Nos. 23-235 and 23-236

In the Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
PETITIONERS

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

DANCO LABORATORIES, L.L.C.,
PETITIONER

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.

JOINT APPENDIX
(Volume 1 of 2)

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients, Plaintiffs, v.	**Case No. _____**

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.

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, 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.

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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).

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 members, and their patients. Drs. Donna Harrison,

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

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 patients. Drs. Jeffrey Barrows and Steven

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[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.

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 suffering complications

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

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.

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[7] Abortion Pill Reversal, https://www.abortionpillreversal.com/abortion-pillreversal/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 girl[8] when the agency authorized the chemical abortion drugs mifepristone and misoprostol for use in the 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. §

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[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.

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 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

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[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/.

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

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[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).

[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),

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]

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

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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).

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]

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

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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.

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

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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://women-help.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).

[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.

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 chemical abortion drugs from Planned Parenthood.[25] The abortionist misdated the baby's gestational age as six weeks, resulting in the at-

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[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/.

[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.

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]

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).

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[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 gTheir Safety and Effectiveness*, Congressional Research Service (May 8, 2018), https://crsreports.congress.gov/product/pdf/R/R41983.

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

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

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 s*erious 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]

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

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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).

> 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

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

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 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

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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.").

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]

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

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

[38] *Id.*

[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/populationcouncil/(last visited Nov. 15, 2022).

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]

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

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[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.

[44] *Id.* at 10.

[45] *Id.*

[46] *Id.* at 10-11.

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]

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

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[47] Ex. 23, FDA Letter to Population Council re: NDA (Feb. 18, 2000) at 5.

[48] *Id.*

[49] Ex. 13, 2002 Citizen Petition at 20.

[50] *Id.*

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 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]

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[51] *Id.*

[52] *Id.*

[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).

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 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]

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

[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.

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]

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

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[61] *Id.* at 2.

[62] *Id.*

[63] *Id.* at 2-3.

[64] *Id.* at 3.

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]

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

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[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/AAPLOGStatement-on-FDA-removing-mifepristone-REMS-April-2021-1.pdf.

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

[67] *Id.*

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] 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

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[68] *Id.*

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

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

[71] *Id.*

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

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

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] 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

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[74] *Id.*

[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).

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 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

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

[78] *Id.* at 1.

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, 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

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[79] *Id.*

[80] *Id.* at 18–23, 41–48.

[81] *Id.* at 19.

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, 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]

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[82] *Id.* at 21-22.

[83] *Id.* at 37.

[84] *Id.* at 24-41.

[85] *Id.* at 49-71.

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

(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]

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[86] *Id.* at 75-76.

[87] *Id.* at 76.

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 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

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[88] *Id.* at 71-75.

[89] Ex. 13, 2002 Citizen Petition at 75.

[90] *Id.* at 76-83.

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 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

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[91] *Id.* at 84-85.

[92] *Id.* at 86.

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

[94] Ex. 26, 2003 Response.

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]."

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,

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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.

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 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-

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[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.

[100] Ex. 29, 2011 Approval Letter at 2–3.

[101] Ex. 27, 2016 Petition Denial.

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 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

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[102] *Id.* at 4 (emphasis added).

[103] *Id.*

[104] *Id.*

[105] *Id.* at 5.

[106] *Id.* at 9.

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 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

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[107] *Id.* at 29.

[108] *Id.* at 15.

[109] *Id.*

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]

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]

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

[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.

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);

(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

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[113] *Id.* at 6-10.

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]

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

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[114] *Id.* at 27.

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 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

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

[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.

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.

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

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

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

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

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

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 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

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[119] *Id.* at 18-19.

[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).

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 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

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[124] *Id.*

[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").

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 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

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[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).

[130] Ex. 18, Niinimaki, *supra* note 14 at 3–4.

[131] Ex. 32, 2016 Summary Review at 20.

[132] *Id.* at 19.

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 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:

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[133] *Id.* at 20.

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

- 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;
- 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 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]

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[135] *Id.*

[136] *Id.* at 13-14.

[137] *Id.*

[138] *Id.* at 14-25.

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.

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

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[139] *Id.* at 18–20.

[140] *Id.* at 20–23.

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

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]

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.

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[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.

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

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]

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

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

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

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]

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

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[147] *Id.*

[148] *Id.*

[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.

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 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');

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[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.pag e&REMS=390.

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

[152] *Id.*

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 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

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[153] *Id.*

[154] *Id.*

[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.

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 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]

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[157] Ex. 43, 2021 FDA Response.

[158] *Id.* at 2-3.

[159] *Id.* at 38.

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 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

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[160] *Id.* at 25.

[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-fdasadverse-event-reporting-system-faers.

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 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

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[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).

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

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

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]

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:

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

[168] *Id.*

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]

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]

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[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").

[170] *See* Compl. ¶¶ 141–158.

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]

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

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[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.

[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.

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 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,

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[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.

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

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]

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

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[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.

[181] Ex. 9, Wozniak Decl. ¶ 24.

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]

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]

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[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.

[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.

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]

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

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[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.

[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.

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]

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

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[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.

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 medicines. [196] This need for blood transfusions

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

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

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

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

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[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-urgentamerican-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.

performed a dilation and curettage (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 members of Plaintiff medical associations, especially given that

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[200] Ex. 52, Jester Decl. ¶ 17.

[201] Ex. 9, Wozniak Decl. ¶¶ 24–25.

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

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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 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 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

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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.

abortion drug, misoprostol, which failed to resolve her complications. When Dr. Skop treated the young woman, Dr. Skop performed a sonogram, 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

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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.

abortion drugs and the demands and expectations that hospitals will put on their physicians.[210]

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]

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[210] Ex. 5, Barrows Decl. ¶ 25.

[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.

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]

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]

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[214] Ex. 4, Harrison Decl. ¶ 33.

[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.

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]

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]

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[217] Ex. 9, Wozniak Decl. ¶ 26.

[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.

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 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]

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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.

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.

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

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[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.

[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.

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 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

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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.

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. 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.

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[229] Ex. 3, Dickerson Decl. ¶¶ 17–20.

[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.

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).

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)." 21C.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

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

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 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.

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

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.

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. 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*

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members' 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.	**Case No. _____**

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.

DECLARATION OF MARIO R. DICKERSON

I, Mario R. Dickerson, a citizen of the United States and a resident of Willow Grove, Pennsylvania, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I serve as the Executive Director of the Catholic Medical Association ("CMA"). Given my involvement in CMA, I am familiar with the organization's history, the issues confronting it, and the views of the organization and its members concerning various emerging issues, including the deregulated use of mifepristone, or RU-486, to accomplish chemical abortions. I am also familiar with CMA members and their practices.

3. CMA is the largest association of Catholic individuals in healthcare. CMA is a national, physician-led community that includes about 2700 physicians and healthcare professionals nationwide.

4. CMA is a nonprofit organization incorporated in Virginia, and its registered agent is in Virginia.

5. CMA's mission is to inform, organize, and inspire its members, in steadfast fidelity to the teachings of the Catholic Church, to uphold the principles of the Catholic faith in the science and practice of medicine.

6. CMA seeks to pursue its mission in conformity to Christ the Divine Physician. Its members are challenged to be a voice of truth spoken in charity, to show how Catholic teachings on the human person, human rights and the common good intersect with and improve the science and practice of medicine, and to defend the sacredness and dignity of human life at all stages.

7. CMA is a member of the Alliance for Hippocratic Medicine (AHM).

8. CMA is committed to taking a Catholic and Hippocratic approach to medicine.

9. Consistent with Catholic teaching, CMA and its members are morally and ethically opposed to all forms of abortion—chemical or surgical.

10. I have spoken with CMA members who have treated women harmed by chemical abortion drugs.

11. The FDA's unauthorized approval of mifepristone (also known as "Mifeprex" and "RU-486") and subsequent elimination of certain safeguards for the use of the dangerous chemical abortion drug regimen, including those found in the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, has led to an increasing risk that women and girls may suffer adverse events from chemical abortion.

12. The FDA has continued to eliminate safeguards such that the chemical abortion drugs can now be administered and dispensed with no in-person examination or oversight by a physician. This leaves physicians, including CMA members, to treat the complications that women and girls suffer due to the actions of the FDA and abortionists.

13. CMA's member physicians include OB/GYNs and emergency department physicians who have treated women suffering complications from chemical abortion.

14. The FDA's actions harm CMA and its member physicians who are called away from other patients to render emergency treatment to women and/or girls who present to emergency departments with symptoms, such as heavy bleeding and severe pain, and more serious complications, including hemorrhage and sepsis caused by chemical abortion drugs. This causes CMA's member physicians much stress and grief, while

impeding their ability to perform their practice of medicine in the manner that they desire.

15. Often, emergency department doctors do not have a prior relationship with these patients and lack access to the patient's medical history. Sometimes these patients were underinformed about the effects of the chemical abortion drug regimen, they may not even know what drugs they consumed, or they are told to say they are suffering a miscarriage if there is a need for them to seek emergency help following a chemical abortion. This leaves doctors at increased risk of liability and could impact their ability to render the best care possible to the patient—all because of the FDA's elimination of necessary safeguards.

16. Moreover, the FDA's removal of necessary safeguards could force CMA members to treat women and girls who present to emergency departments following an elective chemical abortion requiring those doctors to complete an unfinished elective abortion—terminating the life of an unborn child—in violation of their conscience rights.

17. Since 2005, CMA has called upon the FDA to respond to citizens petitions calling for removal of RU-486 from the market in an urgent action. CMA renewed this resolution in 2015.

18. In 2016, CMA enacted a resolution that called for the FDA to require a central registry for all those having a chemical abortion, with mandatory reporting from every state and territory of complications and mortalities from chemical abortions; that the drug be administered only by a physician with surgical privileges at a hospital within 30 minutes of the facility where the drug is dispensed; that the dispensing

physician be responsible for follow-up and handling of complications; and that the patient be informed that the process could be stopped without harm to her or the baby.

19. These resolutions are vital to ensure the safety of women and girls, and to protect doctors, including CMA members.

20. CMA has spent considerable time, effort and resources challenging the FDA's actions—at the expense of other CMA priorities. For example, to implement these resolutions, committees have had to review them, it has taken time during General Assembly meetings to discuss them, which takes our members away from their other business, and it has taken time for our Executive Director and Board to review, taking them away from other priorities such as fundraising and membership recruitment and retention.

21. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain unknown and undercounted. This prevents CMA from providing the public, their members, and their members' patients with accurate statistics and complete information regarding the risks associated with the use of chemical abortion drugs.

22. CMA is a leading national voice on applying the principles of the Catholic faith to medicine. CMA creates and organizes educational resources and events; advocates for members, the Church, and the medical profession in public forums; and provides guidance for bishops and other national leaders on healthcare ethics and policy. The inability to share accurate information on the risks of chemical abortion frustrates and

complicates CMA's purpose to educate doctors, their patients, and the public about these dangers.

Executed this November 12, 2022.

By: [*Signature*]
Mario R. Dickerson

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients, Plaintiffs, v.	**Case No. _____**

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.

DECLARATION OF DR. DONNA HARRISON

I, Donna Harrison, a citizen of the United States of America and a resident of Berrien Center, Michigan, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified obstetrician and gynecologist.

3. I received my medical degree from the University of Michigan and completed my residency at a University of Michigan affiliate hospital, St. Joseph Mercy Hospital.

4. I am a diplomate of the American Board of Obstetrics and Gynecology.

5. I serve as the Chief Executive Officer of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).

6. I also serve as the President of Plaintiff Alliance for Hippocratic Medicine (AHM).

7. I am familiar with AAPLOG, its members, their fields of practice, and AAPLOG's policies and positions, including as set forth in the complaint, which I have reviewed.

8. AAPLOG is the largest organization of pro-life obstetricians and gynecologists ("OB/Gyns") in the world and is headquartered in Indiana. AAPLOG includes OB/Gyns and other physicians, with more than 7,000 medical professionals nationwide and more than 300 members in Texas. AAPLOG members oppose elective abortion and are committed to the care and well-being of their patients including both pregnant women and their unborn children. AAPLOG members are concerned about the adverse impacts of chemical abortion on their practice of medicine.

9. AAPLOG's mission includes advocating on behalf of its members, including in litigation.

10. AAPLOG sues in this case on behalf of itself and its members.

11. I am also familiar with AHM, its members, their members' fields of practice, and AHM's policies and positions, including as set forth in the complaint, which I have reviewed.

12. AHM is a nonprofit organization that upholds and promotes the fundamental principles of Hippocratic medicine. AHM is incorporated in the State of Texas and has its registered agent in Amarillo, Texas.

13. AHM's members include the membership of the American Association of Pro-Life Obstetricians and Gynecologists, American College of Pediatricians, Catholic Medical Association, Christian Medical and Dental Associations, and Coptic Medical Association of North America. In opposing chemical abortion, AHM's members are concerned about the safety and well-being of pregnant women and girls, their preborn children, and chemical abortion's adverse impacts on the practice of medicine.

14. AHM sues in this case on behalf of itself and its members.

15. I am familiar with chemical abortion drugs, their use, and the complications that accompany chemical abortion.

16. As part of my duties and responsibilities at AAPLOG, I have authored several studies on the approval of mifepristone as an abortifacient. Among these, I co-authored two studies with other physicians and scholars examining the adverse events associated with the use of mifepristone. Our studies of the real-world use of mifepristone concluded that significant

morbidity and mortality have occurred following the use of mifepristone as an abortifacient. We recommended that a pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm the gestational age of the unborn child. We concluded that the FDA's adverse event reporting system is grossly inadequate to evaluate real-world complications and significantly underestimates adverse events from mifepristone. One major reason that the FAERS database does not reflect real world complications is that FDA only required the manufacturer to report complications, and the manufacturer in turn obtains data from the abortionists. However, as our studies of the FAERs database indicate, most complications are not handled by the abortion provider, but rather by the Emergency Department, and the Emergency Department physician has no knowledge of the reporting process or obligation to report those complications to the manufacturer or to the FDA. *See* Kathi Aultman, et al., *Deaths and Severe Adverse Events After the Use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues L. Med. 3 (2021), https://pubmed.ncbi.nlm.nih.gov/33939340/; Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 Ann. Pharmacother. 171 (2006), https://pubmed.ncbi.nlm.nih.gov/16380436/.

17. In addition, as part of my duties and responsibilities at AAPLOG, I co-authored a paper comparing the published complications after use of mifepristone from Planned Parenthood in 2009 and 2010 and compared those numbers to the complications in the FDA Adverse Event Reporting System for the same

time period. We found that Cleland identified 1,530 Planned Parenthood mifepristone cases with specific adverse events (AEs) for 2009 and 2010. For this period, FAERS online dashboard includes a total (from all providers) of only 664, and the FDA released only 330 adverse event reports (AERs) through Freedom of Information Act (FOIA) requests. Cleland identified 1,158 ongoing pregnancies in 2009 and 2010. FAERS dashboard contains only 95, and only 39 were released via FOIA requests. We concluded that there are significant discrepancies in the total number of AERs and specific AEs for 2009 and 2010 mifepristone abortions reported in 1) Cleland's documentation of Planned Parenthood AEs, 2) FAERS dashboard, and 3) AERs provided through FOIA. These discrepancies render FAERS inadequate to evaluate the safety of mifepristone abortions. *See* Christina A Cirucci, et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act,* 8 Health Servs. Rsch. & Managerial Epidemiol. 23333928211068919 (2021), https://pubmed.ncbi.nlm.nih.gov/34993274/.

18. I also co-authored a study looking at the real-world effects of the FDA Approval of Mifeprex on Emergency Room utilization after Mifeprex abortions. The massive increased utilization of Emergency Departments to manage abortion complications is a predictable consequence of the FDA's failure to require the same qualifications of Mifeprex abortion providers as were mirrored in the clinical trial for Mifeprex approval.

19. Because the FDA abandoned the post marketing requirement that abortion providers have admitting privileges to handle their own complications and allowed abortion providers who lack the ability to handle complications to dispense Mifeprex, the predictable consequence is the explosion of Mifeprex complications including hemorrhage, adding to the current shortage of blood and blood products across the United States. *See* James Studnicki, et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015*, 8 Health Servs. Rsch. & Managerial Epidemiol. 23333928211053965 (2021), https://pubmed.ncbi.nlm.nih.gov/34778493/.

20. I am familiar with the FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol. As part of my duties and responsibilities at AAPLOG, I co-authored the original 2002 Citizen Petition and the 2019 Citizen Petition filed by AAPLOG and others to challenge the FDA's actions on chemical abortion drugs. As part of my duties and responsibilities at AAPLOG, I also co-authored a study detailing the aberrancies of the FDA Approval process as it affects real-world patients. *See* Byron C. Calhoun & Donna J. Harrison, *Challenges to the FDA Approval of Mifepristone,* 38 Ann. Pharmacother. 163 (2004), https://pubmed.ncbi.nlm.nih.gov/14742814/.

21. In a chemical abortion, women take mifepristone to terminate the pregnancy by killing the preborn child. Women then take misoprostol to expel all pregnancy tissues, including the preborn child, through contractions and cramping.

22. Women who take chemical abortion drugs experience more complications than those who have surgical abortions.

23. There are many intense side effects for women who take chemical abortion drugs, including cramping and heavy bleeding.

24. Since the FDA's 2000 Approval of Mifeprex (the chemical abortion drug regimen consisting of mifepristone and misoprostol), medical professionals have needed to treat women and girls who have suffered from chemical abortion and experienced complications.

25. Mifepristone and misoprostol are serious drugs that should not be administered without medical supervision. The FDA's actions to eliminate the necessary supervision of these drugs harm women and obstetrics professionals, including AHM, AAPLOG, and their members.

26.Since the FDA's 2016 Major Changes to eliminate safeguards for the use of Mifeprex, AAPLOG members have needed to treat an increasing rate of women and girls who suffer complications from chemical abortion.

27. The increase in the frequency of complications harms medical providers—including AHM and AAPLOG members—because they end up managing the increase in complications.

28. When women suffer complications from chemical abortions, it can overwhelm the medical system and consume crucial limited medical resources, including blood for transfusions, physician time and attention, space in hospital and medical centers, and other equipment and medicines.

29. The increased occurrence of complications related to chemical abortions also multiplies the workload of healthcare providers, including AHM and AAPLOG members, in some cases by astronomical amounts. This is especially true in maternity care "deserts" (i.e., geographic areas where there are not a large number of OB/Gyn providers for patients).

30. For OB/Gyn professionals, the increase in complications due to increased use of chemical abortion drugs means that the typical care given to patients goes from simple patient management to complicated patient management. Patients who suffer complications from chemical abortions require significantly more time and attention from providers than the typical OB/Gyn patient requires.

31. In my experience, many patients do not fully understand the nature of chemical abortion or the risks that these drugs present to them. This results in an increase in the frequency of women seeking emergency medical care for side effects such as cramping, heavy bleeding, and severe pain even if they are not suffering an adverse event.

32. I understand that the FDA has removed the requirement for abortionists to report all adverse events for mifepristone.

33. Many doctors likely do not know about the need to report adverse events related to chemical abortion to the FDA. Similarly, many doctors likely do not know how to report adverse events. This means that complications handled by practitioners other than the abortionist are rarely reported to the FDA or the manufacturer.

34. I personally know of practitioners, including AAPLOG members, who have tried to report adverse events related to chemical abortion drugs to the FDA. The process is complicated, cumbersome, and time-consuming. The adverse event reporting requirements and the FAERS submission process harm medical practices by taking away significant time from a doctor to treat and meet with patients.

35. The FDA's decision not to require abortionists to report all adverse events for mifepristone harms women and girls because this deregulatory action creates an inaccurate and false safety profile for the use of mifepristone and misoprostol.

36. Without an accurate picture of the adverse effects of widespread chemical abortion drug use, physicians cannot effectively practice evidence-based medicine. If the FDA is not collecting the vast majority of adverse events to understand the true risk, healthcare providers cannot assess the risks of a particular course of treatment and inform their patients accordingly.

37. The inability of providers to adequately inform women of the known risks associated with chemical abortion drugs precludes women and girls from giving informed consent to taking these drugs. The lack of information also harms the patient-doctor relationship with all medical care providers because the patients no longer trust that their healthcare providers are telling the truth. This even harms organizations and practitioners who do not support or practice chemical abortion, including AHM, AAPLOG, and their members.

38. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion

drugs remain unknown and undercounted. This prevents AHM and AAPLOG from providing the public, their members, and their members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

39. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates AHM's and AAPLOG's purpose to support women's health and to educate doctors, their patients, and the public about these dangers.

40. AHM and AAPLOG need to divert limited time, energy, and resources to compensate for this lack of information by conducting their own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of AHM and AAPLOG, including their efforts regarding the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.

41. On behalf of AAPLOG and serving as the chairperson for AAPLOG' s Subcommittee on Mifeprex, I submitted a Citizen Petition in 2002 challenging the FDA's approval of Mifeprex and requesting an audit of the Mifeprex clinical studies. AAPLOG, as an organization, is concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving Mifeprex put women's lives and health at risk. It took considerable time, energy, and resources to draft the 92-page petition and the 30-page response to comments letter, in addition to compiling

and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

42. Similarly, AAPLOG submitted another Citizen Petition in 2019 challenging the FDA's 2016 major changes to the chemical abortion drug regimen, which I also co-authored. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

43. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, AHM and AAPLOG continue to expend considerable time, energy, and resources on its public advocacy and educational activities regarding chemical abortion drugs-to the detriment of other AHM and AAPLOG priorities and functions. This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs ceases.

44. AHM and AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. The FDA's removal of REMS for safe use—which eliminates in-person

evaluations and follow-up care—places our member doctors at increased risk of being forced to violate their conscience rights. The FDA's actions could force our members into a situation where they must render treatment to a woman in the emergency department suffering complications from chemical abortion while she is still carrying a living fetus, and they must perform a D&C to treat her complications—ending the life of a human being.

Executed this November 11, 2022.

By: [*Signature*]
Donna Harrison, M.D.

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients, Plaintiffs, v.	**Case No. _____**

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.

DECLARATION OF DR. JEFFREY BARROWS

I, Jeffrey Barrows, D.O. M.A. (Ethics), a citizen of the United States and a resident of Blountville, Tennessee, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified obstetrician and gynecologist and am the Senior Vice President of Bioethics and Public Policy for Plaintiff Christian Medical & Dental Associations (CMDA).

3. I practiced obstetrics and gynecology for approximately 18 years. I practiced gynecology in an office setting for an additional ten years.

4. I am familiar with CMDA, its members, their fields of practice, and CMDA's policies and positions.

5. CMDA is a national nonprofit organization headquartered in Tennessee. Its members are more than 13,000 Christian physicians, dentists, and allied healthcare professionals. CMDA has more than 1,200 members in Texas, including more than 600 physicians and approximately 35 OBGYNs.

6. CMDA is opposed to elective abortions as contrary to sacred scripture, respect for the sanctity of human life, and traditional, historical Judeo-Christian medical ethics.

7. CMDA's mission includes advocating on behalf of its members, including in litigation.

8. CMDA brings this suit on behalf of itself and its members.

9. CMDA has members in Texas and around the country who care for pregnant women in hospitals and clinics. CMDA's members care for women who suffer complications from chemical abortions.

10. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain

medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

11. I am familiar with the FDA's approval of chemical abortion drugs in 2000.

12. I am familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.

13. I understand that the FDA's 2016 changes expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks), that it eliminated the in-person administration requirements for chemical abortion drugs, that it eliminated the requirement for a follow-up appointment after those drugs have been taken, and that it eliminated the prescriber reporting requirement for all adverse events except for death.

14. I also understand that the FDA subsequently eliminated the in-person dispensing requirements in 2021.

15. The FDA's actions harm women, practitioners, CMDA members, CMDA as an organization, and the medical profession generally.

16. Mifepristone and misoprostol are dangerous drugs that can potentially harm women. Relaxing the required medical supervision and oversight for patients taking these drugs puts women's health at risk.

17. By eliminating the in-person dispensing requirement and the requirement for a post-abortion follow-up, the FDA has exposed women to a higher likelihood of undetected serious complications.

Specifically, the expanded use of telemedicine for chemical abortions means that some women who are beyond 70 days' gestation because they are mistaken or wrong about the gestational age of their unborn child will take these drugs outside of the appropriate window.

18. Similarly, without in-person visits and sonograms, women with ectopic pregnancies may escape diagnosis, which puts them at a greater risk of serious and life-threatening complications such as rupture of the Fallopian tube and secondary hemorrhage. Undetected ectopic pregnancies are especially dangerous for women because in some cases they can result in extreme bleeding for women.

19. By eliminating the adverse event reporting requirement for all events except death, the FDA has also undermined physicians' ability to practice evidence-based medicine. By failing to collect accurate information about the complications associated with chemical abortion, the FDA leaves doctors without accurate information about the drugs' safety for women.

20. As an organization, CMDA is harmed by the FDA's failure to require reporting of all adverse events, which prevents CMDA from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

21. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates CMDA's purpose to provide professional healthcare and

to educate doctors, their patients, and the public about the dangers of chemical abortion.

22. By removing the requirements for in-person visits, the FDA has increased the risk of malpractice claims against physicians. The best way to prevent malpractice is for physicians to establish relationships with patients who they can treat over time. By doing away with the necessary medical supervision, the FDA will cause more women to present in life-threatening circumstances into the care of hospitalists and emergency department physicians who have no prior history with these patients.

23. By putting more doctors into riskier, emergent medical situations, the FDA's regulatory actions expose physicians to increased claims of liability.

24. The increased risks of exposure to liability and malpractice claims also impacts physicians because it drives up their insurance costs, especially those who practice in the hospital.

25. The FDA's loosening of chemical abortion regulations impacts the standard of care and the demands and expectations that hospitals will put on their physicians. The FDA has radically altered the standard of care for mifepristone and misoprostol. The agency did this without the requisite evidence to support its actions.

26. I am also concerned that the FDA's actions will force CMDA members to complete an unfinished elective abortion in an emergency situation, causing immediate emotional and moral distress for our members who are opposed to elective abortion and do

not want to feel complicit in an immoral, unnecessary procedure.

27. CMDA has been involved with challenging the FDA's approval of chemical abortion drugs for 20 years. In 2002, we submitted a Citizen Petition with other pro-life groups challenging the FDA's actions, diverting valuable time and effort from CMDA's routine functions in order to assist in filing the petition.

Executed this November 12, 2022.

By: [*Signature*]

Jeffrey Barrows, D.O. M.A.

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. QUENTIN L. VAN METER

I, Quentin L. Van Meter, a citizen of the United States and resident of Atlanta, Georgia, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified pediatric endocrinologist.

3. I received my medical degree from the Medical College of Virginia in 1973.

4. I did my pediatric internship (1973-1974) and my pediatric residency (1974-1976) at the Naval Regional Medical Center in Oakland, through the University of California, San Francisco. I completed my pediatric endocrinology fellowship from 1978 to 1980 at The Johns Hopkins Hospital. I also worked as a staff pediatric endocrinologist at the Naval Hospital in San Diego (1980-1986) and was Chairman and Director of the residency training program at the Naval Hospital Oakland (1986-1991).

5. Following a 20-year career in the Navy Medical Corps, I moved to the Atlanta area and joined the Fayette Medical Clinic as a Pediatrician and Pediatric Endocrinologist. To better serve the ever-expanding population of pediatric patients with endocrine disorders, I developed my own full-time pediatric endocrine practice. Specifically, my practice helps children by treating them for disorders related to hormones and the endocrine glands that produce them.

6. I currently serve as the president of the American College of Pediatricians.

7. I am familiar with the American College of Pediatricians, its members, their fields of practice, and the organization's policies and positions, including as set forth in the complaint, which I have reviewed.

8. The American College of Pediatricians is a national organization of pediatricians and other healthcare professionals. Its membership includes more than 600 physicians and other healthcare professionals drawn

from 47 different states across the nation. The American College of Pediatricians has members in the State of Texas.

9. The American College of Pediatricians brings this suit on behalf of itself and its members.

10. I am familiar with the FDA's approval of mifepristone and issuance of a risk evaluation and mitigation strategy (REMS) for the chemical abortion drug regimen, which includes both mifepristone and misoprostol.

11. I understand that prior to the 2000 approval of mifepristone, the FDA never required a clinical study evaluating the safety and effectiveness of chemical abortion drugs on pregnant girls under 18 years of age.

12. As a blocker of the hormone progesterone, mifepristone is an endocrine disruptor and, therefore, could interfere with pubertal development or adversely impact an adolescent girl's developing body and reproductive system. The FDA's failure to require pediatric clinical studies places girls at risk from these drugs, which have the potential to dangerously adversely impact the health, safety, and welfare of the exposed adolescents.

13. To my knowledge, the FDA's 2000 approval of mifepristone for use in girls was unsupported by any scientific data showing that chemical abortion drugs are safe for girls under 18 years of age.

14. By failing to require studies, the FDA's 2000 approval placed young girls going through their reproductive development at risk.

15. Numerous studies have demonstrated that there is an increased risk from chemical abortion drugs to pregnant women and girls as compared to surgical abortion.

16. One recent study discovered that one-third of all post-abortion hospital emergency department visits in 2015 were after use of chemical abortion drugs. The FDA's elimination of REMS and loosening of restrictions increases the risk that girls will suffer complications from chemical abortion drugs.

17. I am also aware that, in 2016, the FDA eliminated the requirement that abortionists report non-fatal adverse events-preventing the agency, women and girls, their doctors, and the public from having an accurate understanding of the complications from chemical abortion drugs and the rate at which they occur.

18. Women, girls and their parents cannot give informed consent to chemical abortions drugs without this necessary information. And doctors cannot accurately apprise their patients about the dangers of chemical abortion drugs without adequate studies elucidating these risks.

19. The American College of Pediatricians is also harmed by the FDA's failure to require reporting of all adverse events because it prevents us as an organization from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

20. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and compromises

our organization's purpose to provide professional healthcare and to educate doctors, their patients, and the public about the dangers of chemical abortion.

21. The American College of Pediatricians has challenged the FDA's continued deregulation of chemical abortion drugs. In 2019, we submitted a Citizen Petition with another pro-life group challenging FDA's 2016 major changes. It took considerable time, energy, and resources to assist in drafting the 26-page petition and compiling and analyzing supporting sources and studies. This effort caused the American College of Pediatricians to divert limited time, energy, and resources from its other priorities and routine functions.

22. The American College of Pediatricians continues to expend considerable time, energy, and resources on its public advocacy and educational activities exposing the risk of harm to women, including pediatric girls, from the FDA's unlawful approval and deregulation of chemical abortion drugs.

Executed this November 11, 2022.

By: [*Signature*]

Quentin L. Van Meter, M.D.

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. CHRISTINA FRANCIS

I, Christina Francis, a citizen of the United States of America and a resident of Indiana, declare under penalty of perjury under 28 U.S.C. § 17 46 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified Obstetrician and Gynecologist (OB/Gyn) in good standing and licensed to practice in Indiana. I have been in active practice for 14 years and have worked for the last six years as an OB/Gyn Hospitalist in Fort Wayne, Indiana.

3. As an OB/Gyn Hospitalist, my practice is completely hospital-based. I manage both high- and low-risk pregnancies and deliveries, obstetric critical care, gynecological emergencies presenting to our Emergency Department, and inpatient obstetric and gynecologic consultations.

4. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG). I am also the CEO-elect of AAPLOG.

5. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.

6. AAPLOG is the largest organization of pro-life obstetricians and gynecologists ("OB/Gyns") in the world and is headquartered in Indiana. AAPLOG includes OB/Gyns and other physicians, with more than 7,000 medical professionals nationwide and more than 300 members in Texas. AAPLOG members oppose elective abortion and are committed to the care and well-being of their patients including both pregnant women and their unborn children. AAPLOG members are concerned about the adverse impacts of chemical abortion on their practice of medicine.

7. AAPLOG's mission includes advocating on behalf of its members, including in litigation.

8. AAPLOG sues in this case on behalf of itself and its members.

9. I am familiar with the FDA's regulation of chemical abortion drugs, including mifepristone and misoprostol.

10. I have seen first-hand the complications that can result from use of these dangerous chemical abortion drugs. Although Fort Wayne does not have an abortion facility, I have seen several women present with complications after seeking chemical abortions with mifepristone and misoprostol.

11. The frequency of these complications has increased since a federal district court first enjoined and set aside the FDA's in-person dispensing requirement for mifepristone in 2020.

12. As an example of how chemical abortion harms my patients and my medical practice, one of my patients had obtained mifepristone and misoprostol from a website, without an in-person visit. She was told that the drugs would come from India. After taking the chemical abortion drugs, she began having very heavy bleeding followed by significant abdominal pain and a fever. When I saw her in the emergency room, she had evidence of retained pregnancy tissue along with endometritis, an infection of the uterine lining. She also had acute kidney injury, with elevated creatinine. She required a dilation and curettage (D&C) surgery to finish evacuating her uterus of the remaining pregnancy tissue and hospitalization for intravenous (IV) antibiotics, IV hydration, and a blood transfusion. I spent several hours with her the day of her surgery/hospital admission, keeping me from my primary patient responsibilities in the labor and

delivery unit and requiring me to call in an additional physician to help cover those responsibilities.

13. As an additional example, a partner of mine and I cared for another patient who also suffered complications from chemical abortion. I had taken care of her when she was hospitalized for hyperemesis gravidarum at 9 weeks 5 days gestation. She was discharged home in good condition after significant improvement with medications. During that hospital stay, she had an ultrasound, which showed a healthy pregnancy with no apparent complications and a strong fetal heart rate. During her hospitalization, she expressed to me that she was considering abortion because of experiencing hyperemesis but was unsure. Approximately one week after her discharge, the patient presented back at our emergency room with heavy vaginal bleeding and unstable vital signs as a result of taking chemical abortion drugs. One of my partners was able to detect a fetal heartbeat. Due to the amount of bleeding that she was experiencing and evidence of hemodynamic instability, however, my partner had no choice but to perform an emergency D&C. The patient needed to be hospitalized overnight for close observation after the D&C. Not only did my partner need to provide several hours of critical care for this patient, but my partner also needed to call in a back-up physician to care for another critically ill patient. And because the preborn baby still had a heartbeat when the patient presented, my partner felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion.

14. As we see an increasing number of complications related to chemical abortions, it will place a greater

strain on our healthcare system (especially in light of the fact that we are in the midst of a nationwide blood shortage and there are several healthcare deserts where there are no OB/Gyn's), and more physicians with ethical and medical objections to abortion will be forced to participate in completing unfinished elective chemical abortions in emergency situations, just as my partner was.

15. AAPLOG members are opposed to being forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion. The objections are both ethical and medical as they stem from the purpose of medicine itself, which is to heal and not to electively kill human beings regardless of their location. Accordingly, AAPLOG and our members are harmed by the FDA's repeated removal of necessary safeguards, which may force them to treat women and girls seeking the completion of an elective chemical abortion.

16. AAPLOG, its members, and their patients are also harmed by the FDA's actions that require prescribers to report only deaths and no other complications associated with chemical abortion. As a physician, I know that other complications have significant impacts on my patients as well as our healthcare system. Therefore, the FDA should require reporting of these complications too. But the system for reporting adverse events is not set up to be conducive for busy physicians to report these complications and takes a significant amount of time.

17. To report complications to the manufacturer, Danco, a form must be printed, filled out by hand, and

then either mailed or scanned and emailed back. Much of the information required by this form is impossible to obtain by the physician seeing the patient if they were not the one who dispensed the chemical abortion drugs (such as lot number and dosage)-forcing me to leave several fields blank. I never received confirmation from Danco whether the complications I reported were recorded or reported to the FDA.

18. In addition to reporting to the manufacturer, the process of reporting to the FDA Adverse Event Reporting System (FAERS) is also cumbersome. The actual form to be filled out is not easy to find online—requiring several steps to get to it. It once took me two hours to get the website to accept submission of the form, taking me away from the care of my other patients. The minimum amount of time I have spent reporting a mifepristone complication to the FAERS is thirty minutes—valuable time that should be spent in patient care.

19. The FDA's failure to require reporting of all adverse events, combined with its inadequate reporting system, prevents AAPLOG from providing the public, our members, and our members' patients with accurate statistics and complete information regarding potential risks associated with the use of chemical abortion drugs.

20. The inability to share accurate information with member physicians, their patients, and the public on the risks of chemical abortion frustrates and complicates AAPLOG's purpose to support women's health and to educate doctors, their patients, and the public about these dangers. It forces physicians to actually provide their patients with inaccurate

information, leading to the lack of fully informed consent for women.

21. AAPLOG needs to divert limited time, energy, and resources to compensate for this lack of information by conducting our own studies and analyses of the available data. This diversion of time, energy, and resources comes to the detriment of other advocacy and educational efforts of AAPLOG, including our efforts regarding the dangers of surgical abortion, the conscience rights of doctors, and the sanctity of life at all stages.

22. In 2002, AAPLOG submitted a Citizen Petition challenging the FDA's approval of Mifeprex and requesting an audit of the Mifeprex clinical studies. AAPLOG, as an organization, is concerned about women's health issues and recognized that the FDA's violations of its standards and rules in approving Mifeprex put women's lives and health at risk. It took considerable time, energy, and resources to draft the 92-page petition and the 30-page response to comments letter, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

23. Later, in 2019, AAPLOG submitted another Citizen Petition challenging the FDA's 2016 major changes to the chemical abortion drug regimen. It also took considerable time, energy, and resources to draft the 26-page petition, in addition to compiling and analyzing supporting sources and studies. This effort caused AAPLOG to divert limited time, energy, and resources from its other priorities and routine functions.

24. Because abortion activists continue to file their own citizen petitions and letters with the FDA asking the agency to eliminate all protections for women and girls who take chemical abortion drugs, and knowing the Biden administration's relentless, politicized efforts to push these drugs throughout the country, AAPLOG continues to expend considerable time, energy, and resources on its public advocacy and educational activities regarding chemical abortion drugs—to the detriment of other AAPLOG priorities and functions. This diversion of time, energy, and resources will not cease until the FDA's approval and deregulation of chemical abortion drugs ceases.

Executed this November 11, 2022.

By: [*Signature*]

Christina Francis, M.D.

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients, Plaintiffs, v.	**Case No. _____**

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.

DECLARATION OF DR. INGRID SKOP

I, Ingrid Skop, a citizen of the United States and a resident of San Antonio, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified obstetrician and gynecologist working for OB Hospitalist Group with privileges in the Baptist Hospital System.

3. I also serve as a Senior Fellow and Director of Medical Affairs at the Charlotte Lozier Institute.

4. I am a member of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), where I served as a member of the board from 2018-2020. I am also a member of the Christian Medical & Dental Associations.

5. I received my medical degree from Washington University School of Medicine in 1992 and completed my residency in obstetrics and gynecology at the University of Texas Health Sciences Center at San Antonio in 1996.

6. My current practice involves delivering babies and performing surgeries in a hospital setting as an obstetric hospitalist. In my prior 25-year career in a large single-specialty OB/GYN practice, I also provided clinic-based obstetric and gynecologic care to women and girls.

7. I have provided written and oral expert testimony about chemical abortion to several state legislatures and to the United States Congress.

8. I have also published the peer-reviewed articles "Chemical Abortion: Risks Posed by Changes in Supervision" and "Medical Abortion: What Physicians Need to Know" in the Journal of American Physicians and Surgeons.

9. The articles I published reflect the research I have performed on the risks associated with

unsupervised chemical abortion—a practice that is becoming more common.

10. A chemical abortion includes providing patients with a combination of two drugs. One drug—mifepristone—blocks hormonal support, killing the unborn child, while the other—misoprostol—induces uterine contractions to expel the unborn child and the pregnancy tissue.

11. The drugs mifepristone and misoprostol may cause serious complications for the women and girls who take them.

12. In my practice, I often treat patients who are admitted through the hospital's emergency department with complications from chemical abortions.

13. In my practice, I have cared for several dozen women in the emergency department who were totally unprepared for the pain and bleeding they experienced due to chemical abortion.

14. In my experience caring for women who have gone through chemical abortion, the doctors who prescribed or administered chemical abortion drugs to these women often did not adequately prepare them for the drugs' effects, so these women could not have truly achieved informed consent.

15. At least a dozen patients have expressed significant emotional distress to me when they viewed the body of their unborn child in the toilet after the chemical abortion.

16. I have treated patients who have experienced trauma and emotional distress because of complications from chemical abortion. Those women

were not anticipating that complications were possible and likely did not have sufficient informed consent to proceed with chemical abortion.

17. In my practice, I have cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled.

18. I have cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both.

19. Complications from chemical abortion are not uncommon. In fact, chemical abortions involve more complications than surgical abortions.

20. The FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion.

21. Given my experience, I expect to see and treat more patients presenting with complications from chemical abortion.

22. For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (*i.e.*, the doctors had to surgically finish the abortion with a suction aspiration procedure).

23. In my office, I treated one young woman who had been bleeding for six weeks after she took the chemical abortions drugs given to her by a doctor at a Planned Parenthood clinic. After two follow-ups at Planned Parenthood, during which she was given additional misoprostol but not offered surgical completion, she presented to me for help. I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication.

24. I have also cared for minor women below the age of 18 who have obtained chemical abortion drugs. Although mifepristone has not been studied specifically in minor women, the FDA has negligently allowed their provision to this special age group, assuming their response will be the same as adult women.

25. The FDA's actions deregulating mifepristone and expanding access to unsupervised chemical abortion harm women and their doctors, including me. Concerns about "unsafe, back-alley abortions" were used to overturn all state abortion restrictions in 1973 and they are being recycled today to allow the abortion industry to continue perpetuating dangerous abortion methods. Yet, a clear-eyed look at the FDA's actions allowing unsupervised "mail-order abortions" shows that they are now promoting illegal, unsafe "chemical coat hangers" to the women they falsely say they want to protect.

26. The FDA's actions harm women, including my patients, because without proper oversight, chemical abortions can become even more dangerous than when they are supervised.

27. The FDA's actions harm women, including my patients, because clinics and physicians prescribing or dispensing chemical abortion drugs, or websites that provide these drugs through mail order delivery without any physician involvement, often underprepare women for the severity and risks of chemical abortion, and they often provide insufficient or no follow-up care to those women. Many women are inadequately prepared for the effects of the drugs, the severity of the pain and bleeding they will experience, the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type. These patients are being abandoned because in many cases there is no doctor-patient relationship, so they often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber.

28. Unsupervised chemical abortion—authorized by the FDA—harms women because they may have underestimated the gestational age of their unborn child. Women who should not be a candidate for chemical abortion because they are past the FDA-approved cutoff of ten weeks gestation may consume chemical abortion drugs, which will increase their chances of complications due to the increased amount of tissue, leading to hemorrhage, infection and/or the need for surgeries or other emergency care.

29. For example, approximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women

at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death. Failure to perform an ultrasound prior to prescribing abortion drugs will cause some women to remain undiagnosed and at high risk for these adverse outcomes.

30. The FDA's removal of the reporting requirement for adverse events of mifepristone harms women by creating an inaccurate safety profile, and it harms my practice because it makes it more difficult to practice evidence-based medicine. The incidence of abortion-related complications remains unknown if there is no accurate system for data collection.

31. The FDA's actions also harm women because the lack of oversight will likely exacerbate human trafficking, which happens frequently in San Antonio. In my practice, part of my care of my patients is ensuring that they are making medical decisions free of coercion. Many trafficked women experience unintended pregnancies and alert doctors serve as an important resource to intervene on behalf of women. Removing the in-person medical interaction removes an opportunity to identify and rescue these women. It also leaves them at risk of being coerced into an abortion they may not desire.

32. Deregulated chemical abortion harms my practice because it increases the number of women who come to the emergency department with complications. When I must perform surgery to deal with complications from chemical abortions, this takes attention away from my other patients. As a hospitalist, I am often supervising multiple laboring patients on labor and delivery. When I am called to the operating

room to address an emergency resulting from chemical abortion, this necessarily means I may not be immediately available if an emergency should occur with one of my laboring patients.

33. Unsupervised chemical abortion is heartbreaking to me because it causes women to suffer unnecessarily, and my patients deserve quality medical care.

34. The FDA's expansion of chemical abortion also harms my conscience rights because it could force me to have to surgically finish an incomplete elective chemical abortion. I object to abortion because it ends a human life. My moral and ethical obligation to my patients is to promote human life and health. But the FDA's actions may force me to end the life of a human being in the womb for no medical reason.

Executed this November 11, 2022.

By: [*Signature*]

Ingrid Skop, MD

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. NANCY WOZNIAK

I, Nancy Wozniak, M.D., a citizen of the United States and a resident of Fishers, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified obstetrician and gynecologist practicing in the greater Indianapolis area. My practice includes obstetrics at two Indianapolis-area hospitals.

3. I am a member of the Board of Directors of Plaintiff American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and serve as AAPLOG's Secretary. I am familiar with AAPLOG, its policy positions, its members, the members' interests and concerns. AAPLOG and its members oppose elective abortions, both surgical and chemical.

4. I am familiar the approval of mifepristone and misoprostol as chemical abortion drugs by the U.S. Food and Drug Administration (FDA) and with the FDA's Risk Evaluation and Mitigation Strategy (REMS) for the use of mifepristone and misoprostol for chemical abortions.

5. A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

6. Under the REMS established by the FDA in 2016 for mifepristone and misoprostol, the agency eliminated (a) the in-person administration requirement, (b) mandatory post-abortion follow-ups, and (c) the requirement that prescribers report all adverse events except death.

7. In 2016, the FDA also expanded the gestational age for approved mifepristone use to 70 days (or 10 weeks) from 49 days (or 7 weeks).

8. The FDA's actions harm patients and practitioners like me.

9. Mifepristone and misoprostol are dangerous drugs that can harm women. Without the appropriate supervision, women taking these drugs are at risk of serious complications and even death in the worst cases.

10. I believe the FDA's expansion of the approved timeframe for mifepristone and misoprostol use to 10 weeks of gestation harms women. An abortionist should never prescribe these drugs to any woman for an abortion after 8 weeks' gestation because I have seen so many women get into trouble with bleeding past that gestational age.

11. Few people die from chemical abortions because of the excellent care they receive from OBGYN doctors, but the infrequency of deaths conceals the danger that these drugs pose to women and girls—especially when administered without proper supervision.

12. In my experience, most of the complications related to the use of mifepristone and misoprostol for chemical abortions result in "near misses" due to the timely intervention of healthcare providers.

13. Recently many states like Indiana have enacted laws to regulate abortions more carefully. To circumvent those laws, abortion providers are relying on increased access to chemical abortion drugs through mail-order schemes or telemedicine.

14. The increasing number of chemical abortions through mail-order or telemedicine methods means that more women will suffer complications from unsupervised use of mifepristone and misoprostol.

15. The risk of complications from chemical abortions is four to seven times greater than from surgical abortions.

16. Currently, many women are now being prescribed mifepristone and misoprostol without a sonogram to verify the gestational age of the unborn child or to rule out ectopic pregnancies or other potential complications.

17. Women have the potential to present to the emergency department with torrential bleeding due to taking mifepristone and misoprostol for a chemical abortion without accurate dating and appropriate supervision. This places enormous stress and pressure on physicians and OB/Gyns who work in hospitals.

18. In my observation, incidents of women presenting to emergency departments with complaints of bleeding are becoming increasingly more common.

19. Due to the FDA's elimination of the adverse event reporting requirements, however, it is impossible to know how frequently women and doctors are facing these complications.

20. The FDA's elimination of the adverse event reporting requirements for nonfatal complications harms doctors' ability to practice evidence-based medicine and to provide their patients about the risks of chemical abortion and obtain their informed consent. Doctors are only as good as the information that they receive.

21. These physicians must treat women in emergency situations without an existing relationship with the patient, without a known gestational age, and without any known medications that the patient may

have been prescribed. This dynamic also increases doctors' exposure to allegations of malpractice and potential liability.

22. The FDA's loosening of regulations related to chemical abortions harms hospitalists by putting them in higher-risk situations with less critical information about patients, which increases their exposure to allegations of malpractice and potential liability.

23. In the last six months, I had an experience treating a woman that illustrates how dangerous and damaging the FDA's actions are to women and practitioners.

24. One of my patients, who was about nine weeks pregnant, had previously been treated by hospital staff for a pulmonary embolism with anti-coagulants. She was advised that she could not seek a chemical abortion because it was contraindicated due to the medications; yet the woman left the hospital and sought an abortion at Planned Parenthood of Indiana. The woman was given mifepristone by the doctor at Planned Parenthood and took the drug. The woman called an Uber for a ride home from Planned Parenthood. The woman began to experience bleeding and other adverse side effects from the mifepristone. The woman's Uber driver did not take her home because she was so ill and instead brought her to the hospital's emergency department. At the hospital, the woman came under my care. The woman had not yet taken the second abortion drug, misoprostol. I treated the patient for the adverse effects she suffered and told her not to take the misoprostol given to her by Planned Parenthood because of the grave risk that she could bleed out and die. The woman had a subsequent ultrasound, which

showed that her unborn child was still alive. I advised the internists treating this patient to avoid administering certain medications that could harm the patient and her unborn child.

25. This experience that I had illustrates one of many "near misses" where women and girls face potentially deadly situations, but they are saved by intervention at a hospital's emergency department.

26. Under the FDA's current reporting requirements, this experience need not be reported as an adverse event. I attempted to report this event to the Indiana Department of Public Health, but my report was rejected because the State said it was not a "true" adverse event because the patient ultimately recovered.

27. In my experience with the patient I just described, I spent a significant amount of time that day working to save her life from unnecessary complications due to the irresponsible administration and use of mifepristone and misoprostol. As a result of the significant time that I devoted to that patient, my time and attention was taken away from my other patients, who also need my care.

28. I also know that many women who are suffering complications from chemical abortions tell their doctors that they are experiencing miscarriages. This phenomenon—regardless of why it occurs—means that doctors cannot be certain of what their patients have taken or are experiencing. The lack of information makes it extremely difficult to provide proper treatment to these patients. This inaccurate information also means that the true number of

incidences of complications from chemical abortions are significantly underreported or not fully known.

29. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: [*Signature*]

Nancy Goodwine-Wozniak, M.D.

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. TYLER JOHNSON

I, Tyler Johnson, D.O., a citizen of the United States and a resident of Leo, Indiana, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I received my Bachelor of Science in Biology from the University of Saint Francis in Fort Wayne. I attended medical school at the Lake Erie College of Osteopathic Medicine. My residency was at Michigan State University's Kalamazoo Center for Medical Studies.

3. I am an emergency department physician certified by the American Board of Emergency Medicine. I practice in the emergency departments of hospitals in northern Indiana. My practice includes treating patients throughout rural northern Indiana into the inner-city of Fort Wayne. I am also the director of emergency medicine at Parkview Dekalb Hospital.

4. I am a member of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG).

5. I am familiar with the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) drug safety program. I am also familiar with the REMS issued by the FDA for the chemical abortion drug mifepristone and misoprostol in 2016.

6. The FDA's 2016 REMS for mifepristone and misoprostol expanded the acceptable gestational age for chemical abortion, eliminated the in-person administration requirement for these dangerous drugs, eliminated mandatory post-abortion follow-up visits, and eliminated the requirement for prescribers to report all non-fatal adverse events.

7. The FDA's actions harm both women and practitioners.

8. Mifepristone and misoprostol are dangerous drugs that have serious effects on a woman's body. Without

the medical supervision, women taking these drugs are at risk of serious and life-threatening complications and even death.

9. I have seen at least a dozen cases of life-threatening complications from the use of abortifacient drugs over the years. These emergency situations are becoming more common as more women are turning to chemical abortion as the FDA has relaxed its regulations.

10. In one case, for example, I treated a woman in the emergency department who had been given an abortion pill from a clinic in Chicago. She took the pill and began to experience heavy bleeding on the drive back to Fort Wayne. By the time she arrived at the hospital, she was unconscious. I performed emergent treatment and gave her a necessary blood transfusion. The patient required further evaluation and observation in the hospital. I have seen multiple cases similar to this one.

11. About a month ago, I treated an 18-year-old woman in the emergency department who was experiencing severe pain. Although the situation was not life-threatening to her, she was terrified, and it was clear to me that she did not understand what she had been given. It is not uncommon for women who take mifepristone and misoprostol to come to the emergency department because the pain is so terrible.

12. Many of the patients I have treated for complications with chemical abortion experience trauma. They usually have no follow-up with the doctors who prescribed or dispensed the abortifacient drugs, and they are not adequately prepared to understand what the drugs will do to them. In these situations, it is

clear to me that these women and girls could not have given informed consent to chemical abortion.

13. In many cases, women are hesitant to tell us that they have taken chemical abortion drugs. On multiple occasions I have treated women in the emergency department who are experiencing extremely heavy bleeding even after they have already passed the unborn child. The women will sometimes eventually explain that they took abortifacient drugs, which helps us understand what is happening to them. I understand that many women are told by staff at the dispensing clinics to tell emergency department doctors that they are experiencing a "miscarriage."

14. Because of the FDA's relaxed regulation of these dangerous drugs, it is extremely easy for women to obtain mifepristone and misoprostol with little or no supervision. This leaves emergency physicians like me to deal with preventable emergent and life-threatening situations after these women have taken these drugs. The unsupervised administration of chemical abortion drugs simply harms women and physicians.

15. The FDA's actions have created a culture of chaos for emergency room physicians. In my experience, patients who are given abortifacient drugs at clinics do not understand what they have taken and are often reluctant to tell emergency doctors what they have taken. This puts me and my colleagues in a position where we have to treat women in emergency situations without crucial information. This culture puts us in increasingly higher risk situations, which increases our exposure to claims of malpractice and liability.

16. The increase in women presenting in the emergency department for complications with chemical

abortions harms other patients too. Because more women are unnecessarily presenting in the emergency department, more of my time and attention is taken away from other patients who need it.

17. I also believe the FDA's elimination of reporting requirements for non-fatal adverse events harms women and practitioners. I believe we are not tracking these medications closely enough to know the extent of the negative side-effects commonly experienced. This also harms physicians' ability to practice evidence-based medicine. Moreover, women and girls cannot give informed consent to chemical abortion when they do not receive accurate information about the risks associated with mifepristone and misoprostol.

18. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion.

Executed this November 11, 2022.

By: [*Signature*]

Tyler Johnson, D.O.

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. REGINA FROST-CLARK

I, Regina R. Frost-Clark, a citizen of the United States and a resident of Michigan, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am board-certified in obstetrics and gynecology. I practice with St. John OB/Gyn Associates, part of Ascension Medical Group.

3. I received my M.D. from Wayne State University and did my residency at St. John Hospital and Medical Center in Detroit, Michigan.

4. I am in a hospital owned practice and am often called to the emergency department for consultations.

5. I am familiar with the approval and regulatory changes by the United States Food and Drug Administration (FDA) regarding chemical abortion. Specifically, I am familiar with the relaxing of supervision requirements for administering these very serious drugs, and I am familiar with the relaxed reporting requirements for adverse events related to chemical abortions.

6. I believe these FDA actions will harm women, including my patients, and my practice.

7. As an OB/Gyn, I have treated several women who have suffered complications from chemical abortions.

8. The wider availability of chemical abortion drugs will result in an increase in the frequency of complications related to the drugs' use.

9. In at least a dozen cases, I have treated women who were suffering significant bleeding after taking chemical abortion drugs. Occasionally, women have to be admitted to the hospital for observation due to bleeding complications.

10. In my experience, women who have been given chemical abortion drugs often do not know what they were given or how much of a particular drug they took.

11. In most instances where I treat women who have complications from chemical abortion drugs, they have received it from an abortion facility. Recently a woman told me she obtained these drugs by herself—likely online—and took them without any medical supervision.

12. The FDA's suspension of the in-person dispensing requirement of mifepristone and misoprostol harms women and doctors because it has resulted in an increase in complications.

13. Without an in-person dispensing requirement for chemical abortion drugs, there is a greater chance that women with a molar or ectopic pregnancy will be given drugs that will be ineffectual, leaving them exposed to potentially deadly complications like a rupture or hemorrhage.

14. Similarly, without an in-person dispensing requirement, patients may be given chemical abortion drugs without a confirmed pregnancy or for an inappropriate gestational age.

15. In these instances, patients may avoid seeking appropriate medical care because they are unaware of the risks they potentially face, which puts them in greater danger of complications.

16. Women presenting with complications from chemical abortion pose a challenging situation because I may not have access to their medical history—either because I am unable to access any medical records from prescribers of the chemical abortion drugs or because they obtained the chemical abortion drugs without any medical oversight to begin with. Additionally, the patients themselves usually do not understand what

they have been given, how much they have taken, or their follow-up instructions.

17. The lack of patient history and knowledge harms my ability to treat patients. For example, with patients experiencing bleeding, the course of treatment will vary if I believe the bleeding is regular or abnormal cyclical bleeding as opposed to bleeding resulting from attempted abortion.

18. I expect to see more and more women with chemical abortion complications as the use of the drugs increases. Because of the increased complications and the limited information available to me due to the FDA's actions, I fear that I will have greater exposure to liability in my practice.

19. The FDA's actions have led to more confusion for patients and providers. The FDA has forced my colleagues and me to make decisions about patient care based on limited information. It also requires me to spend a lot of time trying to reconstruct patient medical histories to best serve my patients.

20. The FDA's actions make it difficult for patients to have informed consent. Doctors cannot confirm the pregnancy, the location of the pregnancy, or the gestational age without an examination. In abortion clinic settings, it is unclear whether patients are seeing the same physician each time. And often there are no patient follow-up visits with the dispensing facility.

21. Under the current practice by those who prescribe chemical abortion drugs like mifepristone and misoprostol, there is no follow-up or additional care provided to patients and therefore no rapport between patients and their physicians. This makes it difficult to

assess who is responsible for these patients when they experience complications.

22. The FDA's removal of the adverse event reporting requirement for all adverse events except death harms my ability to perform evidence-based medicine. I am unable to assess the risks present to women because the FDA's removal of reporting requirements undermines the legitimacy of risk data. For example, Ranitidine, commonly known as Zantac, was pulled from the market due to cancer associations after years of use. Without adverse event reporting, I cannot properly assess the risks that my patients face from abortifacient drugs.

23. I have not reported adverse events that I have witnessed as a result of chemical abortions because the process is so cumbersome. In addition to the burdensome paperwork, it is difficult to file an accurate report given that in many cases I am not certain what the patient was given by the chemical abortion prescriber.

Executed this November 13, 2022.

By: [*Signature*]

Regina Frost-Clark, M.D.

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

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

Plaintiffs,

v.

Case No. _____

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.

DECLARATION OF DR. GEORGE DELGADO

I, George Delgado, a citizen of the United States and resident of San Marcos, California, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am board-certified in family medicine and in hospice and palliative medicine.

3. I serve as a medical advisor to the Abortion Pill Rescue Network and as director of medical affairs of Culture of Life Family Services (COLFS) Medical Clinic.

4. I received my medical degree from the University of California, Davis School of Medicine in 1988 and completed my residency at Santa Monica Hospital/ UCLA Medical Center in 1991.

5. I am a Natural Family Planning (NFP) Medical Consultant trained in NaProTechnology. I have also completed a one-year Certification Program in Health Care Ethics with the National Catholic Bioethics Center.

6. I performed the second recorded successful reversal of chemical abortion in the United States.

7. I established Abortion Pill Reversal, a program that connects women who regret taking the abortion-inducing drug, mifepristone (RU-486), and want to reverse the effects of the chemical abortion regimen.

8. I founded the Steno Institute, a non-profit organization, to conduct, promote and publish high-quality, morally sound health science and clinical research in pro-life areas, including chemical abortion reversal.

9. I published the first peer-reviewed article in the medical literature describing the reversal of the abortion-inducing drug, mifepristone (RU-486), using progesterone. The case study, "Progesterone Use To Reverse The Effects Of Mifepristone," presented a

series of cases demonstrating successful reversal of mifepristone effects in women who chose to reverse the chemical abortion process. Four of six women who took mifepristone were able to carry their pregnancies to term after receiving intramuscular progesterone 200 mg.

10. I co-authored a peer-reviewed article, "A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone," published in Issues in Law & Medicine, Volume 33, Number 1, 2018. The results of the study concluded that the reversal of the effects of mifepristone using progesterone is safe and effective.

11. Based on my review of peer-reviewed studies, I can attest that there are higher levels of complications from chemical abortion than from surgical abortion. For example, the risk of severe bleeding with chemical abortion is five times higher than from surgical abortion.

12. In my family medicine practice, I continue to see patients one day per week while serving primarily in an administrative role.

13. I treat women with Abortion Pill Reversal in my office in addition to treating women who suffer complications from chemical abortions.

14. I see women who have a great deal of regret from undergoing the chemical abortion drug regimen. They are distressed, sad, and feel terrible about what they have done. While it is rewarding to offer these women a chance at reversing chemical abortion, this is some of the most emotionally taxing work I have done in my career.

15. For example, I spoke with one patient who sought to reverse a chemical abortion after taking mifepristone under duress by the abortion doctor. She recounted that the doctor at the abortion center rushed her to make a decision, placed the pill in her bare hand, and told her to take the pill before it melted in her hand and that it was very expensive. She took the pill because of the duress she was under and immediately regretted the decision. She successfully reversed her chemical abortion. This example illustrates how women and girls are not giving informed consent when undergoing chemical abortion and sometimes coerced into taking these drugs.

16. Given my experience, I expect to see and treat more patients presenting themselves with complications from chemical abortion and seeking reversal of mifepristone.

17. My practice renders early prenatal care to mothers and provides care to babies that are born. In doing so, my practice will bill a patient's insurance company for reimbursement for the costs of care. When my patients have chemical abortions, there is a tangible financial loss to my practice in losing the opportunity to render professional prenatal care for the mother or to care for babies who are never born.

18. The FDA's elimination of necessary safeguards for pregnant women and girls, such as removing the requirement for an in-person follow-up examination after a chemical abortion, will increase the demands on my time in my family medicine practice and reduce the time I would like to spend with other patients. I will have to treat an increased number of patients due to

abortion facilities' failure to provide follow-up care to women and girls.

19. Executed this November 14, 2022.

By: [*Signature*]
George Delgado, M.D.

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

ALLIANCE FOR HIPPOCRATIC MEDICINE, on behalf of itself, its members, and their members, and their members' patients; **AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS AND GYNECOLOGISTS**, on behalf of itself, its members, and their patients; **AMERICAN COLLEGE OF PEDIATRICIANS**, on behalf of itself, its members, and their patients; **CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS**, on behalf of itself, its members, and their patients; **SHAUN JESTER, D.O.**, on behalf of himself and his patients; **REGINA FROST-CLARK, M.D.**, on behalf of herself and her patients; **TYLER JOHNSON, D.O.**, on behalf of himself and his patients; and **GEORGE DELGADO, M.D.**, on behalf of himself and his patients, Plaintiffs, v.	**Case No. _____**

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.

DECLARATION OF DR. SHAUN JESTER

I, Shaun Jester, a citizen of the United States and a resident of Dumas, Texas, declare under penalty of perjury under 28 U.S.C. § 1746 that the following is true and correct to the best of my knowledge.

1. I am over eighteen years old and make this declaration on personal knowledge.

2. I am a board-certified obstetrician and gynecologist and am the Medical Director of Moore

County Ob/Gyn in Dumas, Texas. I have been board-certified since 2007.

3. I received my medical degree in 1999 from the Texas College of Osteopathic Medicine at the University of North Texas Health Science Center at Fort Worth.

4. I have a busy medical practice. I am one of three doctors on call. My practice includes cesarean section deliveries, hysterectomies, and other women's health treatments. My practice includes about thirty deliveries each month.

5. A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

6. I understand that the FDA approved chemical abortion drugs for use in the United States in 2000.

7. I am also familiar with the FDA's regulatory changes regarding chemical abortion drugs, especially the REMS issued in 2016 and associated with the use of mifepristone and misoprostol for chemical abortions.

8. I understand that the FDA approved the use of mifepristone up to 70 days (or 10 weeks) of gestation in 2016, which is longer than the previous standard of 49 days (or 7 weeks).

9. I am familiar with the FDA's suspension and elimination of the in-person dispensing requirements for administering these dangerous drugs in 2021.

10. I am familiar with the removal of the requirement for an in-person, postabortion office visit,

which is when a physician determines whether any fetal parts or other products of conception remain. These visits are essential to ensure that women experience no complications after chemical abortion.

11. I am also familiar with the relaxed reporting requirements for adverse events related to chemical abortions.

12. I believe these FDA actions will harm my patients, women, and women's medicine.

13. I believe that the FDA's approval for using mifepristone at a later gestational age, and the elimination of the in-person dispensing requirement and follow-up visit requirement, are especially dangerous for women.

14. Based on my experience, mothers are often mistaken about how far along they are in pregnancy. According to the Listening to Mothers III survey, 26% of women's due dates are changed.

15. Without an in-person visit to obtain an ultrasound, there is no way to be certain about the gestational age of an unborn child. Women may be further along in pregnancy than is currently acceptable for chemical abortion. Similarly, without an in-person examination, it is impossible to rule out an ectopic pregnancy, which would not be terminated by a chemical abortion and could put women at an increased risk of rupture or even death.

16. Based on my experience treating patients, I believe unsupervised chemical abortions are dangerous and potentially life-threatening especially due to increased risk of hemorrhage and/or infection the further along they are after 6 weeks' gestation.

17. For instance, I treated a woman who traveled from Texas to obtain chemical abortion drugs from Planned Parenthood New Mexico to complete an abortion at 10 weeks' gestation. The woman returned to Texas, suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection. At the hospital, I provided her with intravenous antibiotics and performed a dilation and curettage procedure. If she had waited a few more days before receiving care, she could have been septic and died. I reported this adverse event to the FDA.

18. The FDA's actions harm my practice by causing unnecessary harm to my patients that could have been avoided by retention and enforcement of the REMS.

19. Doctors like me serve patients as professional health care providers. I provide care to all women and unborn children, and I give them the best professional services possible. Just like other employed obstetrical providers, my hospital will bill for the cost of obstetrical and medical services rendered. When my patients have chemical abortions, I lose the opportunity to provide these obstetrical and medical services to care for the woman and child through pregnancy and bring about a successful delivery of a new life.

20. Additionally, the wider availability of chemical abortion drugs will result in more patients experiencing complications and the number of patients in emergency situations will rise. These situations are naturally higher risk for both the patient and for the physician providing care. In the chemical abortion case that I reported as an adverse event to the FDA, I had no existing patient relationship or prior knowledge of

the patient's medical history. Such cases can be a high-pressure, high-risk situation for practitioners like me.

21. The FDA's deregulation of these dangerous drugs increases our exposure to liability.

22. There are many contraindications to prescribing mifepristone, including adrenal failure, steroid use, severe anemia, bleeding disorders, the use of intrauterine devices, undiagnosed ectopic pregnancy, and others. I do not believe telemedicine can rule out all contraindications to prescribing mifepristone because some of these conditions can only be ascertained with an in-person examination or lab work.

23. Telemedicine does not allow for a critical ultrasound assessment to rule out ectopic pregnancies and verify that the patients are within the 70 days allowed for chemical abortions. In this way, the FDA's loosening of regulations for abortifacient drugs harms women and practitioners by exposing them to increased risk of complications.

24. I believe the relaxed reporting requirements for adverse events related to chemical abortion drugs harm women and physicians because they create an inaccurate and false safety profile for the use of mifepristone and misoprostol. Many women and girls do not fully understand the nature of chemical abortion and the risks that these drugs present to them.

25. The elimination of mandatory follow-up visits after chemical abortion drugs have been administered is also dangerous and harms women and practitioners. Without follow-up visits, physicians cannot identify potential complications like sepsis and hemorrhage, lingering products of conception, and others until the

patient is at a critical time or it is too late to help the patient.

26. I care for my patients and give them the best medical care and guidance that I can. I believe that chemical abortions harm women, including my patients, and harm the medical practice. The elimination of REMS critical to ensuring safe use of the chemical abortion drugs prevents doctors from fulfilling their oath to "do no harm" by permitting the administration of abortifacient drugs to patients without full knowledge or appreciation for the impact those drugs would have on them.

27. As with my patient who suffered an adverse event, it disturbed me that she was not informed that it was not normal to bleed for multiple weeks and that if she had a routine follow-up visit, as required by past REMS, this situation could have been avoided before requiring overnight hospitalization and her being at risk for developing sepsis.

Executed this November 14, 2022.

By: [*Signature*]

Shaun Jester, D.O.