol, the agency eliminated (a) the in-person administration requirement, (b) mandatory post-abortion follow-ups, and (c) the requirement that prescribers report all adverse events except death.
7. In 2016, the FDA also expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks).
8. The FDA's actions harm patients and practitioners like me.
9. Mifepristone and misoprostol are dangerous drugs that can harm women. Without the appropriate supervision, women taking these drugs are at risk of serious complications and even death in the worst cases.
10. I believe the FDA's expansion of the approved timeframe for mifepristone and misoprostol use to 10 weeks of gestation harms women. An abortionist should never prescribe these drugs to any woman for an abortion after 8 weeks' gestation because I have seen so many women get into trouble with bleeding past that gestational age.
11. Few people die from chemical abortions because of the excellent care they receive from OBGYN doctors, but the infrequency of deaths conceals the danger that these drugs pose to women and girls—especially when administered without proper supervision.
12. In my experience, most of the complications related to the use of mifepristone and misoprostol for chemical abortions result in "near misses" due to the timely intervention of healthcare providers.

13. Recently many states like Indiana have enacted laws to regulate abortions more carefully. To circumvent those laws, abortion providers are relying on increased access to chemical abortion drugs through mail-order schemes or telemedicine.

14. The increasing number of chemical abortions through mail-order or telemedicine methods means that more women will suffer complications from unsupervised use of mifepristone and misoprostol.

15. The risk of complications from chemical abortions is four to seven times greater than from surgical abortions.

16. Currently, many women are now being prescribed mifepristone and misoprostol without a sonogram to verify the gestational age of the unborn child or to rule out ectopic pregnancies or other potential complications.

17. Women have the potential to present to the emergency department with torrential bleeding due to taking mifepristone and misoprostol for a chemical abortion without accurate dating and appropriate supervision. This places enormous stress and pressure on physicians and OB/Gyns who work in hospitals.

18. In my observation, incidents of women presenting to emergency departments with complaints of bleeding are becoming increasingly more common.

19. Due to the FDA's elimination of the adverse event reporting requirements, however, it is impossible to know how frequently women and doctors are facing these complications.

20. The FDA's elimination of the adverse event reporting requirements for non-fatal complications harms doctors' ability to practice evidence-based medicine and to provide their patients about the risks of chemical abortion and obtain their informed consent. Doctors are only as good as the information that they receive.

21. These physicians must treat women in emergency situations without an existing relationship with the patient, without a known gestational age, and without any known medications that the patient may have been prescribed. This dynamic also increases doctors' exposure to allegations of malpractice and potential liability.

22. The FDA's loosening of regulations related to chemical abortions harms hospitalists by putting them in higher-risk situations with less critical information about patients, which increases their exposure to allegations of malpractice and potential liability.

23. In the last six months, I had an experience treating a woman that illustrates how dangerous and damaging the FDA's actions are to women and practitioners.

24. One of my patients, who was about nine weeks pregnant, had previously been treated by hospital staff for a pulmonary embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given

mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse side effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die. The woman had a subsequent ultrasound, which showed that her unborn child was still alive. I advised the internists treating this patient to avoid administering certain medications that could harm the patient and her unborn child.

25. This experience that I had illustrates one of many "near misses" where women and girls face potentially deadly situations, but they are saved by intervention at a hospital's emergency department.

26. Under the FDA's current reporting requirements, this experience need not be reported as an adverse event. I attempted to report this event to the Indiana Department of Public Health, but my report was rejected because the State said it was not a "true" adverse event because the patient ultimately recovered.

27. In my experience with the patient I just described, I spent a significant amount of time that day working to save her life from unnecessary complications due to the irresponsible administration and use of mifepristone and misoprostol. As a result of the significant time that I devoted to that patient, my time and attention was taken away from my other patients, who also need my care.

28. I also know that many women who are suffering complications from chemical abortions tell their doctors that they are experiencing miscarriages. This phenomenon—regardless of why it occurs—means that doctors cannot be certain of what their patients have taken or are experiencing. The lack of information makes it extremely difficult to provide proper treatment to these patients. This inaccurate information also means that the true number of incidences of complications from chemical abortions are significantly underreported or not fully known.

29. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: _____
Nancy Goodwine-Wozniak, M.D.

Exhibit 10

Declaration of Dr. Steven A. Foley

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; **JANET WOODCOCK, M.D.**, in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration **PATRIZIA CAVAZZONI, M.D.**, in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**; and **XAVIER BECERRA,** in his official capacity as Secretary, U.S. Department of Health and Human Services,

Defendants.

Case No. _____

DECLARATION OF DR. STEVEN A. FOLEY

I, Steven A. Foley, a citizen of the United States and a resident of Carmel, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.
2. I am board-certified in obstetrics and gynecology. I practice in Angola, Indiana, and Evansville, Indiana.
3. As a hospitalist, I am associated with several hospitals and cover the emergency department for hospitals. As an OB/Gyn in a hospital setting, I have treated numerous women who have suffered complications from abortions.
4. I have practiced obstetrics and gynecology in Indiana and other states for many years.
5. I am a member of Plaintiff Christian Medical and Dental Associations.
6. During my time in Colorado, I was one of the only OB/Gyn doctors available to many patients. For example, during my time working in the plains of Colorado, it was 120 miles to the next OB/Gyn doctor.
7. I believe regulatory actions of the United States Food and Drug Administration (FDA) on chemical abortion will harm my practice and my patients.

8. Women suffer more complications from chemical abortions than surgical abortions.

9. The removal of the supervision requirements before administering chemical abortion drugs harms patients because it does not allow a doctor to establish gestational age, determine whether the woman has an ectopic pregnancy, or to check the Rhesus (Rh) levels of the patients. Giving women abortifacient drugs without these simple screening steps is simply against the standard of care and will cause more complications.

10. The FDA's actions will especially harm my practice in Indiana since the state's ban on abortions after 15 weeks took effect on September 15, 2022. This means more women will turn to chemical abortion drugs that they are able to obtain online and through the mail because they will seek to use these drugs to obtain surreptitious abortions after the gestational age limit. The increase in number of women taking chemical abortion drugs, especially later in gestational age, will lead to an increased demand in the emergency department.

11. Under the current practice by those who prescribe and dispense chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients. Instead, with no established relationship with a physician, patients are simply left to report to the emergency room when they experience adverse effects.

12. Many women are underinformed on the severity of the effects associated with chemical abortions, including the duration and severity of bleeding, the pain associated with the process, and the emotional trauma that they experience.

13. When chemical abortion drugs work as intended, a woman will effectively deliver her unborn child and the placental and any other pregnancy tissues.

14. Many women who report to the emergency department do not disclose that they have taken abortifacient drugs. In some instances, women will tell medical providers that they are suffering a miscarriage. The lack of information or misinformation received by doctors by their patients impacts the course of treatment and the care that doctors can provide.

15. Because abortionists do not adequately inform a woman or a girl about what happens during a chemical abortion and give these drugs to her to take outside of the abortion facility, I have needed to treat and care for many women who have presented to the emergency department with intense bleeding and other effects of the chemical abortion drugs—although not considered complications from the regimen.

16. I have also treated several women for abortion-pill reversal, where women seek to stop a chemical abortion from occurring after they have taken mifepristone. I prescribe the drug progesterone for these patients in an attempt to save their pregnancy. These women experience mental anguish

over the experience of having chosen chemical abortion, and some of them do not feel like they were properly advised as to what they were choosing.

17. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data.

Executed this November 13, 2022.

By: _____
Steven A. Foley, M.D.

Exhibit 11

Byron Calhoun, *The maternal mortality myth in the context of legalized abortion*, 80 The Linacre Quarterly 264 (2013)

The Linacre Quarterly 80 (3) 2013, 264–276

Systematic Review

The maternal mortality myth in the context of legalized abortion

Byron Calhoun

West Virginia University-Charleston, Charleston, WV, USA

It was quoted recently in the literature that "The risk of death associated with childbirth is approximately 14 times higher than with abortion." This statement is unsupported by the literature and there is no credible scientific basis to support it. A reasonable woman would find any discussion about the risk of dying from a procedure as material, i.e., important and significant. In order for the physician–patient informed consent dialogue to address this critical issue, the physician must rely upon objective and accurate information concerning abortion. There are numerous and complicated methodological factors that make a valid scientific assessment of abortion mortality extremely difficult. Among the many factors responsible are incomplete reporting, definitional incompatibilities, voluntary data collection, research bias, reliance upon estimations, political correctness, inaccurate and/or incomplete death certificate completion, incomparability with maternal mortality statistics, and failing to include other causes of death such as suicides. Given the importance of this disclosure about abortion mortality, the lack of credible and reliable scientific evidence supporting this representation requires substantial discussion.

Keywords: Maternal mortality, Childbirth, Elective abortion

Abortion Mortality: Mythology and Methodology

It was quoted recently in the literature that "The risk of death associated with childbirth is approximately 14 times higher than with abortion" (Raymond and Grimes 2012). This statement is unsupported by the literature and there is no credible scientific basis to support it.

A reasonable woman would find any discussion about the risk of dying from a procedure as material, i.e. important and significant. In order for the physician–patient informed consent dialogue to address this critical issue, the physician must rely upon objective and accurate information concerning abortion. There are numerous and complicated methodological factors that make a valid scientific assessment of abortion mortality extremely difficult. Among the many factors responsible are incomplete reporting, definitional incompatibilities, voluntary data collection, research bias, reliance upon estimations, political correctness, inaccurate and/or incomplete death certificate completion, incomparability with maternal mortality statistics, and failing to include other causes of death such as suicides.

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Given the importance of this disclosure about abortion mortality, the lack of credible and reliable scientific evidence supporting this representation requires substantial discussion.

Abortion data are unreliable

For any assessment of the health risks of abortion, it is necessary to obtain complete statistics on the incidence and prevalence of abortion as well as its mortality and morbidity in the USA. But, there is no federal reporting requirement and thus, only *estimates* are available (see, for example, Grimes 2006; Raymond and Grimes 2012). Only 26 states require providers to report abortion complications to the Centers for Disease Control (CDC) (Saul 1998; Guttmacher Institute 2009). States that do report incidence data are plagued by incomplete and inconsistent reporting, underreporting, and the lack of a national legal mandate to report.[1] Abortion data are simply not complete and those provided are merely *estimates* with huge variance, and are subject to considerable error. Current incidence *estimates* by the CDC exclude abortions in California, District of Columbia, New Hampshire, and New Jersey. The CDC data are unreliable because they base their *estimates* on voluntary submissions by state health departments, whose accuracy is widely acknowledged to be inconsistent and unreliable. "Many state health departments are able to obtain only incomplete data from abortion providers, and in some states, only 40–50 percent of abortions are reported" (Jones et al. 2008). Furthermore, CDC data regarding maternal mortality are collected by two different agencies using two different definitions and data sources: the National Vital Statistics System (NVSS) and the Pregnancy Mortality Surveillance System (PMSS). For the years 1995–1997, the NVSS reported 898 maternal deaths and the PMSS system reported 1,387 pregnancy related deaths. Therefore the total number of pregnancy related deaths for the time period was the 1,387 documented in the PMSS system. However, only 54 percent of pregnancy related deaths were reported in both systems (MacKay et al. 2005). This disparity in reporting demonstrates that even within the CDC, there is lack of comparability of data regarding pregnancy related deaths. It is from this inaccurate data that abortion mortality data is derived, and, as a result, the CDC has cautioned medical professionals to not make comparative statements based upon CDC data.

The only other institution which collects abortion data is the Guttmacher Institute (GI).

The abortion reporting by GI is based on voluntary submissions in their periodic polling of abortion providers who are simply asked to guesstimate the number of procedures performed, by trimester, proximity to provider, etc. The scientific validity and utility of this unconventional data gathering method is minimal since it does not capture all providers, who in turn are simply estimating annual data. It cannot be relied upon in identifying national incidence. Despite this, in this case, GI submitted a sworn affidavit that the only data they rely upon is that provided by the CDC, which is inherently unreliable. GI is a special affiliate of Planned Parenthood Federation of America, the largest single provider of abortions in this country. GI is an advocacy center whose expressed purpose is to broadly support abortion rights and to limit abortion regulation: "The Institute works to protect, expand and equalize access to information, services and rights that will enable women and men to…exercise the right to choose abortion…" (http://www.guttmacher.org/about/mission.html).

Because GI seeks to protect abortion rights, it would be disinclined to provide data which could interfere with unrestricted abortion. Also, in GI's periodic survey of abortion providers, physicians performing abortions face an obvious conflict of interest: disclosure of abortion complications may fuel state laws restricting access if GI publishes all data gathered. In short, GI data are not credible as it is incomplete and inherently biased. Even GI's own publications confirm this: "Without question, reputable published science should tell readers about potential conflicts of interest" (Sonfield 2005), which it obviously does not do.

There are other methodological problems with abortion data that make it largely unreliable:

(a) It is widely acknowledged that abortion is underreported in the U.S. with less than half of all abortions reported by women in face-to-face interviews (Jones and Kost 2007). The most likely effect of this systematic underreporting across studies is an overly favorable assessment of health risks due to abortion since women often do no report their abortion history (Jones and Kost 2007).
(b) There are no fetal death certificates issued when an abortion occurs. Abortions are often underreported by women and thus do not appear in their medical records. As a result, disease state or complications are not linked to abortion since it is largely not reported and thus, invisible in epidemiological research. When the patient's medical records are incomplete, any aggregated abortion mortality or morbidity reporting and analyses reflect this systematic bias.
(c) Most women do not return to the abortion clinic for follow-up care and assessment. Many abortion providers do not have after hours contact numbers or merely send patients with problems post-abortion to local emergency rooms to be seen by other healthcare providers. It has been estimated that more than two out of three women do not return for follow-up appointments at the abortion clinic (Picker Institute 1999).

Definitional issues regarding maternal mortality are problematic and not comparable

The numbers of women who die from abortion are largely unknown due to poor quality reporting and definitional issues. Abortion-related deaths are captured in some standardized definitions but not in others where they are undifferentiated from spontaneous abortions (Chang et al. 2003; Harrison 2009). The World Health Organization (WHO) has acknowledged: "…all existing estimates of maternal mortality are subject to greater or lesser degrees of uncertainty" (World Health Organization 2004). Because the data are so incomplete, the WHO has used seven different methods to estimate maternal death (World Health Organization 2004, 2007). Maternal mortality is difficult to measure precisely because routine recording of deaths tend not to be complete within civil registration systems. Even if such deaths were recorded, the woman's pregnancy status may not have been known and the death would therefore not have been reported as a maternal death even if the woman had been pregnant. Horon (2005) estimated that physicians completing death certificates after a maternal death fail to report that the woman was pregnant or had a recent pregnancy in 50 percent or more of the cases. In most developing-country settings where medical certification of cause of death does not exist, accurate attribution of female deaths as maternal death is difficult to impossible. Even in developed countries

where routine registration of deaths is in place, maternal deaths may be considerably underreported (World Health Organization 2007). Additionally, reliance upon death certificates in maternal mortality assessments has been shown to be considerably unreliable and underestimates abortion related mortality (Reardon et al. 2004a).

Abortion-related deaths are not easily or accurately identified. Among the definitions used to capture abortion mortality are:

- *Maternal deaths* are defined by the WHO as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes. Suicide, unintentional injuries, or homicide are not included as causes of death in this definition (Deneux-Tharaux et al. 2005). In WHO's International Classification of Diseases, coding criteria obfuscated deaths by requiring only complications be reported versus the treatment itself. According to the WHO (2004, 4) "all existing estimates of maternal mortality are subject to greater or lesser degrees of uncertainty."
- *Late maternal deaths* are defined as "the deaths of a woman from direct or indirect obstetric causes more than 42 days but less than one year after termination of pregnancy."
- *Pregnancy-related deaths*, including from direct and indirect obstetric causes, are defined as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death." *Direct obstetric deaths*: "those resulting from obstetric complications of the pregnant state (pregnancy, labor, and puerperium), from interventions, omissions, incorrect treatment, or from a chain of events resulting from any of the above." *Indirect obstetric deaths*: "…those resulting from previous existing disease or disease that developed during pregnancy and which was not due to direct obstetric causes, but which was aggravated by physiologic effects of pregnancy" (Hoyert 2007). In the U.S. Abortion Mortality Surveillance System, Elam-Evans et al. (2003) concluded that existing methods and systems for capturing abortion related deaths are inadequate and underreported.
- *Pregnancy-associated deaths*, developed by the Centers for Disease Control and Prevention, and with the Maternal Mortality Special Interest Group of the American College of Obstetricians and Gynecologists, define a death from any cause during pregnancy or within 1 calendar year of delivery or pregnancy termination, regardless of the duration or anatomical site of the pregnancy (Wilcox and Marks 1995). Pregnancy-associated deaths include not only deaths commonly associated with pregnancy such as hemorrhage, pregnancy-induced hypertension, and embolism—which are captured in the WHO definition—but also deaths not traditionally considered to be related to pregnancy such as accidents, homicide, and suicide. Pregnancy associated death also includes deaths occurring 43–365 days following termination of pregnancy. Because cause-of-death information on death certificates cannot identify deaths from non-maternal causes or deaths occurring 43 or more days following termination of pregnancy as associated with pregnancy, additional sources of data must be used for complete assessment of all pregnancy-associated deaths (Horon and Cheng 2001). Even with pregnancy-associated deaths there is considerable differentiation between states as to case definition and comparability to

CDC estimates of pregnancy associated maternal mortality ratios (Mascola et al. 2004; Horon 2005).

Yet another way of examining abortion related mortality is calculating a national case-fatality rate: the number of known legal induced abortion-related deaths per 100,000 reported legal induced abortions. This would assume that all abortion deaths are identified from direct and indirect causes, as well as immediate and delayed causes up to 1 year after termination of pregnancy. Even if this were possible, which it is not at this time, this rate could not be calculated because a substantial number of abortions occur in non-reporting states. Thus, the denominator (total number of abortions in the United States) is unknown.

The above definitions indicate that there are only two criteria used in indentifying maternal deaths: (1) medical causes of death and (2) timing of pregnancy-related death. By excluding all other categories that are not due to physical complications, other deaths are simply not captured, including suicide and other indirect deaths which result from physical, psychological, interpersonal, or behavioral problems linked to abortion as the marker event. Causes of deaths resulting directly from abortion are identified. However, abortion may also worsen or initiate physical, psychological, interpersonal, and maladaptive behavioral pathways which can lead to diminished mental or physical health and eventuate in death. These cumulative risk factors which can substantially contribute to abortion mortality are identified. Research by Gissler et al. (2005), Reardon et al. (2004a), Christiansen et al. (2006), and Kavanaugh et al. (2009) support such a broadened assessment of pregnancy associated deaths. The impact of substance abuse, depression, anxiety, and suicide resulting from abortion is considerable. As a result, indirect abortion-associated deaths are likely to be many times higher than those deaths directly caused by obstetric complications.

Measurement issues of maternal mortality are problematic

The computation of maternal mortality is most commonly a ratio of the number of maternal deaths during a given period per 100,000 live births during the same period. But other measures are also in use: maternal mortality rate (number of maternal deaths in a given period per 100,000 women of reproductive age during the same time period) and lifetime risk of maternal death (risk of death once a woman has become pregnant). The difficulty and complexity of measuring maternal mortality are evident in the following areas:

(a) There are gross difficulties inherent in measuring maternal mortality and definitions regarding precisely what constitutes a death due to pregnancy/birth are evolving.
(b) There is a lack of consensus regarding how long after pregnancy resolution a death is appropriately linked with the pregnancy.
(c) The two national sources of abortion statistics (CDC and the Guttmacher Institute) are plagued by significant levels of underreporting. Further, discrepancies exist between the two national sources, a minimum 12 percent discrepancy was reported (Strauss et al. 2007).
(d) For various reasons (incomplete medical records, lack of fetal death records), deaths due to abortion are often not recorded as resulting from the procedure, with only the immediate cause of death (e.g., embolism, sepsis, and hemorrhage) provided.

(e) Women, who experience serious, life-threatening health complications as a result of abortion usually go to a hospital emergency room and are not seen by their abortion providers. Their deaths will therefore not be counted.

(f) Abortion-related deaths (from physical complications of the procedure) are reported as maternal deaths.

(g) The death statistics tabulated for abortion focus on "uncomplicated abortion"; whereas the statistics for childbirth incorporate complicated delivery (e.g., caesarian delivery). If "uncomplicated delivery" is compared to "uncomplicated abortion," the risk of dying from abortion is twice as high. Maternal mortality caused by abortion is *twice* as high compared to women with vaginal deliveries, when caesarean deliveries are excluded (Lanska et al. 1983). Further, analyses do not control for co-morbidities in relation to abortion and pregnancy.

(h) The available statistics do not address long-term and less direct causes of death associated with abortion and childbirth. Over time the risk of death associated with abortion increases due to enhanced likelihood of substance abuse, cancer, future pregnancy complications, and suicide ideation, whereas with the risk of dying from these causes are lessened dramatically after completion of a term pregnancy without abortion.

The contemporary definition of pregnancy-related deaths that restricts inclusion of a maternal death to within 42 days of delivery is likely to capture the majority of deaths associated with a full-term pregnancy (see Figure 1 adopted from Chang et al. 2003). However, many of the most serious health risks associated with abortion noted above are more insidious and occur over a much less compressed time period.

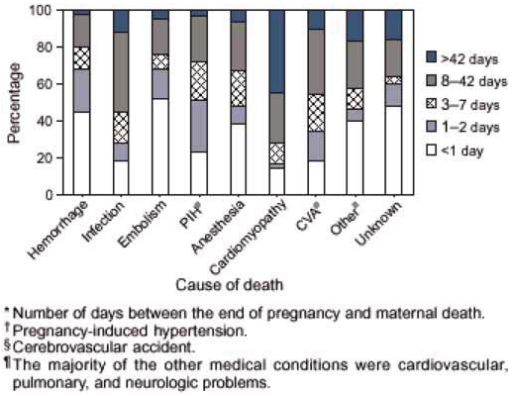

Figure 1. *Distribution of pregnancy-related deaths, by cause of death and time interval—United States, 1991–1999.*

National data compare deaths associated with term pregnancies to deaths associated with abortion at any point in pregnancy. This is a flawed technique that has produced an over-estimation of maternal mortality and an under-estimation of abortion mortality. The two central issues are detailed below:

(a) Maternal mortality is determined by dividing maternal deaths by live births as opposed to pregnancies. Deaths due to ectopic pregnancies (the leading cause of death in the first trimester), molar pregnancies, miscarriage, and stillbirth are represented in the numerator, but not in the denominator. According to the CDC only 60 percent of pregnancy-related deaths occur in conjunction with a live birth. This means that 40 percent of the deaths are never represented in the denominator, resulting in a dramatically over-inflated maternal mortality rate. Moreover, the majority of women who survive ectopic pregnancies, molar pregnancies, miscarriage, and stillbirth will not be in the data at all since their pregnancies do not result in live births.

(b) Maternal mortality and abortion mortality statistics are not analogous because maternal mortality statistics do not take into consideration the stage of gestation, whereas abortion mortality statistics are predominantly based on first trimester losses. Appropriate comparisons would be prospective in nature with same gestational point comparisons related to the risk of death associated with the two reproductive outcomes. Existing statistics compare maternal deaths at any point in pregnancy and the post-partum period to abortion deaths, which primarily occur in the second and third months of pregnancy since most abortions are in the first trimester. Bartlett et al. (2004) examined national U.S. data from 1988 to 1997 and found: the relative risk of abortion-related mortality increased dramatically with gestational age of the procedure increasing from 14.7/100,000 procedures at 13–15 weeks gestation, to 29.5/100,000 procedures at 16–20 weeks gestation, and to an astounding 76.6/100,000 procedures at/or after 21 weeks gestation.

Comparisons conducted with no regard for the gestational stage in which the death occurs are flawed for several reasons:

(a) Deaths occurring during the first 6 weeks of pregnancy (when maternal morbidity and mortality are highest) are classified as maternal deaths and are lumped together with deaths associated with birth and delivery. This is inappropriate in that the intended outcome of these early pregnancies is unknown.
(b) Women who reach the common point of awareness that they are pregnant and make the decision to abort (2 weeks late on the menstrual period or 6 weeks pregnant) have already survived beyond the period of the pregnancy's greatest risk.
(c) Abortions do not typically occur very early and are impossible beyond 9 months of gestation when most maternal deaths comprising the maternal mortality statistics occur. Therefore, valid gestational period comparisons can only logically be made in the latter half of the first trimester through the end of the third trimester. During the second and third trimesters, abortion-related mortality is equal to and then exceeds that of childbirth (Bartlett et al. 2004).

Gestational period comparisons would only be valid with sophisticated controls for a variety of socio-demographic factors (age, income, education, marital status) based on sound evidence that women belonging to particular socio-demographic groups (e.g., very young and older women) are more at risk for adverse pregnancy events occurring during pregnancy and the post-partum period.

As indicated earlier in this report, maternal mortality and morbidity are largely based on incomplete data and estimates. In the case of WHO and maternal mortality, definitional issues together with rampant statistical manipulation generate even more inaccurate estimates. In an attempt to identify abortion-related mortality, WHO researchers advocated combining the incidence of spontaneous and induced abortion together, and then correcting for the incidence of spontaneous abortion. According to Harrison (2009), one of the WHO researchers acknowledged: "We make huge adjustments to make the numbers turn out right. More than fifty percent of some numbers are 'adjusted'" (Harrison 2009, 4).

There are powerful financial, socio-political, and interpersonal forces potentially

driving the concealment of abortion-related deaths. The same facilities that report the data run the risk of being more closely scrutinized or even closed if there are deaths at their facilities. Deaths associated with abortion are likely to become highly publicized and could result in legal restrictions. Finally, abortion-related deaths may be concealed, because the family is unaware there was a termination or if the family is privy to the information there is likely to be a strong motivation to hide it in order to protect the family from further grief or shame.

Abortion Mortality Compared to Childbirth: Rresearch Evidence

According to Kaunitz (1985), induced abortion is the fifth leading cause of maternal mortality in the U.S. Even so, this finding is likely to be an underestimation as most abortion-related deaths are either not reported, or not captured in the existing definitions and national data collection from state health departments. Other deaths resulting from abortion remain excluded: suicide, avoidable deaths due to injuries, accidents, substance abuse, and cumulative and contributory disease states.

A number of factors enter into the relative risks of dying from abortion compared to childbirth, in addition to the methodological issues identified above. These include patient age, operator skill and experience, race, gestational age, type of procedure employed, pre-existing physical and mental health, etc.

In a growing body of literature, childbirth is protective against death from non-obstetric causes, including breast cancer and suicide in both the immediate and long term (Gissler et al. 1996, 2005; Marzuk et al. 1997; Thorp et al. 2003; Carroll 2007). In a large, health record-linked U.S. study spanning 8 years, women who aborted compared to those who delivered, were 62 percent more likely to die from any cause. Suicide carried a 154 percent increased risk (Reardon et al. 2002). In Finland, using a comprehensive health data linkage system, Gissler et al. (1997) examined death rates up to 1 year after abortion and found a 4 times higher risk among women who aborted versus those who carried to term. Similar adverse findings were reported in subsequent studies: mortality was lower after a birth (28.2/100,000) than after an induced abortion (83.1/100,000)—a 3 times higher mortality risk for abortion compared to childbirth (Gissler et al. 2004b); abortion was associated with a 6 times higher risk for suicide compared to birth (Gissler et al. 2005). Without such record-linkage, 73 percent of all pregnancy-associated deaths would have been missed if they were based only upon death certificates. The percentage of deaths due to abortion would have been even higher (Gissler et al. 2004a). In the U.K., Morgan et al. (1997) reported a similar increased risk of suicide for women electing abortion versus delivery: 8.1 suicide attempts per thousand among those who had abortions compared to only 1.9 suicide attempts per thousand among those who had given birth. Both Hoyer and Lund (1993) and Appleby (1991) found childbirth overall to be risk protective against suicide.

Most striking are the findings by Gissler et al. (2005) that the age group from 15 to 24 years is significantly prone to suicide in the context of an abortion with an increase of almost 50 percent in the suicide rate compared to non-pregnant women (Christiansen et al. 2006). For U.S. women aged 15–19 years, suicide is the third leading cause of death corresponding to 7.5 percent of deaths.

According to Chang et al. (2003), the literature commonly reports three main causes of abortion-related death: infection

(33.9%), hemorrhage (21.8%), and embolism (13.9%); additional abortion-related causes of death include ectopic pregnancy, perforation or rupture of the uterus, and anesthesia complications among others. Hemorrhage and infection deaths from abortion are nearly 8 times and 9 times greater when compared to the percentage of maternal deaths attributed to these causes in live-birth.

Gissler et al. (2004a) compared the pregnancy-associated mortality ratio for the different pregnancy outcomes (live births and stillbirths, spontaneous abortions and ectopic pregnancies, and induced abortions) for all childbearing Finnish women. They reported: "The pregnancy associated mortality ratio per 100,000 pregnancies increased only slightly for live births and stillbirths, but became sevenfold for spontaneous abortions and ectopic pregnancies, and 5.5-fold for induced abortions. The outcome-specific denominator also revealed that the crude risk of a pregnancy-associated death was more than twice as high after a spontaneous abortion or an ectopic pregnancy and more than three times as high after an induced abortion than after a live birth or stillbirth" (Gissler et al. 2004a, 453). Pregnancy-associated deaths have usually been calculated using the number of live births as the denominator. Gissler et al. (2004a) demonstrated that calculating pregnancy-associated deaths per 100,000 pregnancies with a specific pregnancy outcome gives a very different and improved picture (Gissler et al. 2004a).

Reardon et al. (2004b) estimated that there were between 2,132 and 7,036 excess deaths per year among women who abort and 766 to 4,021 deaths due to violent causes. These researchers further reported that abortion-related increases in smoking are likely to result in 3,740 more lung cancer deaths in the lifetimes of the 1.4 million women who abort each year in the U.S. (Reardon et al. 2004b). Available evidence points to numerous unexamined pathways where abortion can increase a woman's chance of dying from either direct and immediate complications or after prolonged exposure to adverse disease and dysfunctional coping in the future.

The true number of deaths related to pregnancy might increase from 30 to 150 percent with active surveillance (Chang et al. 2003; Deneux-Tharaux et al. 2005). Until more robust research is undertaken accounting for multiple confounders in national prospective studies, statements about abortion being many times safer than childbirth are unreliable and false. Existing research does not support this allegedly factual assertion. A reasonable patient would want to be informed of the risks of death related to abortion *from all causes*.

Abortion Mortality: Most Recent Research Evidence

In a carefully done study using 42 years of United Kingdom National Health data comparing England, Wales, and Scotland with Northern Ireland and parallel national data from the Republic of Ireland found that countries with legal abortion actually had a higher maternal mortality rate per 100,000 live births (Ireland's Gain 2011). In fact, Carroll's maternal mortality rates of 8/100,000 and 10/100,000 live births in England, Wales, and Scotland are eerily familiar to the maternal mortality rate of 8.8/100,000 quoted for the U.S. in Raymond and Grimes (2012). The Raymond and Grimes (2012) mortality rate of 0.6/100,000 for abortion is simply not supported by good data (i.e., real data from a national database not estimates) and the present literature. In fact such assertions about abortion mortality seem

to represent a biased misuse of statistics and maternal mortality calculations.

Koch et al. (2012a, b) demonstrated in their study of Mexico and abortion the problem of significant overestimation of maternal mortality when not utilizing actual data from a national database (Coleman et al. 2012). Koch et al. (2012a, b) accessed the national database to compare the Federal District of Mexico (Mexico City) with the remainder of Mexico and found a *10-fold* overestimation of abortion mortality in the Federal District of Mexico. Previously, maternal mortality in Mexico had been thought to be linked to lack of access to legal abortion. However, maternal deaths fell 30 percent in Mexico in spite of the lack of access to legal abortion. Koch et al. (2012a, b) noted that abortion legalization in the Federal District of Mexico did nothing to lower maternal mortality in the Federal District of Mexico City. In fact, the maternal mortality ratio of maternal deaths compared to abortion deaths per 100,000 live-births decreased from 1.48 to 1.14 in Mexico during the interval from 2007 to 2012 (Koch et al. 2012a, b). Koch's conclusion was that maternal health in Mexico would be better served with better access to emergency and specialized obstetrical care not abortion (Koch et al. 2012a, b).

Coleman et al. (2012) review mortality rates in Denmark's linked data base for the 25-year interval from 1962 to 1993, which included over 1 million women with complete reproductive outcomes including abortions, live births, and spontaneous miscarriages. They found that the risk of death was 6 times greater among women who had never been pregnant compared to women who delivered. There was increased risk of death was 45, 114, and 191 percent for 1, 2, and 3 abortions, respectively, compared to women who had ever given birth during the same time period (Coleman et al. 2012). Maternal death rates compared to abortions were reduced by 108 percent for 2 births and reduced by 63 percent for 3 or more births (Coleman et al. 2012). This significant study with linked, database data overturns previous assertions based on limited and incomplete data demonstrating increased death rates with abortion compared to live births. Further, it shows the dose-related effects of multiple abortions on increasing maternal death rates compared to giving birth.

Abortion laws have been liberalized in countries where there have been large numbers of deaths attributable to clandestine abortions. Those who favor liberalizing abortion laws assume that the health of women is better served by providing abortion. Koch et al. (2012a, b) challenged this assertion recently in their paper covering 50 years of maternal deaths in Chile. Koch et al. (2012a, b) found by utilizing national birth registry statistics over two separate epochs: one with legal abortion covering 1957–1988 and one with prohibition of abortion covering 1989–2007. They found by careful analysis that the legal status of abortion had no relationship to the reduction in maternal mortality. Rather, the reduction in maternal deaths during pregnancy was related to the better education and obstetrical care for women available in the different time periods (Koch et al. 2012a, b).

Certainly critically important issue of maternal mortality in women's health requires the use of accurate data that is only available with the collection of data at a national level in a comprehensive national health database that includes all of women's reproductive outcomes linked to abortion and all other health variables. Such a database must also provide open access to all researchers to evaluate this critical women's health issue. We urge the

establishment and financial support of a national healthcare database for the United States with the inclusion of *all* reproductive outcome variables and associations: including elective abortions.

Endnote

1. See, for example, the Guttmacher Institute's critique of CDC incidence data: "The estimates presented in this report are subject to some limitations and should be considered provisional. First, not all states are included; the estimates assume that changes in abortion incidence in the excluded states are similar to the overall trend seen in the reporting states. Second, the completeness of abortion reporting to state health departments can vary from year to year. We attempted to exclude all states that had inconsistent reporting, but if (for example) reporting improved in some states we included, it would mean that earlier state reports were too low and that the percentage decline we calculated was too small. In such cases, our new estimates of the number of abortions would be too high" (Finer and Henshaw 2006, 3).

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Exhibit 12

The FDA and RU-486: Lowering the Standard for Women's Health: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong. 4 (2006)

UNITED STATES HOUSE OF REPRESENTATIVES
GOVERNMENT REFORM COMMITTEE

OCTOBER 2006

THE FDA AND RU-486: LOWERING THE STANDARD FOR WOMEN'S HEALTH

STAFF REPORT

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I. EXECUTIVE SUMMARY

This report explores the Food and Drug Administration's activities as they relate to RU-486 – the abortion pill – including the highly unusual process by which the drug was approved, the failures to ensure that the drug is dispensed as the Food and Drug Administration (FDA) requires, the subsequent illnesses, hospitalizations and deaths known to be associated with the drug and the failure to provide any meaningful restrictions despite evidence of its association with a 100% fatal septic infection.

On May 17, 2006, Congressman Mark Souder, Chairman of the Subcommittee on Criminal Justice, Drug Policy and Human Resources ("Subcommittee"), House Committee on Government Reform, convened a hearing to inquire into the safety of the FDA-approved drug Mifeprex (the trade name for mifepristone) commonly known as RU-486. The hearing was entitled, "RU-486 - Demonstrating a Low Standard for Women's Health?" The Subcommittee's hearing followed several months of investigative inquiries with the FDA after the Agency's July 2005 disclosure that four women had died of a septic infection after taking RU-486 to induce an abortion.[1]

This Subcommittee Staff Report ("Report") provides background information about RU-486, including the reasons the drug was brought to market. It also explores the allegation that FDA disregarded various statutes and rules in the RU-486 approval process, and it examines RU-486's safety record in the United States. The accumulation of safety data from "real world" use of the drug in America has allowed Subcommittee investigators to more completely grasp FDA's understanding of the risks posed by RU-486 when it approved the drug on September 28, 2000.

Based on the significant demonstrated danger this drug poses to women, the Report examines options for withdrawing this drug from the market.

II. BACKGROUND

RU-486 is the common name for mifepristone, which in the United States is marketed under the trade name Mifeprex. Shanghai HuaLian Pharmaceutical Co., Ltd.[2] of China produces the drug, which is imported and distributed by Danco Laboratories, [3] a corporate entity located in the Caribbean nation of the Cayman Islands. RU-486, Danco's sole product, [4] is approved for the

[1] FDA Public Health Advisory: Sepsis and Medical Abortion, July 19, 2005. Available at http://www.fda.gov/cder/drug/advisory/mifeprex.htm (last visited October 14, 2006).

[2] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Senator Jim DeMint (August 11, 2006) (on file with Subcommittee).

[3] *See, Foes criticize Chinese manufacture of abortion pill for U.S.*, CNN.com, (Oct. 13, 2000) at http://archives.cnn.com/2000/HEALTH/women/10/13/abortionpill.plant.ap/index.html (last visited October 10, 2006).

[4] Unlike other drug companies with multiple products that are approved by or in application before the FDA--and which therefore cooperate with the FDA to withdraw drug products when recognizable problems arise--Danco has

termination of an established pregnancy through 49 days development (LMP),[5] when used in conjunction with the prostaglandin, misoprostol.[6]

RU-486 terminates pregnancy by blocking progesterone receptors in the uterus, a hormone necessary for the maintenance of pregnancy.[7] This leads to degeneration of the uterine lining, blocking nutrition to the prenate, thus resulting in its death.[8] Mifeprex is used in combination with a prostaglandin called misoprostol, which causes contractions that expel the contents of the uterus.[9] This is an off-label use for misoprostol, which contains an FDA-mandated black-box warning against using the drug during pregnancy.[10]

Under the protocol approved by the FDA – one considerably less stringent than the agency's proposed protocol leaked to the public a few months prior to approval – if the patient is

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no other products for which it must be answerable to the FDA. *See also,* Rogoff, Natasha L, *Haven or Havoc?*, PBS Frontline, February 19, 2004 at http://www.pbs.org/wgbh/pages/frontline/shows/tax/schemes/cayman.html.

[5] FDA Approval Memo (September 28, 2000); "LMP" refers to the first day of the last menstrual period, and is the customary measure of gestational age, from approximately 14 days pre-fertilization of the conceptus.

[6] The FDA examined misoprostol to see if the deadly *Clostridium Sordellii* bacteria that killed four California women after taking RU-486 was associated with misoprostol, rather than the Mifeprex: "An FDA Public Health Advisory in mifepristone dated July 22, 2005 reported 4 cases of septic death in California following the use of mifepristone and intravaginal misoprostol for medical abortion. For this reason, DRUP [Division of Reproductive and Urologic Products] and DDRE [Division of Drug Risk Evaluation] met on July 19, 2005, to discuss searches of the AWRS database to further investigate this cluster of repo0rts. At this meeting, DDRE agreed to provide 3 consults to examine this issue… The proposed consults were as follows:

- Consult #1: Review of all reports of serious infections with misoprostol in women of childbearing age
- Consult #2: Review of all reports for suspected intravaginal products with a fatal outcome
- Consult #3: Review of all serious, unusual infections with intravaginal products."

"This review did not identify any new safety signal associated with intravaginal product administration, especially in regards to infection or pregnancy status." FDA Office of Drug Safety Postmarketing Safety Review, December 8, 2005 (on file with the Subcommittee).

The FDA also tested the manufacturing lots from which the misoprostol was distributed and eliminated that drug product as a source of contamination that would have caused the fatal *C. Sordellii* infections. *See* Marc Fischer, M.D., M.P.H., CDC, *Clostridium sordelli Toxic Shock Syndrome Following Medical Abortion*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/fisher.pdf (last visited October 20, 2006).

[7] See., e.g., University of Chicago Department of Obstetrics and Gynecology, Information on Hormonal Imbalance, available at http://babies.bsd.uchicago.edu/endo/hormoneImbalance.htm (last visited October 10, 2006).

[8] Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989).

[9] Pfizer (along with their generic subsidiary) and Teva Pharmaceuticals, the makers of misoprostol, have never filed a New Drug Application to seek approval from the FDA for its use in abortion. It was approved for use with ulcers, and is contraindicated for pregnancy. Pfizer's German affiliate recently pulled the drug from the market.

[10] Cytotec (misoprostol) Full Revised Label, April 17, 2002, available at www.fda.gov/cder/foi/label/2002/19268slr037.pdf (last visited October 10, 2006).

found to be a candidate for a chemical abortion (according to criteria such as gestational age of 49 days or less, absence of ectopic pregnancy and a host of health contraindications), she is given 600 mg of Mifeprex to consume at once and instructed to return two days later to consume orally 400 mcg of misoprostol. Patients are further instructed to return in 14 days for a follow-up, which could include a surgical abortion in the three percent to 7.9% of cases in which the chemical abortion fails.[11]

Many providers, however, deviate from the FDA protocol, extending the RU-486 abortion cut-off to 56 and even 63 days' gestation,[12] cutting the dose of Mifeprex by two-thirds, and handing the patient misoprostol pills to insert vaginally at home two days later.[13] Failure rates at these gestational ages are approximately 17% and 23% respectively.

In the decade preceding FDA approval of RU-486 for use in the United States, advocates of RU-486 promoted the drug as a private, easy, safe and effective method of pregnancy termination,[14] offering women the choice of ending pregnancy at an earlier stage and in a less "invasive," instrumented manner, when compared to surgical and suction abortion methods.[15] In sum, the public was told that access to RU-486 had everything to do with women's privacy and choices.

Cited as justification for RU-486 approval and use were the following goals: "defusing the abortion conflict,"[16] putting abortion "into the medical mainstream and out of this ghettoized place it's been in,"[17] making "abortion … more socially acceptable,"[18] "expanding the number

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[11] See Mifeprex Label ("Medical abortion failures should be managed with surgical termination." Also, "Each patient must understand…that medical abortion treatment failures are managed by surgical termination.") at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited October 10, 2006).

[12] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

[13] Evidence of this method deviation can be found in many Adverse Event Reports, including those reporting on the deaths of four California women from toxic shock related to *C. Sordellii*.

[14] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26.

[15] Planned Parenthood of New York City Press Release, December 4, 2000: "Women will now have access to this option of a very safe, early abortion without undergoing an invasive procedure. … By allowing women to take part in their own care, mifepristone offers women more privacy in their decisions and control over their bodies."

[16] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[17] *Ibid*, quoting Carole Joffe, professor of sociology, University of California-Davis.

[18] *Ibid*.

of abortion providers"[19] and even advancing the U.S. aim of "population control"[20] in the developing world. One vocal advocate explained: "Abortion in the U.S. is this degraded, shameful, violence-surrounded thing. …It's not like that in Europe. So that makes our context for medical [e.g., RU-486] abortion unique."[21] Safety and efficacy questions were brushed aside with assurances that several hundred thousand women in France and China had already used RU-486 to induce abortion.[22]

One might reasonably wonder why, when the surgical option is readily available and exponentially safer,[23] the FDA would approve, or the abortion industry would support, a chemical procedure that subjects women to increased pain and risk. To answer this question, it is helpful to understand abortion industry fears concerning the dwindling number of providers, and to assess the industry's leverage and access within the FDA.

The National Abortion Federation reported in May 2004 that the "number of abortion providers has declined by 37% since 1982."[24] In 1997, 36% of ob/gyns reported ever performing elective abortions.[25] Among them, 57% were fifty years of age or older and another 30% were 40 or older.[26] In other words, the abortion industry perceived that—unless drastic measures were taken—it was in danger of losing nearly 57% of its doctors by 2012 and 87% of its doctors by 2022, significantly reducing the availability of abortion in the United States.[27]

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[19] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Seattle abortion provider Suzanne Poppema, M.D.

[20] Nathanson, Bernard, "Drugs for the Production of Abortion: A Review," Obstet & Gyn Survey 25:8; 727-731 (1970); Renate Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 59: "It is a further misconception to believe that this [RU-486] research took place in order to expand or improve women's 'choices' to control their reproduction. Quite unmistakenly, the concept evolved as a means of population control. More than 20 years ago, the Center of Population Research of the U.S. National Institutes of Health became interested in the corpus luteum and called for research to determine whether to find 'means to inhibit corpus luteum function is a desirable goal'. The specific intention of such research was to restrict population growth in countries that were judged to be 'under-developed.' If successful, the method(s) could be extended to groups in the United States, Black, Hispanic and Native American Women (Department of Health, Education and Welfare, NIH, USA, 1969)."

[21] Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Carole Joffe, professor of sociology, University of California-Davis.

[22] Lawrence Lader. A Private Matter: RU-486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 115-117.

[23] The Alan Guttmacher Institute, an affiliate of Planned Parenthood, reports that the mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. *See*, Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318.

[24] Abortion Access Project, Fact Sheet: The Shortage of Abortion Providers, May 6, 2004, available at www.abortionaccess.org/AAP/publica_resources/fact_sheets/shortage_provider.htm (last visited October 10, 2006).

[25] Kaiser Family Foundation, *Abortion*, Issue update, Menlo Park, CA: Kaiser Family Foundation, May 1999.

[26] *Ibid.*

[27] Lawrence B. Finer and Stanley K. Henshaw, "Abortion Incidence and Services In the United States in 2000," Perspectives on Sexual and Reproductive Health, 2003, 35(1):6-15.

The industry, then, out of concern for its own preservation, pinned its hopes on chemical abortion. A Kaiser Family Foundation survey, for example, noted: "Many reproductive health groups in the U.S. have looked to widespread availability and marketing of mifepristone … to expand access to abortion in this country."[28] Pediatrician Eric Schaff, who oversaw at least one RU-486 trial, put the matter somewhat more crudely. Objecting to an FDA proposal (never formally adopted) that any doctor dispensing RU-486 would have to be trained in surgical abortion, Dr. Schaff explained, "The whole idea of [RU-486] was to increase access. … [The FDA proposal] kills the drug if it can't be used by primary care providers."[29]

Despite the problems associated with RU-486 (discussed in depth in Section III, below), it looked like a panacea for the abortion industry. Advocates predicted that the number of providers would increase. The Kaiser Family Foundation stated that one-third of all ob/gyns who did not perform abortions said they would be "very" or "somewhat" likely to prescribe mifepristone for abortions if approved by the FDA.[30] Furthermore, rather than limiting abortion procedures to medical doctors alone, advocates saw an opportunity for nurse practitioners, nurses, and others to administer abortions to women.[31]

In June 1989, one year after its introduction into the French market, the FDA issued an import alert on RU-486. The concern was that women would obtain the drug themselves and use it without support from a physician. The wisdom of this policy is supported by the fact that, as the RU-486 label states, nearly *all* users of RU-486 will experience adverse events.[32] But it wasn't long before Democrats, led by then-Representative Ron Wyden of Oregon, seized this opportunity to politicize the approval process.

Under the auspices of the Committee on Small Business's Subcommittee on Regulation, Business Opportunities and Energy, as early as September 18, 1990, Representative Wyden was investigating the FDA's import alert on RU-486, alleging that the FDA's overriding concerns for the alert were political, rather than medical, and that the actions of the FDA were preventing cures for several diseases, including breast and brain cancer, Cushing's disease, glaucoma and

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[28] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[29] Sheryl Gay Stolberg, "F.D.A. Adds Hurdles in Approval of Abortion Pill," *New York Times*, June 8, 2000.

[30] Kaiser Family Foundation, News Release, June 8, 2000, available at www.kff.org/womenshealth/20000613a-PressRelease2.cfm (last visited October 10, 2006).

[31] Press release, Ibis Reproductive Health, the National Abortion Federation, and the Abortion Access Project, May 9, 2006, available at www.prochoice.org/news/releases/20060509.html (last visited October 10, 2006).

[32] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006): "Nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction."

diabetes. Two hearings in his committee followed, one in November of 1990[33] and another in December, 1991.[34]

Following these hearings, Representative Wyden introduced legislation to prohibit the FDA from taking any action to bar the import of RU-486 unless the FDA finds that it is being imported for an illegal use.[35]

It is interesting to contrast the interests of Representative Wyden and the abortion industry with the concerns of the American Medical Association (AMA), which offered this view about the health and safety of women who might obtain and use RU-486 without a physician's supervision:

> "[I]t is the AMA's understanding that RU-486 poses a severe risk to patients unless the drug is administered as part of a complete treatment plan under the supervision of a physician…Rumors exist that the FDA, due to political pressure, is standing in the way of research on RU-486. We do not believe this to be true. On the contrary, it is the FDA's responsibility to ban a drug that has not met legal and regulatory requirements for importation into the United States. Because RU-486 has not met these requirements, the FDA complied with its charge and acted well within its authority in issuing its June 9, 1989, automatic detention import alert concerning the drug."[36]

In the meantime, women's groups orchestrated an offensive consisting of media stunts to exert political pressure on the FDA. Lawrence Lader, founding chairman of the then-National Abortion Rights Action League (NARAL), and Ms. Leona Benton, who volunteered to serve as a "test case," traveled to Europe to acquire RU-486 with the specific purpose of being apprehended by Customs agents when they returned on July 1, 1992.[37] Agents seized the pills, and 45 members of the press showed up to publicize her "plight."

Ms. Benton immediately filed suit against the FDA in federal district court (Brooklyn), and Judge Charles Sifton ruled in her favor on July 14. Before she could physically recover the confiscated pills, however, government attorneys filed an appeal with the U.S. Court of Appeals for the Second Circuit, where a three-judge panel reversed Judge Sifton's order. The U.S. Supreme Court accepted an expedited appeal and, on July 17, ruled 7-2 against releasing the

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[33] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990).

[34] *Safety and Effectiveness of the Abortifacient RU-486 in Foreign Markets: Opportunities and Obstacles to U.S. Commercialization: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Dec. 5, 1991).

[35] H.R. 875 "RU-486 Regulatory Fairness Act of 1991," introduced February 6, 1991.

[36] *RU-486: The Import Ban and its Effect on Medical Research: Hearing before the House Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business*, 101st Cong. (Nov. 19, 1990) (statement of Dr. John P. Seward, Board Member, American Medical Association).

[37] Lawrence Lader, A Private Matter: RU 486 and the Abortion Crisis. Amherst, N.Y.: Prometheus Books, 1995, 135-136.

pills.[38] In the interim, she and Lawrence Lader gained widespread publicity concerning RU-486 in the media. She had a surgical abortion.[39]

In that same month, Public Media Video released a documentary financed by the Chicago abortion advocacy group, Women's Issues Network, entitled, "Science Held Hostage: RU-486 and the Politics of Abortion," hosted by Cybil Shepard. They held a screening on Capitol Hill.

In the six years since approval, mounting evidence points unavoidably to one conclusion: the political motivations for bringing RU-486 to the U.S. market overwhelmed considerations of women's health and safety.

In a September 28, 2000 interview following the announcement of the FDA's approval of RU-486, then-FDA Commissioner Dr. Jane E. Henney stated: "Politics had no role in this decision."[40] That assurance has been called into question by documents made public this year which reveal the Clinton Administration's vigorous role from 1993 forward[41] in facilitating the abortion drug's entry and approval. The actors behind these documents approached approval as a matter of logistics rather than as involving an open-minded scientific inquiry. One memorandum goes so far as to advise the Administration on how to contextualize the anticipated FDA approval of the drug in terms of "promoting women's health and maintaining the close relationship of the Administration to these [pro-choice women's] groups."[42]

However, had the FDA undertaken a thorough review of the scientific literature evaluating RU-486/prostaglandin abortions before approving RU-486, the agency would have been alerted to paramount safety concerns. Certainly, the FDA Medical Officer's Review, discussed in detail below, falls short of endorsing the safety of RU-486. Even so, only two additional studies are referenced in the Medical Officer's Review[43] apart from discussion of the U.S. clinical trials and the two so-called "pivotal French trials" conducted by the manufacturer. In light of this omission, and more significantly, in light of the FDA's approval of RU-486, one wonders why numerous studies demonstrating the inherent risks to women who undergo RU-486 abortions did not appear to influence the FDA's decision to approve RU-486.

And, in fact, such a thorough review of medical and scientific literature on RU-486 had already been published in 1991 by three women who describe themselves as pro-choice

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[38] *Benten v. Kessler*, 505 U.S. 1084 (1992).

[39] *Ibid*., at 139.

[40] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate," *The New York Times*, September 29, 2000.

[41] See, various documents compiled by Judicial Watch, Inc.. and appended to "A Judicial Watch Special Report: The Clinton RU-486 Files," April 26, 2006, available at http://JudicialWatch.org/archive/2006/jw-ru486-report.pdf.

[42] HHS Chief of Staff Kevin Thurm, Memorandum to White House Director of Public Policy Carol Rasco, Subject: RU-486, dated May 11, 1994.

[43] Beverly Winikoff *et al*., "The Acceptability of Medical Abortion In China, Cuba and India," *Int Fam Plan Perspect*. (1997) 23:73-78 & 89; and J.T. Jensen *et al*., "Outcomes of Suction Curettage and Mifepristone Abortion in the United States," *Contraception* (1999): 153-159.

feminists. A brief synopsis of some of the studies they review will help set the context for the discussion of the FDA's approval process, which follows in Part II (below).

Renate Klein,[44] Janice G. Raymond[45] and Dr. Lynette J. Dumble[46] co-authored a "comprehensive literature review and analysis of hundreds of medical and scientific articles on RU 486/PG [prostaglandin], a large percentage of which have a connection with Roussel Uclaf,"[47] the pharmaceutical company that developed RU-486 in the 1980s.

The first clinical trial of RU-486 in humans took place in October 1981 in Geneva, Switzerland after only 17 months of animal research with rats, rabbits and monkeys,[48] although the results of animal trials were not such a resounding success that they justified the rush to human trials. "RU 486 caused the death in two out of three monkeys in toxicity tests,"[49] for example. None of the eleven women in Geneva who were given 200 mg of RU-486 per day for three consecutive days died, but only nine pregnancies were terminated (eight after five days and the ninth at nine days). Furthermore, one woman claimed initially as a "success" later required uterine evacuation, and another woman needed emergency surgery and a blood transfusion due to heavy bleeding.[50] Klein *et al.* describe how the Parisian newspaper *Liberation* reported on the Geneva trial: "Liberation commented that, given these associated complications and risks, RU 486 was no 'abortion miracle.' *Liberation* also reported that RU 486 is not only an anti-progesterone but an anti-glucocorticosteroid which can take the place of cortisone in the adrenal glands, and that contraindications emanating from this double action of the drug could be a problem,"[51] as it turned out to be for two out of three monkeys.

Roussel Uclaf staff proceeded next to clinical trials on small groups of women in France, Sweden, Australia, Holland, the United States of America, England, Finland and China. The manufacturer supplied RU-486 for these trials, and its staff and consultants co-authored articles reporting on the results.[52] The success rates (defined as "a complete termination of pregnancy

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[44] Ms. Klein is a biologist, professor of sociology and women's studies and author/editor of numerous books on reproductive technologies.

[45] Then Professor, University of Massachusetts and associate director of MIT's Institute on Women and Technology.

[46] Then visiting professor of surgery at the University of Texas and senior research fellow in the University of Melbourne's Department of Surgery, Royal Melbourne Hospital.

[47] Renate Klein *et al.*, RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 4.,.

[48] *Ibid*., at 9-10.

[49] Lawrence Lader. RU486: The Pill that Could End the Abortion Wars and Why American Women Don't Have It. Reading, Mass.: Addison-Wesley Publ. Co., 1991, 17-26, at 48.

[50] Renate Klein *et al.*, RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 10, citing Etienne-Emile Baulieu, "RU-486 as an Antiprogesterone Steroid: From Receptor to Contragestion and Beyond," *Journal of the American Medical Assn*. 262:13; 1808-1814 (October 6, 1989)..

[51] *Ibid*., at 10.

[52] *Ibid*.

without the need for further medical intervention") using RU-486 alone ranged from 54%[53] and 61%[54] to a high of 85%[55] and 90%[56] -- at best substantially below the 99% success rate for surgical abortion.

The Kovacs *et al*. trial, finding a 61% average efficacy, illustrates some of the risks encountered in RU-486 use. A total of 37 women "with amenorrhea of 42 days or less" were given RU-486 twice daily for four days at several different levels of dosage. All patients attended three follow-up visits at one, two and five-to-six weeks after the "therapy" began. In three patients (8%) pregnancy was unaffected by the drug. Two patients required blood transfusion and curettage due to heavy bleeding, and another was found at the second follow-up visit to have an extra-uterine pregnancy. Kovacs *et al*. concluded that "treatment with RU 486 may provide a novel therapy for 'menstrual regulation' but the efficacy of the treatment needs to be improved to compete with alternatives such as vacuum aspiration."[57]

In 1984, researchers in Sweden began using a prostaglandin in conjunction with RU-486 to improve efficacy rates (achieving complete abortions in 32 of 34 women subjects, or 94%), without, however, having first undertaken basic research into the potential adverse effects arising from interactions between these drugs.[58]

In late 1988, the French Minister of Health issued approval for the marketing of RU-486 in France.[59] A distinguished committee of scientific and medical experts, which included the president of France's National Academy of Medicine, the head of Nephrology Department, Necker Hospital (Paris), research directors at the (French) National Institute for Health and Medical Research and National Center for Scientific Research, began reviewing data on 30,000 women who by then had used RU-486. In April 1990, this committee issued its scathing "Report of the International Inquiry Commission on RU 486", which faults the approval of RU-486 on several grounds and which warns of the inherent and well-documented risks of RU-

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[53] Herrmann, W.L., Wyss, Rolf, Riondel, A., Philibert, Daniel, Teutsch, Georges, Sakiz, Eduoard and Baulieu, Etienne-Emile. (1982). Effet d'un stéroide antiprogesterone chez la femme: interruption du cycle menstruel et de la grossesse au début. *C R Acad Sci Paris* 294.933-938.[The effect of an anti-progesterone steroid on women: interruption of the menstrual cycle and early pregnancy. Reports of Proceedings of the Academy of Sciences, Paris].

[54] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[55] Couzinet, Béatrice, Le Strat, Nelly, Ulmann, André, Baulieu, Etienne-Emile and Schaison, Gilbert. (1986). Termination of early pregnancy by the progesterone antagonist RU 486 (Mifepristone). *New England Journal of Medicine* 315.1565-1570.

[56] Grimes, David A., Mishell, Daniel R., Shoupe, Donna and Lacarra, Maria. (1988). Early abortion with a single dose of the antiprogestin RU-486. *American Journal of Obstetrics and Gynecology* 158: 1307-1312.

[57] Kovacs, L., Sas, M., Resch, B.A, Ugocsai, G. Swahn, Marja-Lisa, Bygdeman, Marc and Rowe, PJ. (1984). Termination of early pregnancy by RU 486 - an antiprogestational compound. *Contracep* 29.399-410.

[58] Bygdeman, Marc and Swahn, Marja-Liisa. (1985). Progesterone receptor blockage: Effect on uterine contractility and early pregnancy. *Contraception* 32; 45-51, cited in Klein *et al*., RU 486: Misconceptions, Myths and Morals. Melbourne, Aus.: Spinifex Press, 1991 The book is out of print, but the full text is available at http://www.spinifexpress.com.au/non-fict/ru486.htm (last visited October 20, 2006) at 11.

[59] Report of the International Inquiry Commission on RU 486, April 1990, available at http://www.trdd.org/RU486/RUCIEE.HTM (last visited Oct. 18, 2006).

486/prostaglandin abortions. They note cardiovascular and respiratory risks – a full year before the first such fatality, but already evident from the report of one woman who lapsed into a 36-hour-long coma during an RU-486 abortion.[60]

Among the many serious issues raised by the International Inquiry Commission on RU 486 are these:

- the "very strong anti-glucocorticoid" effect of RU-486 (with which the FDA is now familiar, following the deaths from septic shock of four California women)
- the continued uncertainty surrounding RU-486's mode of action
- the necessity of using a prostaglandin to achieve marginally acceptable effectiveness, in light of the known serious side effects of prostaglandin
- metrorrhagia in over 90% of cases, lasting from 1 to 35 days (in "many cases an emergency 'Revision Uterine' [uterine evacuation] was necessary to contain the hemorrhaging. In certain cases, the only recourse was an emergency blood transfusion, with all the risks this involves.")
- "Beyond far heavier risks [compared to] the surgical method … there is – with the medicinal method – an uncertainty about the result during 5 to 12 days," as well as
  - "failure for 5% of the women who will therefore undergo surgery,
  - "around 5 to 10% persistent hemorrhages will need medicinal or surgical treatment,
  - "absolute necessity, some days after abortion, to [perform] an ultrasound examination and a HCG dosage, to be completely sure there [are] no traces of the fetus."
- the risks to women who do not return for follow-up treatment
- recently published studies demonstrating "a strong stimulating effect by RU 486 on the growth of a breast cancerous cellular line"[61] and immune system inhibition.[62]

On immune system inhibition, one wonders how the FDA could have failed to take note of the World Health Organization's 1991 study,[63] in which "9 of the 341 women (2.6%) with complete abortion and … 5 of the 17 subjects (29.4%) with incomplete abortion" had to be given "antibiotic therapy to prevent or cure suspected genitourinary infection" during the six-week follow-up period.[64] Nearly *thirty percent* of incomplete abortions involved infection.

A last example of facts the FDA should have taken into account in the agency's review of RU-486 is the personal story of Tamara Keta Hodgson, a nurse who took part in the RU-486

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[60] *Ibid*.

[61] The referenced report cites RT Bowden, JR Hissom, MR Moore. (1989) "Growth stimulation of T47D human breast cancer cells by the anti-progestin RU-486," *Endocrinology* 124; 2642-2644.

[62] BJ Van Voorhis, DJ Anderson, and JA Hill (1989), "The effects of RU 486 on immune function and steroid-induced immunosuppression in vitro," *J Clin Endocrinol Metab* 69:1195-1199.

[63] World Health Organization. (1991) "Pregnancy termination with mifepristone and gemeprost: a multicenter comparison between repeated doses and a single dose of mifepristone. *Fertil Steril* 56: 32-40.

[64] *Id*., at 37.

trials conducted by Dr. David Grimes in Los Angeles. In a letter published in the *Los Angeles Times* under the heading "Pros and Cons of 'Dr. Grimes' bitter pill,' " Ms. Hodgson writes:

> I took RU-486 in December, 1986, when I was three weeks pregnant. Twenty-four hours later I began to have severe cramping and started vomiting. When this had gone on for 10 to 12 hours, a friend took me to the County-USC Emergency Room. After an excruciating pelvic exam, I was given a shot of Demerol, which did nothing, and a prescription for a prostaglandin inhibitor to slow down the process, which did relieve the pain. I had mild bleeding for a few days and then six days after taking the drug, I began to hemorrhage. I continued to bleed or spot until mid-March, 1987.
>
> I'm not sure why I had such an extreme response. I chose to take the drug rather than have a surgical abortion because it had been presented to me as a relatively benign experience. I also thought it might help advance the causes of both science and women.
>
> Do I think RU-486 should be licensed in the United States? I'm not sure. I had access to many resources not available to the general population of women who might take this drug. I am a registered nurse who works at one of the most sophisticated hospitals in the world. I was cared for by the research team investigating the drug. I had no children who needed to be cared for.
>
> The same cannot be said for women of the Third World. It also cannot be said for women in the United States who do not have access to adequate health care.[65]

Despite all this, what many abortion advocates promoted as a "miracle pill"[66] has turned out to be anything but. Even before its approval, the medical community knew what American women would soon learn by experience:

- mifepristone interferes with the body's immune response[67]

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[65] *Los Angeles Times*, May 6, 1990, at E-20.

[66] David Van Biema, "But Will It End the Abortion Debate?" *Time*, June 14, 1993; available at http://www.time.com/time/magazine/article/0,9171,978680,00.html (last visited October 20, 2006).

[67] *See*, Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also*, Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of

- it is more inconvenient than surgical abortion[68]
- it is more painful[69]
- it is less effective[70]
- it is associated with more adverse events[71]
- it causes more frequent and more severe hemorrhage than its surgical counterpart[72]

> the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[68] *See* FDA Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006):

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients…

[69] *See, e.g.*, B. Elul, et.al, *Side Effects of Mifepristone-Misoprostol Abortion Versus Surgical Abortion, Data From a Trial in China, Cuba, and India*, Contraception 59:107-114, 111 (1999): China—60.3% chemical, 36.0% surgical patients experienced pain / cramps; Cuba—89.2 % chemical, 65.4% surgical; India—61.9% chemical, 36.8% surgical.

[70] *See, e.g.*, Beverly Winikoff, et. al., *Safety, efficacy and acceptability of medical abortion in China, Cuba, and India: A comparative trial of Mifepristone-misoprostol versus surgical abortion*, Am. J. Obstet. Gynecol. 431, 434 (Feb. 1997). Failure Rates: China—chemical 8.6%, surgical .4%; Cuba—chemical 16.0%, surgical 4.0%; India—chemical 5.2%, surgical 0%.

[71] *See, e.g.*, E. Cabezas, *Medical versus surgical abortion*, 63 Internat. J Gynecol. & Obstet. Supp. 1, S141, S144 (1999). Cramping: chemical 60.0%, surgical 48.3%; Nausea: chemical 30.6%, surgical 8.9%; Vomiting: chemical 15.1%, surgical 2.0%.

[72] *See Ibid.*, chemical abortion patients experienced 2.3 days of heavy bleeding, 4.8 days of normal bleeding, and 4.9 days of light bleeding compared to 0.3, 1.8, and 3.3 days for surgical, respectively. Furthermore, 50.8% of chemical abortion patients bled more than expected, compared to 7.3% for surgical patients; and 64.1% of chemical abortion patients bled longer than expected, compared to 18.7% of surgical abortion patients. *See also*, Y.F. Chan, et.al.,

The safety issues associated with RU-486 are discussed in depth in Section III, below.

III. RU-486 APPROVAL IRREGULARITIES

Since FDA approved RU-486 in September 2000, a number of criticisms have been lodged against FDA alleging procedural irregularities in the approval process.[73] The Subcommittee investigators were aware of these criticisms and requested information from FDA regarding the issues raised by opponents of the approval. This section assesses the claims made and FDA's responses to the following allegations: 1) that FDA's approval was based solely on data from uncontrolled trials; 2) that FDA used Subpart H unlawfully when it approved the drug and, furthermore, that the clinical data used in support of the application was insufficient to satisfy Subpart H requirements; and, 3) that FDA unlawfully mandated the unapproved use of a drug, misoprostol, as part of the RU-486 abortion regimen.

A. The Approval was Unlawfully Based Solely on Data from Uncontrolled Trials

FDA's reputation as the world's foremost regulator of drug products is based largely on the rigor which it demands for data submitted in support of drug applications. The law requires, in Section 505(d)(5) of the Food, Drug and Cosmetic Act, that FDA shall not approve a drug when "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."[74] "Substantial evidence" means "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . ."[75]

Over the years, FDA's high standard in supervising the production of clinical trial data has been referred to as its "gold standard." Typically, FDA requires data from two clinical trials that are randomized, blinded and controlled against a "comparator" – often a placebo but more typically an alternative therapy.[76] FDA's Section 314.126(e) indicates that "[u]ncontrolled

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Blood Loss in Termination of Early Pregnancy by Vacuum Aspiration and by Combination of Mifepristone and Gemeprost, Contraception 47:85-95, 90 (1993): Groups receiving 200mg, 400mg, and 600mg of mifepristone experienced an average loss of 84.1ml, 99.9ml, and 101.4ml of blood respectively (ranges were 16.8 - 371.3ml, 16.7 - 524.3ml, and 20.8 - 472.4ml, respectively) compared to an average blood loss of 53.2ml for patients undergoing a vacuum aspiration abortion (range of 29.3ml - 226.0ml).

[73] For example several groups have filed a "citizen petition" with FDA regarding RU-486's approval. *See* Citizen Petition of the American Association of Pro Life Obstetricians and Gynecologists, the Christian Medical Association, and Concerned Women for America, Request for Stay and Repeal of the Approval of Mifeprex (mifepristone) for the Medical Termination of Intrauterine Pregnancy through 49 Days' Gestation, Docket No. 02P-0377 (filed Aug. 20, 2002) ("Mifeprex Citizen Petition"). On October 10, 2003, these groups filed a response to the Danco Laboratories and the Population Council's Opposition to the Citizen Petition which was filed in March 2003. These documents are available in FDA Docket No. 02P-0377.

[74] 21 U.S.C. § 355(d)(5).

[75] 21 U.S.C. § 355(d).

[76] FDA issued a guidance document in 1998 ("Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products," May 1998)("FDA Clinical Evidence Guidance") that outlines the

studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness."[77] The question of whether the RU-486 trial data was produced solely by uncontrolled clinical trials was examined by the Subcommittee investigators.

The French and American trial data were generated by trials in which the participants were given mifepristone and misoprostol to chemically end pregnancies. The RU-486 regimen was judged to have been effective, "defined as the termination of pregnancy with complete expulsion of the conceptus without the need for a surgical procedure."[78] The studies measured the rate at which RU-486/misoprostol abortions succeeded or failed at different gestational ages.

However, neither the French nor American RU-486 trials randomized trial participants concurrently against either a placebo or the most similar RU-486 alternative, first-trimester surgical abortion.[79] Neither the French trials,[80] nor the American trial was concurrently controlled.[81] Furthermore, no discussion of controls can be found in FDA analyses of the French trials[82] or in the Spitz Study[83] that reported the results of the U.S. trial. Thus, the question arose as to whether the RU-486 trials were in fact uncontrolled.

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requirements of its drug trial policies with respect to proving effectiveness. Additionally, FDA has signed on to the principles enunciated in documents produced by the International Conference on Harmonization on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH").

[77] 21 C.F.R. § 314.126(e).

[78] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[79] Blinding would have been very difficult to achieve with respect to the medical personnel performing the surgical abortion or dispensing the drugs to the patient, but blinding of abortion evaluators might have been achievable. In any event, scientifically rigorous randomized and concurrently controlled trials could have been performed with limited or no blinding.

[80] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone), at 2-4 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[81] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[82] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[83] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

At the Subcommittee's May 17, 2006 hearing, *RU-486: Demonstrating a Low Standard for Women's Health?,* Dr. Woodcock, Deputy Commissioner for Operations for the Food and Drug Administration, asserted in her written testimony for the Subcommittee that "[FDA's] finding of drug effectiveness was based on a comparison to a historical control of the expected rate of continued pregnancy."[84]

In response to a post-hearing Subcommittee question, FDA noted that the historical control, used in the RU-486 clinical trials, comprised of "the well-established data and pool of medical knowledge concerning both the natural course of pregnancy itself, including the well-documented rate of spontaneous abortion or miscarriage (less than 20%), and surgical abortion."[85] We take this to mean that the spontaneous abortion rate and the rate of induced abortion were together subtracted from the expected rate of ongoing pregnancy. It is important, then, to examine the FDA's claim that the French and U.S. trials were historically controlled.

First, FDA's assertion that the French and U.S. trials were historically controlled appears to be a *post hoc* assertion. There is no mention of any control group in the Spitz Study;[86] the word "control" does not appear in the article. Moreover, an FDA statistician reviewing the French trial data asserted that "[i]n the *absence of a concurrent control group* in each of these studies, it is a matter of clinical judgment whether or not the sponsor's proposed therapeutic regimen is a viable alternative to uterine aspiration for the termination of pregnancy"[87] (emphasis added). The reviewer made no mention of a historical control to which mifepristone would be compared, and it is well known that controls have to be specified *before* trials are performed. The lack of a prior delineation of the controls demonstrates that FDA's claims are not supported by the record.

Second, the U.S. RU-486 trials were conducted with specific groups of persons excluded. The Spitz Study[88] lists those disqualified from participation as follows:

> "Women with liver, respiratory, renal, adrenal, or cardiovascular disease, thromboembolism, hypertension, anemia, insulin-dependent diabetes mellitus, coagulopathy, or known allergy to prostaglandins were excluded, as were women less than 18 years of age or those more than 35 years of age who smoked more

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[84] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform,* 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[85] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[86] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

[87] Center for Drug Evaluation and Research, Food and Drug Administration, Statistical Review and Evaluation for NDA 2-687 (Mifepristone) at 7-8 (May 21, 1996). The French trial is referred to as FFR/91/486/14. Available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf.

[88] Spitz, Bardin, Benton, and Robbins, "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," 338 *New England Journal of Medicine* (1998), 1241-47.

> than 10 cigarettes per day and had another cardiovascular risk factor. Women were also excluded if they had in situ intrauterine devices, were breast-feeding, were receiving anticoagulation or long-term glucocorticoid therapy, had adnexal masses, had ectopic pregnancies, or had signs or symptoms suggesting they might abort spontaneously.[89]

Yet when FDA was asked what populations were excluded from its control group, the Subcommittee was told that "[a] historical control group does not include specific individuals, but rather is based on experience historically derived from the adequately documented natural history of the condition."[90] FDA made this additional point: "Thus, historical control populations usually cannot be assessed with respect to certain variables, such as the inclusion or exclusion of specific sub-populations."[91] This answer is methodologically insufficient, and it underscores the conclusion that, regardless of FDA's statement to the contrary, these trials were uncontrolled. The trial and control groups must be matched to each other in almost all possible ways if there is to be a meaningful control. If it was not possible to match the populations with the historical data set, then a concurrent control should have been used.

Finally, FDA allowed the use of uncontrolled trials for medical abortion because it defined the clinical endpoint too restrictively.[92] Neither spontaneous nor medical abortions produce only simple zero or one outcomes – that is, one-dimensional instances of success or failure. Not all abortions, whether spontaneous or medical, pass by themselves. Many require surgical intervention to be completed, or serious complications may ensue. FDA's cramped definition of RU-486 "effectiveness" ignores this.[93] A control should have been used in the RU-486 trial that compared different methods of producing the experimental outcome – first-trimester pregnancy termination – while assessing each method's ability to manage highly predictable, regular complications of medical abortion (*i.e.*, hemorrhage, incomplete abortion). As the International Conference on Harmonization[94] has noted, "non-defined" external controls

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[89] *Ibid*, at 1241-2.

[90] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17, 2006) (on file with Subcommittee).

[91] *Ibid.*

[92] *Ibid.*

[93] *Ibid.* ("In the case of medical abortion, determining the effectivness of the drug is straightforward, because it is relatively easy to determine whether the pregnancy has been terminated. Therefore, it is unnecessary to utilize a randomized clinical trial design.").

[94] FDA, "International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials," *Notice*, 62 Fed. Reg. 66113 (Dec. 17, 1997) (*FDA Guidance (ICH: E8): General Considerations*). The International Conference on Harmonization "is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health." *See* www.ich.org (last visited October 10, 2006).

– those in which "a comparator group [is] based on general medical knowledge of outcome" – are "particularly dangerous" and "such trials are generally considered uncontrolled."[95] Such a characterization pertains in instances like this in which the study's dependent variable (i.e., the termination of pregnancy) has been defined so narrowly as to give the false impression of complete knowledge of a simple medical outcome.

B. FDA's Abuse of Subpart H

RU-486 was approved through an important part of FDA's drug approval rules called "Subpart H."[96] In the Subcommittee's May 17 hearing, Dr. Woodcock told the Subcommittee, "FDA approved the Mifeprex NDA [new drug application] under Subpart H at the sponsor's request because the Agency determined that post-marketing distribution restrictions on the product were necessary to ensure its safe use."[97]

These rules were promulgated by FDA in 1992 as part of an attempt to correct perceived deficiencies in FDA's approval process made apparent by the need to quickly develop drugs for HIV/AIDS patients. However, in order to benefit from the provisions contained in Subpart H (*e.g.*, its restricted distribution provisions in the case of RU-486) certain conditions must be satisfied, and in the RU-486 instance, Subpart H was unlawfully used for its approval.

Inducing Medical Abortion Does Not Qualify for Subpart H

Supbart H can only be applied to drug products "that have been studied for their safety and effectiveness in treating *serious or life-threatening illnesses*…."[98] (emphasis added). FDA was aware of this requirement, and FDA asserted in its approval memo to the Population Council "that the termination of an unwanted pregnancy is a *serious condition* within the scope of Subpart H…."[99] (emphasis added).

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[95] *FDA Guidance (ICH E10): Choice of Control Group* at 5 (§ 1.3.5). Section 2.5.4 adds the following point to this discussion: "An externally controlled trial should generally be considered only when prior belief in the superiority of the test therapy to all available alternatives is so strong that alternative designs appear unacceptable and the disease or condition to be treated has a well-documented, highly predictable course. It is often possible, even in these cases, to use alternative, randomized, concurrently controlled designs."

[96] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).. The Subpart H rules are found at 21 C.F.R. § 314.500ff.

[97] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf. We note that the Mifeprex Citizen Petition references a letter from Sandra Arnold of the Population Council to FDA, dated Sept. 6, 2000, in which she vociferously protests Mifeprex's approval under Subpart H. Mifeprex Citizen Petition at 20 (". . . it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable. We ask FDA to reconsider.").

[98] 21 C.F.R. § 314.500.

[99] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4

Linguistic gymnastics notwithstanding, pregnancy or the termination of pregnancy is not a "serious or life-threatening illness," and therefore does not fall within the defined reach of Subpart H; the term "serious condition" is not found in the Subpart H rule. Subpart H is intended for the treatment of "serious or life-threatening illnesses," not conditions. There are situations in which pregnancies become serious or life-threatening, but the underlying condition is not "serious or life-threatening." Moreover, pregnancy itself is not an illness. There are situations in which serious or life-threatening complications may arise, but these are atypical events.

It is difficult to find a credible counter-argument from FDA or any private party defending the use of Subpart H to approve RU-486. This is not a mere technicality. If the condition being treated did not qualify for Subpart H approval, then the various restrictions that could be imposed pursuant to Subpart H to ensure the safe distribution of the drug would not have been available to the agency.

The FDA imposed several such restrictions on the distribution of Mifeprex.[100] (These restrictions, however, are less rigorous than what was initially proposed prior to approval.[101])

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

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Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[100] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[101] FDA "Division Director Memo to File" on Mifepristone NDA, September 17, 1996 (on file with the Subcommittee): "The applicant has appropriately proposed that drug distribution be limited to licensed physicians (with prior training in assessing the length of pregnancy, in diagnosing ectopic pregnancy, and in the performanceof surgical abortion) who will attend educational seminars on the safe use of this regimen." The final restrictions allow for distribution under the supervision of a physician, rather than limiting it to licensed physicians, and do not require educational training on the safe use of the regimen.

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

In addition, the Population Council agreed to two post-marketing studies on the effects of RU-486 on women[102] (though earlier reviews considered six post-marketing studies, four of them were dropped when the drug was approved[103]). In the six years since the approval of RU-486, these studies have not been completed.[104]

The RU-486 Trials Did Not Establish a "Substantial Benefit" for Subpart H

In addition to being intended for drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses, Subpart H is intended only for those products that "provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy.)"[105] FDA's Approval Memo stated that, for RU-486, "….[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[106] The French and American clinical trial data did not satisfy the requirements established in the

[102] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[103] Center for Drug Evaluation and Research, Food and Drug Administration, Office Memo to Population Council (documenting the approval action for RU-486) September 28, 2000. Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

[104] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[105] 21 C.F.R. § 314.500.

[106] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000). Available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited October 15, 2006).

Subpart H rules for establishing a meaningful therapeutic benefit to patients over existing treatments.

First, RU-486 was not approved for a medical indication intended for only the treatment of patients who were intolerant of surgical abortion. It was approved to treat the general population of women seeking first-trimester abortions. FDA baldly asserted that there was a clinical benefit for chemical abortion, and made no effort to produce statistical evidence of an actual benefit.

Second, surgery is an integral part of the RU-486 abortion process, because a substantial proportion of women require D&C's after beginning the mifepristone regimen. Therefore, women who have RU-486 abortions must be able to tolerate the surgical procedure. This fact alone makes it all the more difficult to accept FDA's bald assertion of a meaningful therapeutic benefit above that presented by surgical abortion. While such a benefit may exist, the law requires FDA to make its judgments based on scientific evidence. Subpart H requires that both safety and effectiveness be established for the Subpart H drug above the existing standard of care. At the very least, FDA should have required the drug sponsor to conduct non-inferiority trials to generate data for the drug application.

Third, even though some women may prefer RU-486 abortions over surgical abortions, that fact does not establish the existence of a therapeutic benefit in and of itself. One can imagine numerous ways of delivering therapies that are more desirable for the patient – for example, pills rather than injection – but FDA must establish this fact statistically.

Fourth, it appears that no concurrently-controlled trials comparing medical and surgical abortion were required by FDA, because the Agency already knew that medical abortion—i.e., abortion by RU-486—is unambiguously inferior to surgical abortion with respect to safety and effectiveness. Prior to the approval of the RU-486 NDA, the FDA medical officer made the following observations about studies that had compared medical and surgical abortion:

> [In a study comparing medical and surgical abortion in India, Cuba, and China (n = 1373)], [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion (8.6% versus 0.4% in China, 16.0% versus 4.0% in Cuba, and 5.2% versus 0% in India)…. Three patients (all medical abortions) received blood transfusions. This is a serious potential disadvantage of the medical method. On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[107]
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> [In another non-concurrent study of 377 patients comparing mifepristone to surgical abortion in the U.S patients], [f]our mifepristone patients required curettage for acute bleeding while no surgical patients did. Nine mifepristone

[107] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

> patients required curettage to manage ongoing pregnancy while no surgical patients did. Five mifepristone patients required suction curettage because of incomplete abortion while no surgical patients did. Fourteen mifepristone and eight surgical patients required suction curettage for persistent bleeding. The median time delay for therapeutic curettage was significantly longer in the mifepristone group than in the surgical group (35 days versus 8 days). Mifepristone patients experienced significantly longer postprocedure bleeding than did surgical patients. The mean difference in bleeding days between cohorts was 9.6 days (95% CI, 6.8, 12.4)…. Overall, mifepristone abortion patients reported significantly higher levels of pain, nausea, vomiting, and diarrhea during the actual abortion than did surgical patients… Mifepristone patients reported more problems during the follow-up interval than did surgical patients. Post-abortion pain occurred in 77.1% of mifepristone patients compared with only 10.5% of surgical patients…. Nausea or vomiting in the follow-up interval was common in the mifepristone group (68.6%), but rare among surgical patients."[108]

Given these comments, it is impossible to conclude that RU-486 medical abortions provide a meaningful therapeutic benefit over surgical abortion. Consequently, FDA's approval of the RU-486 NDA using Subpart H was unjustified and unlawful.

C. The Highly Unusual Placement of Misoprostol on the Mifeprex Label

When FDA approved the Population Council's RU-486 application it also mandated the use of another drug, misoprostol, as part of a two-drug abortion regimen. The use of misoprostol was not only an unapproved or off-label use – it was actually contraindicated at that time.[109] This aspect of the approval highlights another irregular component of FDA's approach to reviewing the RU-486 NDA. Shortly after FDA's approval of mifepristone, Peter Barton Hutt, a former FDA general counsel and noted commenter on food and drug law, told the Wall Street Journal that FDA appeared to have created "an extraordinary precedent", because FDA was "seemingly encouraging a drug's unapproved use."[110] He added that the agency is in an "embarrassing and uncomfortable position."[111]

The Subcommittee's questions to FDA on this matter have produced some information but no clear sense as to what FDA's policy is with respect to placing off-label or contraindicated drug uses on another drug's label.[112]

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[108] *Ibid*.

[109] On April 17, 2002, the misoprostol label was amended to remove "the contraindication and precaution that Cytotec should not be used in women who are pregnant."

[110] Rachel Zimmerman, "Clash Between Pharmacia and FDA May Hinder the Use of RU-486," *Wall Street Journal* (Oct. 18, 2000): at B1.

[111] *Ibid*.

[112] In addition to questioning the FDA on this matter, the Subcommittee has looked for, and failed, to find any FDA Guidance documents on this topic.

Attention is drawn to two problems. First, it is well known that the NDA-holder for misoprostol (Searle) did not want to have its product used or labeled to reflect off-label uses as an abortifacient. [113] Thus, FDA mandated misoprostol's use in this abortion regimen and placed information about Searle's product on the Mifeprex label. Second, the entire edifice of FDA's regulation of drugs rests on the principle that only indications whose effectiveness has been demonstrated with "substantial evidence" may be placed on the label. FDA has procedures by which new indications can be approved using the supplementary new drug applications. No supplementary drug application was ever filed for misoprostol's use as an abortifacient.

In her prepared testimony before the Subcommittee, Dr. Woodcock noted that the FDA was "aware that questions ha[d] been raised about the use of misoprostol, a drug indicated for the prevention of NSAID-induced gastric ulcers, in the medical abortion regimen with mifepristone, without a separate approval and labeling of misoprostol for this use."[114] She then observed that numerous cases existed "where the labeling of one drug recommends its use with a second drug without the approval of the sponsor of the second drug."[115]

This statement is troubling and warrants further investigation. First, Woodcock's use of "recommends" is grossly inaccurate. In the Mifeprex regimen, the use of misoprostol is mandated. A physician might use an off-label variant of the regimen and, therefore, use another prostaglandin, but the Mifeprex label gives very specific directives to use misoprostol.[116] The non-optional nature of the regimen is carried forward into the language of the Patient Agreement Form which states: "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)."[117] Second, Subcommittee investigators finds it problematic that FDA can dictate that a drug – under the proprietary control of a firm whose NDA has been approved – can be approved for a use to which it objects.

In a letter to Chairman Souder, FDA provided two examples in which non-approved uses appear on FDA-approved labels.[118] The examples relate to coronary heart disease and metastatic

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[113] See letter from Searle warning against the use of misoprostol in abortion: http://www.fda.gov/medwatch/safety/2000/cytote.htm (last visited October 20, 2006).

[114] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

[115] *Ibid*.

[116] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[117] Mifeprex Patient Agreement, Item # 6, available at http://www.fda.gov/cder/drug/infopage/mifepristone/patientAgreement20050719.pdf (last visited October 20, 2006).

[118] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee). *See also*, See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Janet Woodcock, M.D., Deputy Commissioner for Operations, FDA) Available at http://reform.house.gov/UploadedFiles/Woodcock%20Testimony.pdf.

breast cancer, and the relevant labels should be read to understand the comments that follow.[119] Some comments are in order. First, there is no *mandated* use of the second/off-label drug in either example. Second, in the coronary disease case, the drugs were designed and approved to work on aspects of cardiovascular system-blood pressure regulation. There is nothing unusual in this use of drugs intended to manage cardiac failure.

These facts provide a qualitative difference with the Mifeprex regimen in which misoprostol was *not* designed to work to produce abortions – or uterine contractions for that matter. Rather, misoprostol was a medication intended to protect the gastro-intestinal tract from adverse events related to the use of non-steroidal anti-inflammatory medication – an indication far removed from misoprostol's novel application as an abortifacient.

Finally, FDA's Herceptin/Taxol example is somewhat disingenuous. After reading each drug's label, one recognizes that Taxol is approved for metastatic breast cancer treatment as a single agent, and so is Herceptin, but neither is specifically indicated for metastatic breast cancer treatment where no prior chemotherapy has been given. The combination use is approved (but not MANDATED) for patients with metastatic breast cancer overexpressing HER2 protein who have not received any prior chemotherapy.

Both drugs are approved for use in metastatic breast cancer. Herceptin's indication is more specifically tied to use when there is overexpression of HER2 protein. If there has been no other chemotherapy given then both may be used together. FDA seems to be splitting hairs when it claims that the use of Taxol in such cases is off-label. That characterization depends upon a fine distinction having to do with a specific tumor marker and whether or not other chemotherapy had been used.

The tenuousness of FDA's examples leads the Subcommittee to conclude that FDA is having difficulty finding examples that parallel the mandated, dissimilar off-label use of misoprostol in the Mifeprex regimen.

IV. SAFETY

Since the introduction of RU-486 to the U.S. market, the FDA has acknowledged, as of May 2, 2006, the deaths of six women associated with the drug, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection.[120] These and other cases have added up to a total of 1070 adverse event reports (AERs) as of April 2006.[121]

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[119] The relevant information can be found using the website: <www.rxlist.com>.

[120] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[121] Numbers do not convey the full story. More telling are the first-hand accounts of women who have lived these events. Below are some examples from the Individual Safety Reports (ISRs) which describe in detail the type of experience RU-486 chemical abortion has turned out to be (mistakes are as they appear in the originals):

Event of January 1, 2000, reported September 27, 2000, one day before the approval of Mifeprex: "I was issued RU-486 in effort of obtaining an abortion. I followed directions exactly, and after taking the ru-486, I was in

excrutiating physical pain, for at least 12 hours straight and I was bleeding extremely excessively. I was bleeding through my pants but was in so much pain I couldn't even clean myself. It was the worst physical pain I've ever experienced in my life. This extreme pain was constant the whole 12 hours, it did not let up at all the whole time. I vomited continuously but couldn't even hold my head up. I had unbelievable abdominal pains, I can't even put in words. I couldn't speak, eat, drink, sit up, and had difficulty breathing. The only thing I could do was lie on the floor and pull my hair to deal with the pain. I couldn't clean myself or go to the bathroom, I thought I was going to die. After about 7 hours of this, I really wanted to die because I couldn't take the pain anymore. I wanted to call the hospital but I was hours from any hospital because I went to our cabin in a remote area to have privacy during this time. The administering clinic was closed since it was the weekend…. I was not informed of the extent of these side effects, I was told it would be just like a menstrual period. I never would have taken this had I been properly informed, even of the possibility of those effects…I was not told that this drug was experimental and not approved by the FDA…I believe they outright lied to me…when I returned to the clinic after the abortion was complete, they were not very attentive or interested in me, I explained to them my pains even though they didn't ask me any questions. I filled out a questionairre that they gave me before I took the drug and they said I have to do the questionnaire ever couple hours during the abortion, but when I offered it to them upon return, they didn't even want the questionaire, they didn't take it."

Event of July 26, 2002, reported September 28, 2002: "28 year old Gr5. Para 2 Ab 2 at 6 weeks 5 days gestation received 200 mg Mifeprex on [redacted] and inserted 800 mcg misoprostol vaginally on [redacted] at 11:00 a.m. The bleeding was 'normal' until 3:30 p.m. when it became heavier. That evening she stated 'it was like water coming out of me' and she felt dizzy. That evening she reported that she briefly 'passed out' twice. She went to an emergency room and received [missing] litres of IV fluid and had a D&C. Her hemoglobin on arrival was 8.7 gm/dl and was [missing] gm/dl after the D&C. She was started on iron supplementation. On [redacted] her hematocrit was 28% at the clinic and she reported that she was resting, on limited to light activity and doing well."

Event of August 15, 2004, reported July 25, 2005: "I took RU-486 last year and it caused me serious problems. After 15 days after taking it I hemorrhaged while at work requiring subsequent D&C, then had an infection that would not go away despite multiple antibiotics. I ended up being hospitalized and having multiple tests due to the infection and pain. I was hospitalized for four days in september of last year. Even after being hospitalized I was very ill for quite some time. I believe it took me until December to fully recover, during this time I lost quiet a bit of weight and had to enter counseling as a result of all the problems after using RU486."

Event of October 31, 2002, reported August 13, 2005: "Previous to 2002 I had two pregnancies and two live births…In 2002, 2003, and 2004, I had a three abortions at a very early stage, using the 'French' pill—RU-486—with each being almost exactly a year apart. I had the same experience each time. I developed a very bad case of bacterial vaginosis…I also was told to insert the final pill vaginally in all three cases. I had no idea it could even be taken orally."

Event of September 8, 2004, reported August 17, 2005: "I was given 2-step Abortion Pill. In the middle of the night I was awoken by severe abdominal pains. Having had endometriosis has built my pain tolerance quite high, but this pain was excruciating. Between the pain and diarrhea, I wanted to pass-out. I laid on the cold tile of the bathroom floor for 4 hours to keep me from fainting and because I couldn't get up. I thought it would eventually taper off, but after 4 hours I was exhausted and couldn't tolerate the pain. I yelled until my sister woke up to help me and asked her to call 911. She knew that I never go to the hospital, much less ask for 911, she immediately called. At the hospital, blood tests –b-hcg- kept coming back positive and I was still in alot of pain. They sent me for ultrasounds, blood tests again, and pelvic exams. I asked for more morphine, but they told my sister that they gave me the maximum dose and were surprised that I was still moaning of pain. The doctor said that my body was going through labor over and over, but wasn't ridding of anything. After the 3rd pelvic exam and blood test, the HCG count started coming down."

Event of December 14, 2005, reported December 27, 2005: "Approximately 2 1/2 weeks after taking Mifeprex and Cytotec to end a pregnancy, I began having very heavy bleeding. This was after I had not bled for a week, and after a 2 week follow up at a clinic—in which was told I was fine—I began hemorraging on the evening of the 14th, passing clots approximately 3 inches in size. I went through approximately 7 pads in 2 hours. The clinic wanted me to wait until the morning to get care from their facility, but when we called the local ER, they told me I needed to come in right away to get examined. I was cold, weak, and fatigued during the 2 hours my bleeding was excessively heavy. Unfortunately I was not able to make it into the ER because I am a single mother of 4, and had noone to care

A. Adverse Events for RU-486

These reports are based on the FDA's Adverse Event Reporting System (AERS), a voluntary system, with inherent underreporting. Common estimates of the proportion of adverse events actually captured by FDA in AERS are from one to ten percent. FDA acknowledges that it does not capture all adverse events associated with a drug: "When evaluating reports from the AERS system, it is important to recognize several caveats. First, *accumulated case reports cannot be used to calculate actual incidences of adverse events or estimates of risk for a product, as the reporting of adverse events is a voluntary process with inherent underreporting*"[122] (emphasis added).

The Government Accountability Office (GAO) has also commented on the underreporting of Adverse Events: "FDA cannot establish the true frequency of adverse events in the population with AERS data. The inability to calculate the true frequency makes it hard to establish the magnitude of a safety problem, and it makes comparisons of risks across similar drugs difficult."[123]

FDA nonetheless claims that it is capturing most adverse events associated with RU-486: "Because healthcare professionals who prescribe Mifeprex have agreed in writing" (with the manufacturer, Danco, *not* the FDA) "to report 'any hospitalizations, transfusions or other serious events' to the manufacturer, FDA believes that there are unlikely to be significant numbers of serious adverse events, including deaths, associated with Mifeprex that have not been reported to the Agency."[124]

During the Subcommittee staff's review of the 1070 Adverse Event Reports that had been reported through April 2006, ISRs were found that had been submitted through MedWatch, the voluntary reporting mechanism for AERS, rather than through Danco. FDA acknowledged that these reports were not matched by reports submitted through Danco,[125] undermining the Agency's claim that it is capturing most adverse events.

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for my children. Luckily for me, the bleeding lessened. I was told it was 'normal' to bleed for up to 4 weeks, but I am NOW at day 32 and still bleeding."

[122] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[123] Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process GAO-06-402 March 31, 2006.

[124] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (July 31, 2006) (on file with Subcommittee).

[125] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (June 30, 2006) (on file with Subcommittee).

In light of FDA's repeated claim that it captures most RU-486-related adverse events—despite the Agency's own acknowledgement of underreporting and experience to the contrary—it is important to note that there is no true enforcement mechanism, either by Danco or the FDA, for ensuring that doctors report all adverse events, and there is little incentive on the part of the prescribing physician to do so.[126]

Even Danco has noted that the FDA's "obligatory" reporting system is of little value. In 2003, Dr. Richard Hausknecht, Medical Director for Danco, wrote that "[t]he obligatory reporting of adverse events is limited to transfusions, hospitalizations, ongoing pregnancies or 'other serious adverse events,' which allows considerable subjective judgment on the part of the providers. In addition, the reporting of other common adverse events may not be reported at all."[127]

Moreover, emergency room personnel and medical professionals who do not prescribe RU-486, but who may likely treat the infected or hemorrhaging patient, or provide surgical intervention, *have no obligation whatsoever to report adverse events for RU-486*, even assuming that the healthcare worker is aware the patient took the RU-486 drug regimen.[128] In such scenarios, prescribing physicians may remain unaware of adverse events that take place after they administer RU-486, alleviating them of reporting requirements. This underscores the fact that there is not an accurate picture of the total adverse events that are being experienced with this drug.

In addition to the fact that there is no accurate number of adverse events to serve as a realistic "numerator" for evaluating the rate of adverse events actually being experienced in the population, the FDA does not use an accurate figure for the true number of patients who have taken RU-486 as a "denominator." Rather, FDA accepts and reports "estimates" proposed by Danco. The most recent estimate is that 612,000 women in the U.S. have used RU-486 as of July 24, 2006.[129]

This estimate is likely inflated, since Danco arrives at its estimate by basing it on the number of packages sold (in three-pill packages of 200 mg pills) and multiplying that number by three to account for the number of doses that are given at the off-label 200 mg dose (rather than

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[126] Although RU-486 is approved for use through 49 days of pregnancy, it is commonly prescribed in the United States up to 63 days of pregnancy. Physicians also commonly prescribe a dosing regimen that is different from that approved by the FDA. Therefore, it has been suggested that in fact there is a *dis*incentive on the part of prescribing physicians to report adverse events that may be attributed to a physician's negligence or willingness to prescribe a regimen that is outside the FDA-approved regimen for RU-486.

[127] Hausknecht, R., "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003) 463-465.

[128] Treating personnel might never know that a woman has taken RU-486; Women who seek medical treatment for adverse reactions after RU-486 may be too sick to disclose, may fail to disclose, or may simply refuse to disclose (because she does not want it in her medical record) that she has taken the RU-486 drug regimen.

[129] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (August 17. 2006) (on file with Subcommittee).

the FDA approved 600 mg dose).[130] That Danco is allowed to provide a loosely-figured *estimate* flouts the restricted approval provision for RU-486, which requires Danco to distribute the drug with a tracking system allowing the company to track packages "to the patient level while maintaining patient confidentiality."[131]

For FDA to rely upon guesses as a basis for understanding safety problems with RU-486 is highly problematic. Danco's estimate is used as the denominator for determining the rate of adverse events associated with the drug. The larger the denominator, the lower the percentage of adverse events. This inaccuracy of using Danco's estimate is inexcusable in light of the way the estimate is relied upon to determine and discuss the rate of adverse events associated with RU-486.

B. RU-486 Safety Issues Known Prior to Approval

Prior to FDA's approval of RU-486, the Agency's own medical experts recognized that any benefits that could be gained from the use of this drug for a "medical abortion" were limited at best and that significant dangers were inherent in its use. These dangers are especially acute when compared to surgical abortion. According to the FDA's medical reviewer, writing before the drug's approval:

> This method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This, then, leaves only a three week period for the women to secure this method of abortion.
>
> Another disadvantage of this method of pregnancy termination is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.
>
> In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans (limb defects and skull defects)...
>
> [In a comparison of medical termination of pregnancy with surgical termination,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical

[130] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

[131] CDER Office Memo to Population Council, September 28, 2006. At http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf (last visited September 28, 2006).

> abortion…[and] increased with gestational age. Specific symptoms and adverse events, including cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients… On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients….[132]

The negative physical experience of RU-486 was explained this way by Dr. Tom Tvedten, an abortion provider in Little Rock, Arkansas: "With medical termination, the discomfort is significant because they have to go through mini-labor…There's a lot of hard cramps and usually significant bleeding. It's cheaper, safer and less painful to have a surgical termination."[133]

In fact, as explained in the RU-486 label, "nearly all of the women who receive Mifeprex and misoprostol will report adverse reactions, and many can be expected to report more than one such reaction,"[134] including: abdominal pain; uterine cramping; nausea; headache; vomiting; diarrhea; dizziness; fatigue; back pain; uterine hemorrhage; fever; viral infections; vaginitis; rigors (chills/shaking); dyspepsia; insomnia; asthenia; leg pain; anxiety; anemia; leucorrhea; sinusitis; syncope; endrometritis / salpingitis / pelvic inflammatory disease; decrease in hemoglobin greater than 2 g/dL; pelvic pain; and fainting.[135]

The FDA's Medical Officer's review notes that, "[m]ore than one adverse event was reported for most patients…Approximately 23% of the adverse events in each gestational age group were judged to be severe."[136]

In addition to these known, startling adverse effects, of which the FDA was aware during the RU-486 NDA review process, the incredibly high failure rate of the drug was also known, averaging 14.6% in the U.S. trial testing the drug through 63 days gestation.

The FDA's Medical Officer's review noted that in the U.S. trial of 2015 women, "[a] total of 295 patients were classified as having failed medical abortion."[137] This represents a

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[132] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[133] John Leland, *Under Din of Abortion Debate, an Experience Shared Quietly*, N.Y. TIMES, Sept. 18, 2005, *at* http://www.nytimes.com/glogin?URI=http://www.nytimes.com/2005/09/18/national/18abortion.html&OQ=_rQ3D1&OP=41647c1fQ2FQ2AQ7EklQ2AbBG)ABB7FQ2AFqqjQ2AqQ2FQ2A42Q2A-_7VB-_YQ2A42_lBA7VB-vC7KY. (Quoting Dr. Tom Tvedten of Little Rock, Arkansas).

[134] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[135] *Ibid.*

[136] Medical Officer's Review of Amendments 024 and 033, Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments, Finalized November 22, 1999 (dated January 27, 2000), available at http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf (last visited September 28, 2006).

[137] *Ibid*.

failure in 14.6% of total patients. "Of these patients, 79 (27%) had ongoing pregnancies, 126 (43%) had incomplete abortions, 30 (10%) requested and had surgical terminations, and the remaining 60 (20%) patients had surgical terminations performed because of medical indications directly related to the medical procedure."[138]

The "best" outcome was in the patient group consisting of women whose pregnancies were less than or equal to 49 days. In this group, 7.9% of patients required surgical intervention after taking RU-486. As the gestational age increases, the failure rate of RU-486 increases rapidly, to 17% in the 50-56 days gestation group, and 23% in the 57-63 days gestation group.

By any objective standard, a failure rate approaching eight percent and requiring subsequent surgical intervention as the "best" outcome is a dismal result. Nonetheless, the Medical Officer stated that "[t]he 92% success rate in the ≤ 49 days group is an acceptable one."[139] This failure rate, along with the anticipated adverse events that patients would experience, is explicit in the FDA Medical Officer's review, and also part of the RU-486 label.[140]

Despite these known problems with adverse events and high failure rates, the FDA recommended and gave approval for distributing this drug to women.

B. Post-Approval Hemorrhage, Infections and Deaths

As stated above, the FDA has acknowledged the deaths of six U.S. women associated with RU-486, nine life-threatening incidents, 232 hospitalizations, 116 blood transfusions and 88 cases of infection. [141] A quarter all the patients were hospitalized.[142] These and other cases add up to a total of 1070 adverse event reports (AERs) as of April 2006.

A review[143] of only a portion of all the reported AERs demonstrates in real world experience how women have suffered after taking dangerous drug. Out of only 607 unique adverse events submitted to the FDA, the high number of serious and life-threatening events is startling:

> The most frequent [adverse event reports] were hemorrhage (n=237) and infection (66). Hemorrhages included 1 fatal, 42 life threatening, and 168 serious case; 68 required transfusions. Infections included 7 cases of septic shock (3 fatal, 4 life-threatening) and

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[138] *Ibid*.

[139] *Ibid*.

[140] Mifeprex Label, available at http://www.fda.gov/cder/foi/label/2005/020687s013lbl.pdf (last visited September 28, 2006).

[141] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[142] *Ibid*.

[143] M. M. Gary, D. J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, The Annals of Pharmacotherapy, February 2006, 40.

> 43 cases requiring parenteral antibiotics. Surgical interventions were required in 513 cases (235 emergent, 278 nonemergent). Emergent cases included 17 ectopic pregnancies (11 ruptured). Second trimester viability was documented in 22 cases (9 lost to follow-up, 13 documented fetal outcome). Of the 13 documented cases, 9 were terminated without comment on fetal morphology, 1 was enrolled in fetal registry, and 3 fetuses were diagnosed with serious malformations, suggesting a malformation rate of 23%.[144]

Since this review by Gary and Harrison, there have been hundreds more adverse event reports and two additional reported septic infection deaths. Nearly all among the afflicted and dead who experienced these serious adverse events following RU-486 were healthy women of child-bearing age. (This is in sharp contrast to other drugs with inherent risks—Viagra, for example—which result in adverse events often after repeated use over long intervals of time, in patients with other risk factors associated with age or disease.) Without access to emergency room services, women who suffered severe hemorrhage would have died.

In total, there are eight known deaths following RU-486: four Californians and one Canadian from *C. Sordellii* septic infection; a Tennessee woman with ruptured ectopic pregnancy; a Swedish teen, from massive hemorrhage; and a British female, from "unknown etiology," (but her clinical presentation of shock and an autopsy revealing one liter of blood in her stomach makes sepsis a plausible etiology).[145]

Five of the eight known deaths following the use of RU-486 have been the result of a toxic shock-like syndrome initiated by the bacteria *C. Sordellii.* This bacteria is thought to exist in low numbers in the reproductive tracts of many women and is normally contained by the immune system.[146] Experts in immunology,[147] pharmacology[148] and maternal-fetal medicine[149]

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[144] *Ibid*.

[145] *Ibid*.

[146] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[147] *See*, Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486.")

[148] *See*, Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

have suggested that because RU-486 interferes with the immune response, the bacteria, if present, are then able to flourish, causing a widespread, multi-organ infection in the woman.

The infections are *not* accompanied by a fever, and symptoms match those that are expected after taking the RU-486 regimen (cramping, pain, bleeding, nausea, vomiting), making detection of the fast-spreading infection difficult. Each of the women infected with *C. Sordellii* after RU-486 were dead within five to seven days.

The FDA describes the clinical presentation of *C. Sordellii* infection the following way:

- Rapid onset of influenza like symptoms (nausea, vomiting, and weakness)
- Hypothermia or *absence* of fever
- *Absence* of purulent discharge
- Localized pelvic tenderness may be *absent*
- Elevated hematocrit and marked leukemoid reaction
- Progressive refractory hypotension
- Marked edema with peritoneal and pleural effusions
- Rapidly fatal despite aggressive treatment[150] (emphasis added).

To investigate the nature of the *C. Sordellii* bacteria, the FDA and CDC held the "Emerging Clostridial Disease" workshop on May 11, 2006.[151] Workshop presenters – experts in the fields of pharmacology, immunology, and maternal-fetal medicine – noted that the rapid growth of the *C. Sordellii* bacteria likely forecloses effective treatment;[152] that there is no currently identifiable "window of opportunity" for treatment once a woman is infected, even with major interventions such as hysterectomy;[153] and that antibiotic prophylaxis was unlikely to provide any protection in the RU-486 / *C. Sordellii* context.[154] The fatality rate has been 100% for the women who contracted *C. Sordellii* infection after RU-486.

In an effort to dismiss any association between RU-486 and the *C. Sordellii* deaths, some have promoted the idea that *C. Sordellii* is linked to pregnancy and childbirth, not the abortion pill. However, in five years, five women have died from this infection after taking RU-486. In contrast, the FDA has noted that there were "only five additional cases not associated with

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[149] *See*, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[150] Food and Drug Administration "Center Director Briefing" June 27, 2005 (on file with the Subcommittee).

[151] A full transcript for the meeting is available at: http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[152] Letter to the Editor, James A. McGregor and Ozlem Equiles, *Risks of Mifepristone Abortion in Context*, Contraception 2005, 71: 161.

[153] Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Transcript available at http://www.fda.gov/cder/meeting/clostridial/transcript.pdf (last visited October 13, 2006).

[154] *Ibid*.

mifepristone/misoprostol retrieved with a text search of the entire AERS database"[155] of 3.5 million records.[156]

Distinguishing the 100% fatality rate with this infection following RU-486 among women who were otherwise healthy, the FDA noted, "[t]he patients in these 5 [non-RU-486 related] cases had weakened or altered immune function due to chemotherapy and age (neonatal & elderly patients), and use of multiple antibiotics. None of these five cases involved intravaginal product administration and 3 cases had a fatal outcome. *In contrast to these 5 additional cases in [3.5 million] AERS, the 4 U.S. confirmed cases of Clostridium Sordellii infection with medical abortion involved healthy patients and all cases had fatal outcome*"[157] (emphasis added).

A more extensive database search for any reported *C. Sordellii* infections since 1925 found a total of eleven fatal cases related to post-partum/ob-gyn infection or to spontaneous abortion.[158] In contrast with this small number of cases (11 since 1925) five women in five years are known to have died from *C. Sordellii* following RU-486.

Experts studying the immune suppression properties of RU-486 have found that it has the ability to block innate immune response.[159] Lazar had published information as early as 1992

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[155] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[156] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[157] Memorandum, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, April 12, 2006, From [redacted], Division of Drug Risk Evaluation, Through: [redacted] Division of Drug Risk Evaluation, TO: [redacted] Division of Reproductive and Urologic Products. Subject: Supplementary investigations related to reports of fatal infections associated with mifepristone and misoprostol use for medical abortion. [handwritten note: DFS 4/17/06 Consult #3]

[158] Dennis L. Stevens, M.D., PhD., *Clostridium sordellii: Clinical Settings, Diagnostic Clues and Pathogenic Mechanisms*, Public Workshop on Emerging Clostridial Disease," (CDC Conference Center: Atlanta, Georgia, May 11, 2006). Available at http://www.fda.gov/cder/meeting/clostridial/stevens.pdf (last visited October 13, 2006).

[159] *See*, Jeanette I. Webster and Esther M. Sternberg, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Products*, Journal of Endocrinology 2004, 181:207-221 ("Natural and synthetic glucocorticoids protect against the lethal effects of many bacterial and viral components...agents that block the hypothalamic-pituitary-adrenal axis, as in…mifepristone…enhance lipopolysaccharide (LPS) and endotoxin lethality and LPS-induced fever. Even the normally endotoxin-nonresponsive C3H/HeJ mice could be made endotoxin sensitive by RU-486."). *See also*, Ralph P. Miech, *Pathophysiology of Mifepristone-Induced Septic Shock Due to Clostridium Sordellii*, The Annals of Pharmacotherapy, September 2005, 39:

> "Mifepristone is a potent progesterone antagonist that, in addition to its ability to block glucocorticoid receptors, blocks progesterone receptors...Blockade of progesterone receptors…results in rejection of the developing placenta and death of the embryo. Prolonged ischemia of the decidua and the embryonic placenta causes necrosis [death] of these tissues. Mifepristone also [causes] cervical dilation and liquefaction of the cervical mucus plug. The

about the increase in fatal septic infection in mice after receiving RU-486, which caused the survival rate to drop dramatically from the control level of 71% to only 15%.[160] Nonetheless, the theory that RU-486 suppresses the immune system was only noted by the FDA as late as 2003,[161] and it wasn't until 2004 that the Agency conducted the minimal inquiry of a literature review to examine the immune suppression properties of RU-486:.

> "The Division of Anti-Infective Drug Products (DAIDP) reviewed the medical literature to examine the potential impact that either or both mifepristone and misoprostol might have on human immune function. They concluded, 'Systemic levels of mifepristone and misoprostol may both influence the host response to infection via their anti-inflammatory effects, respectively. In theory, *these effects may predispose an individual to infection or may predispose an infected individual to a worse outcome*. Such roles are apparently dependent on dose, timing, and rates of uptake and intracellular degradation in different target tissues'"[162] (emphasis added).

Beyond this, there is little more in the thousands of pages of documents provided to the Subcommittee to indicate an extensive FDA examination of the immune suppression properties of RU-486.

In the meantime, women who take RU-486 are exposing themselves to an exponentially greater risk of infection or death as compared to the alternative of surgical abortion. The risk of death from infection is at least ten times greater than surgical abortion during the first eight weeks of pregnancy.[163] In addition to *C. Sordellii* infection, women taking RU-486 have developed other infections following the abortion pill regimen. The FDA has acknowledged 88 reported cases of infection following RU-486.

The most frequent serious adverse event is hemorrhage, where women who lost enough blood as to require transfusions. These cases of massive hemorrhage comprise 12% of the RU-

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> combined loss of a closed cervix and the protective cervical mucus plug permits contamination of the decidua and the intrauterine necrotic cells with aerobic and anaerobic bacteria from the normal vaginal flora."

See also, Sharon Worchester, *Mifepristone Deaths Raise Unanswered Questions*, Ob. Gyn. News, (October 1, 2005) at 13. (Quoting Dr. James A. McGregor)("Mifepristone has multiple pharmacologic properties that may interfere with innate immune responses to infection, toxin exposures, and inflammatory stimuli.").

[160] G. Lazar, *et al.*, *Modification of septic shock in mice by the antiglucocorticoid RU 38486*, 36 Circulatory Shock 180 (1992).

[161] FDA Division of Anti-Infective Drug Products, Report of Medical Officer Consultation (Intravaginal Misoprostol), November 19, 2003, at 4 (on file with the Subcommittee)..

[162] FDA Mifeprex plus Misoprostol Postmarketing Safety Review, November 15, 2004, at 24 (on file with the Subcommittee).

[163] *See*, Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318. The mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available for women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. The rate could be higher, if an accurate numerator is used for the true number of patients who have taken RU-486.

486 AERS.[164] A review of the AERS through September 2005 finds that fifteen women suffered hemorrhages so serious that they lost over half of their entire blood volume and would have died without rapid access to emergency room services.[165]

According to Dr. Donna Harrison, who testified before the Subcommittee at the May 17 hearing *RU-486: Demonstrating a Low Standard for Women's Health?*, "In my experience as an ob-gyn, the volume of blood loss seen in the life-threatening cases is comparable to that observed in major surgical trauma cases like motor-vehicle accidents. This volume of blood loss is rarely seen in early surgical abortion without perforation of the uterus, and it is rarely seen in spontaneous abortion."[166]

As with other adverse events associated with RU-486, no risk factors for hemorrhage have been identified. Rather, they are unpredictable and sporadic.[167]

The proven health risks and demonstrated association with fatal septic infections necessarily prompt urgent consideration of this drug's immediate withdrawal from the market.

V. RECOMMENDATIONS

The high incidence of adverse events has prompted Danco, in cooperation with the FDA, to take steps to alert women and the medical community to the dangers of the drug:[168]

- "Dear Health Care Provider" Letter, April 19, 2002 (warning of danger of ruptured ectopic pregnancies).[169]
- "Dear Emergency Room Director" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[170]
- "Dear Health Care Professional" Letter, November 12, 2004 (warning of infection, heavy bleeding and ruptured ectopic pregnancy).[171]
- Updated label, December 22, 2004 (reflecting danger of infection, heavy bleeding and ruptured ectopic pregnancy).[172]

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[164] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources (May 2, 2006) (on file with Subcommittee).

[165] See *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of Donna Harrison, M.D.) Available at http://reform.house.gov/UploadedFiles/Harrison%20Testimony%20-%20scan%20test.%20w%20attchmts.pdf.

[166] *Ibid*.

[167] *Ibid*.

[168] See Danco's website, http://www.earlyoptionpill.com/.

[169] Available at http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.pdf (last visited October 14, 2006).

[170] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf (last visited October 14, 2006).

[171] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

- "Dear Health Care Provider" Letter, July 19, 2005 (warning of the cases of fatal septic shock).[173]
- Updated label, July 19, 2005 (warning of danger of fatal *C. Sordellii* infections).[174]

In light of the significant health risks posed by this drug, the current restrictions, and the letters and label changes subsequent to approval are demonstrably insufficient to protect women from the dangers of RU-486. Rather, the FDA possesses the authority to suspend or withdraw approval of the drug under various provisions. The most important, and perhaps necessary and justified for removing RU-486 from the market, is the Imminent Hazard authority possessed by the Secretary of Health and Human Services.

"Imminent Hazard" is defined and the criteria to be considered are set forth in 21 CFR 2.5:

> (a) Within the meaning of the Federal Food, Drug and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The imminent hazard may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an imminent hazard of such occurrence exists.
>
> (b) In exercising his judgment on whether an imminent hazard exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

Under this provision, the Secretary's decision is subject to judicial review, but the courts are deferential to the Secretary's conclusions.[175] Within the context of RU-486, the unpredictability and frequency of serious adverse event and death (discussed in Section III above) warrants withdrawal of this dangerous drug from the market.

The FDA also possesses the authority to unilaterally withdraw approval of a drug under 21 CFR 314.530. RU-486 falls into the withdrawal categories of this provision:

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[172] Available at http://www.fda.gov/cder/foi/label/2004/020687lbl_Revised.pdf (last visited October 14, 2006).

[173] Available at http://www.fda.gov/medwatch/safety/2005/mifeprex_deardoc_071905.pdf (last visited October 14, 2006).

[174] Available at http://www.fda.gov/cder/drug/infopage/mifepristone/DearHCP.pdf (last visited October 14, 2006).

[175] See *Forsham v. Califano*, 442 F. Supp. 203 (D. D.C. 1977)(this case appears to be the only instance in which the "imminent hazard" authority of the HHS Secretary has invoked). See also *RU-486: Demonstrating a Low Standard for Women's Health? Hearing before the House Subcommittee on Criminal Justice, Drug Policy and Human Res., Committee on Government Reform*, 109th Cong. (May 17, 2006) (statement of O. Carter Snead, Assoc. Professor, University of Notre Dame Law School). Available at http://reform.house.gov/UploadedFiles/Snead%20Testimony.pdf.

(a)(1) A post-marketing clinical study fails to verify clinical benefit

Since its approval, RU-486 has been associated with six known U.S. deaths of healthy women.[176] The safety problems associated with RU-486 are discussed above. Additionally, because women who visit the emergency room arrive with symptoms virtually identical to those associated with miscarriage,[177] deaths within the U.S. following the use of RU-486 may be higher, but unreported.

Moreover, as discussed above, the mortality rate for surgical abortion for the first eight weeks of pregnancy is 0.1 per 100,000.[178] The makers of RU-486 report that 575,000 women have used the drug (based on units shipped, not units prescribed, and based on the assumption that one tablet—rather than the FDA-approved three—is administered to the patient;[179] the actual number of women who have taken the drug may be much lower). Using the figure of 575,000 women having taken RU-486, this works out to a known death rate of approximately 1.39 per 100,000, nearly *14 times* greater than surgical abortion. As noted above, Subpart H drug approval is conditioned on "meaningful therapeutic benefit." The statistics demonstrate that medical abortion is far more dangerous than the existing treatment of surgical abortion, which is proof of a lack of clinical benefit.

(a)(3) Use after marketing demonstrates that post-marketing restrictions are inadequate to assure safe use of the drug product

Experience shows that post-marketing restrictions on RU-486 are inadequate to assure the safe use of the product, because the medical community has ignored them on a widespread basis. As noted earlier in this report, abortion providers routinely use RU-486 beyond the time periods approved by the FDA[180] and with dosing regimens that stray from the FDA's approved

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[176] Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee).

[177] "Dear Emergency Room Director" Letter from Danco Laboratories to emergency room directors, (Nov. 12, 2004), *at* http://www.fda.gov/cder/drug/infopage/mifepristone/DearER.pdf.

[178] Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353:22 *at* 2318.

[179] *Ibid.*

[180] Some abortion providers (e.g., Planned Parenthood of New York City at www.ppnyc.org/services/factsheets/mifep.htm, Capital Care Women's Center at www.capitalcarewomenscenter.com/services.php, and Camelback Family Planning at www.camelbackfamilyplanning.com/abortionpill.html.), even advertise the availability of RU-486 through 63 days LMP, by which time the rate of incomplete abortion, infection, and other complications rises sharply. In U.S. clinical trials, the failure rate for RU-486 abortions jumps to 17% at 50-56 days LMP, and to 23% at 57-63 days LMP, from 8% at 49 days or less. Irving Spitz *et al*., "Early pregnancy termination with mifepristone and misoprostol in the United States," *New England Journal of Medicine* 1998, 338:1241-47.

regimen.[181] While off-label use of drugs is common, it runs contrary to the entire purpose of the regulatory regime approved for RU-486 under Subpart H.

The FDA is aware of the medical community's refusal to heed the regulations it instated on RU-486. In its own words, the FDA "is aware that…some [physicians] may have chosen to use a modified version of the Patient Agreement form. However, these decisions are made by physicians exercising their own judgment about what is best for their patients**.**"[182]

This is contrary to the detailed Risk Management Program, explained in the FDA memo detailing the drug's approval, which states: "the signed agreement form will be given to the patient for her reference and another kept in the medical records," and "[the prescribing physician] must provide each patient…with a copy of the Medication Guide and Patient Agreement, give 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."[183] The FDA determined that these restrictions were critical to the safe use of the drug, and in spite of this, physicians have refused to heed them.

(a)(4) The applicant fails to adhere to the post-marketing restrictions agreed upon

Although the FDA stipulated that the manufacturer have systems in place to track the distribution of RU-486 "to the patient level," and that require physicians to "record the Mifeprex package serial number in each patient's record,"[184] Danco has not provided reliable patient numbers, but rather estimates.[185]

In addition to the FDA requiring patients to sign a Patient Agreement form, the Population Council agreed, as part of the approval process, to "auditing prescribers to ascertain whether they have obtained signed copies of the Patient Agreement forms." It is unclear whether the Population Council, Danco, or any other entity associated with the production of RU-486 has adhered to this requirement.

(a)(5) The promotional materials are false or misleading

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[181] R. Hausknecht, "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67 (2003): 463-65: "Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg)."

[182] Letter from Patrick Ronan, Associate Commissioner for Legislation Department of Health and Human Services FDA to Hon. Mark E. Souder, (March 16, 2006) (on file with Govt. Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources).

[183] Memorandum from FDA Center for Drug Evaluation and Research to Population Council 6, (Sept. 28, 2000) (available at http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf).

[184] *Ibid.*

[185] Richard Hausknecht, Medical Director for Danco, described how Danco estimates the usage figures for RU-486: "Denominators… were estimated from sales figures. Although the FDA-approved regimen specified a single oral dose of mifepristone 600 mg, many physicians are using a lower dose (200 mg), …[an] estimated range was based upon Planned Parenthood practices and National Abortion Federation (NAF) polling of their membership practices…[and by] [a]djusting for utilization patterns of providers." *Contraception* 67 (2003): 463-65.

The FDA conditioned approval of RU-486 on tracking its use "to the patient level." In spite of this, the manufacturer estimates the usage of its drug for its promotional materials.[186] This affects the perceived safety of the drug, as the manufacturer may be overstating its actual usage in comparison with the adverse events reported.

Both the "Imminent Hazard" provision and the regulatory provision for approval withdrawal under Subpart H provide sufficient authority for the Administration to remove this dangerous drug from the market.

VI. CONCLUSION

The integrity of the FDA in the approval and monitoring of RU-486 has been substandard and necessitates the withdrawal of this dangerous and fatal product before more women suffer the known and anticipated consequences or fatalities. RU-486 is a hazardous drug for women, its unusual approval demonstrates a lower standard of care for women, and its withdrawal from the market is justified and necessary to protect the public's health.

[186] *Ibid*. *See also*, Letter from David W. Boyer, Assistant Commissioner for Legislation, to Hon. Mark E. Souder, Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, (May 2, 2006) (on file with Subcommittee); *FDA Announces Mifeprex Not Cause of One of Two Recent Abortion-Related Deaths*, KAISER NETWORK DAILY REPORTS, (April 11, 2006) *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=36534. ("We stand behind the safety profile of the drug, which has been used by approximately 575,000 women in this country since FDA approval in 2000," quoting Cynthia Summers, director of marketing and public affairs at Danco Laboratories, originally in Wall Street Journal, April 11, 2006.)