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

[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]."

[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.

[redacted] 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]

[redacted] 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

[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.

[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.

By: s/ *Erik C. Baptist*

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**Pro Hac Vice Application forthcoming*