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

THE STATE OF MISSOURI; THE STATE OF KANSAS; and THE STATE OF IDAHO, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; JANET WOODCOCK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services, Defendants.	)	Case No. 2:22-cv-00223-Z

COMPLAINT

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

2. The FDA has failed in this responsibility. Specifically, it failed America's women and girls when it chose politics over science and approved risky, untested

chemical abortion drugs for use in the United States. And it has continued to fail them by turning a blind eye to these harms and repeatedly removing even the most basic precautionary requirements associated with the use of these risky drugs.

3. To date, the FDA's review, approval, and deregulation of chemical abortion drugs has spanned three decades, crossed several presidential administrations, and encompassed six discrete agency actions. Plaintiffs challenge these actions by the FDA and ask that the Court hold them unlawful, set them aside, and vacate them.

4. In particular, Plaintiff States challenge three agency actions: (1) the 2016 rollback of most of the safety precautions FDA had put in place when it approved mifepristone in 2000; (2) the 2019 FDA approval of generic mifepristone; and (3) the 2021 and 2023 policy allowing these drugs to be sent by mail.

5. The first and third of these actions have already been preliminarily enjoined to the benefit of the plaintiffs who brought the instant case. That was affirmed on appeal. *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210 (5th Cir. 2023).

6. Because Plaintiff States have standing (as established below), Fifth Circuit precedent thus establishes that Plaintiff States are also entitled to a preliminary injunction with respect to those actions.

7. The Fifth Circuit concluded that the plaintiffs in *Alliance for Hippocratic Medicine* "did not introduce evidence showing that they are likely to be injured by the 2019 Generic Approval"—*i.e.*, the second agency action Plaintiff States

challenge—and thus preliminary injunctive relief was not warranted for those plaintiffs. *Id.* at 241. Plaintiff States, in contrast, attach evidence to this complaint showing that they are harmed by the 2019 approval of generic mifepristone. Ex. 36, Studnicki Affidavit.

8. In January 1993, President Clinton directed his cabinet to take the steps necessary to legalize chemical abortion drugs in the United States.

9. President Clinton and his agency officials then pressured the foreign manufacturer of the key chemical abortion drug, mifepristone (also known as "Mifeprex") to donate the U.S. patent rights of the drug to the Population Council—an entity focused on global population control.

10. After receiving the patent rights to mifepristone, the Population Council submitted a new drug application for its mifepristone drug to the FDA and worked closely with Clinton's FDA during the review process. Unsurprisingly, the Population Council obtained the agency's approval for the drug on September 28, 2000—less than eight years later.

11. The only way for the FDA to approve a chemical abortion drug was for FDA to use its accelerated drug approval authority. This required that the FDA call pregnancy an "illness" and argue that these dangerous chemical abortion drugs provide a "meaningful therapeutic benefit" over existing treatments.

12. Pregnancy is not an illness, and chemical abortion drugs do not provide a "therapeutic benefit" over surgical abortion. The FDA exceeded its regulatory authority by approving the drug based on these transparently false conclusions.

13. The FDA's decision to approve the drug also required the agency to disavow science and the law. The FDA never studied the safety of the chemical abortion 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, a violation of the Pediatric Research and Equity Act (PREA). The FDA also disregarded the substantial evidence that chemical abortion drugs cause even more medical complications than surgical abortions.

14. Since it approved the drug, the FDA has not followed the science, reversed its approval, or fixed the mistakes inherent in its approval. To the contrary, the FDA has doubled down on its actions and later removed the few safeguards that were originally in place.

15. In 2002, several organizations "filed a citizen petition, asking FDA to revoke its approval of mifepristone." *AFH*, 78 F.4th at 225. The petitions explained that the FDA violated federal laws by approving the chemical abortion drugs and ignoring the substantial evidence that these drugs harm women and girls. It was not until fourteen years later, in March 2016, that the FDA rejected these petitions. *Id.*

16. On the same day that the FDA rejected the citizen petitions, the FDA made additional "major changes" to the chemical abortion drug regimen. These changes included eliminating crucial safeguards for pregnant women and girls.

17. By way of example, one of these changes included the FDA extending 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.

18. Numerous studies show that there are increased risks from chemical abortion drugs to pregnant women and girls as the baby's age advances from seven weeks to ten weeks, due in part to significant growth of the placenta and the baby during that period.

19. Other major changes that occurred in 2016 include that the FDA: (1) changed the dosage and route of administration for the chemical abortion drugs; (2) reduced the number of required in-person office visits before the chemical abortion drug could be described from three to one; (3) expanded who could prescribe and administer chemical abortion drugs beyond medical doctors; and (4) eliminated the requirement for abortionists to report non-fatal complications from chemical abortion drugs. All of these changes were made without any objective clinical investigations or studies that evaluated the safety and effectiveness of this new chemical abortion regimen or any safety assessment of its side effects on the developing bodies of girls under 18 years of age.

20. The FDA's 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 regime.

21. The Population Council was not the only entity that sought to benefit economically from the FDA's rapidly loosening restrictions. In 2019, the FDA approved a generic version of Mifeprex without requiring any new clinical investigations or studies that evaluated the drug's safety and effectiveness under either the requirements of the FFDCA or any specific safety assessments on girls as set forth under PREA.

22. In April 2021, the FDA's new management, installed by the Biden Administration, issued a "Non-Enforcement Decision" for mifepristone. Under this decision, 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 despite a statute expressly disallowing that conduct. 18 U.S.C. § 1461.

23. As with the 2000 approval, several organizations filed a citizen petition in 2019 challenging the 2016 changes. *AFH*, 78 F.4th at 226. This petition included an in-depth discussion of how the agency violated the law by ignoring the growing and substantial evidence that these dangerous drugs harm women and girls. Two and a half years later, in December 2021, the FDA rejected almost all the relief sought in the citizen petition.

24. Also in December 2021, the Biden FDA announced that it would permanently allow abortionists to send chemical abortion drugs through the mail, in blatant violation of statutory law. 18 U.S.C. § 1461.

25. This decision by the FDA harms women and girls who undergo chemical abortions. Additionally, the Biden FDA's decision further assists sex traffickers and sexual abusers to force their victims to get abortions without authorities able to identify these victims.[1] In fact, the State of Texas, where this lawsuit is being heard, has directly 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]

26. In addition to the legal and scientific failings by the FDA noted 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 actions to eliminate the in-person dispensing requirement—failed to account for or to 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, through its words and actions FDA permitted and sometimes even encouraged these illegal activities.

27. FDA has spent over two decades shamelessly flouting federal statutes and its own regulations. Now, Plaintiffs ask the Court to step in and protect women

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[1] *See*, *e.g.*, Laura J. Lederer & Christopher A. Wetzel, *The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities*, Annals of Health Law, Winter 2014 at 61, 73, 77–78 (noting that survivors in the study "reported that they often did not freely choose the abortions they had while being trafficked," that 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] 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).

and girls by holding unlawful, setting aside, and vacating the FDA's actions to both approve chemical abortion drugs and eviscerate crucial safeguards for those who undergo this dangerous drug regimen.

JURISDICTION AND VENUE

28. 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.

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

30. This Court has jurisdiction under 28 U.S.C. § 1361 because this lawsuit is an action to compel an officer of the United States or any federal agency to perform his or her duty.

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

32. This Court has jurisdiction to issue equitable relief necessary and appropriate 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).

33. This lawsuit 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 this Court's inherent equitable powers.

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

35. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the facts, events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of this action is situated in this district. Plaintiff States bring this intervention action in the same district and division in which an action involving the same subject matter is already pending. Defendants are United States officers or agencies 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.

PARTIES TO THIS ACTION

36. Plaintiff the State of Missouri is a sovereign state of the United States of America. Missouri sues to vindicate its sovereign, quasi-sovereign, and proprietary interests.

37. Plaintiff the State of Kansas is a sovereign state of the United States of America. Kansas sues to vindicate its sovereign, quasi-sovereign, and proprietary interests.

38. Plaintiff the State of Idaho is a sovereign state of the United States of America. Idaho sues to vindicate its sovereign, quasi-sovereign, and proprietary interests.

39. Defendant FDA is an agency of the federal 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. FDA's headquarters is located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

40. Defendant Robert Califf, M.D., named in this lawsuit in his official capacity, is the Commissioner of Food and Drugs at the FDA. Dr. Califf is responsible for supervising all of the activities of the FDA, including the approval of new drug applications and the issuance, waiver, suspension, or removals of a REMS. Dr. Califf's official address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

41. Defendant Janet Woodcock, M.D., named in this lawsuit 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 at the FDA to develop and implement key public health initiatives. She also oversees the agency's day-to-day functions. Dr. Woodcock served as the Acting Commissioner of Food and Drugs from January 20, 2021, until February 17, 2022. Dr. Woodcock's official address is 10903 New Hampshire Avenue, Silver Springs, Maryland 20993.

42. Defendant Patrizia Cavazzoni, M.D., named in this lawsuit in her official capacity, is the Director of the FDA's Center for Drug Evaluation and Research. Dr. Cavazzoni is responsible for the regulation of drugs throughout their lifecycle, the regulation of 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 necessary to protect the public from harmful drugs. Dr. Cavazzoni's official address is 10903 New Hampshire Avenue, Silver Springs, Maryland 20993.

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

44. Defendant Xavier Becerra is the Secretary of HHS and is named in this lawsuit in his official capacity. Defendant Becerra is responsible for the overall operations of HHS, including the operations of the FDA. His official address is 200 Independence Avenue SW, Washington, D.C. 20201.

45. Collectively when applicable, all aforementioned defendants are referred to herein as the "FDA" or "Defendants." Plaintiffs' claims against Defendants includes all employees, agents, or successors in office of Defendants.

46. All federal officials named as Defendants in this action are subject to the APA. 5 U.S.C. § 701(b); 5 U.S.C. § 551(1).

FACTUAL ALLEGATIONS

47. This action challenges the FDA's repeated, long-running failure to abide by its legal obligations to protect the health, safety, and welfare of women and girls and comply with statutory law when the FDA authorized the chemical abortion drugs mifepristone and misoprostol for use in the United States. FDA compounded these failures when it eliminated necessary safeguards for pregnant women and girls who undergo this dangerous drug regimen.

48. The FDA has never had the authority required to approve these drugs for sale to the public. In 2000, the FDA approved chemical abortion drugs under its authority in 21 C.F.R. § 314, Subpart H (Subpart H). The relevant section of 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).

49. Chemical abortion drugs like mifepristone do not treat serious or life-threatening "illnesses." Pregnancy is a normal physiological state that many women experience at least once in their life. Pregnancy rarely leads to complications that threaten the life of the mother or child and, following delivery, almost all women return to their normal routine.[3] Although pregnancy can sometimes be associated with illness, it is not itself an "illness."

50. Chemical abortion drugs like mifepristone do not provide a "meaningful therapeutic benefit" to women and girls over existing treatments.

51. On the contrary, the FDA's approval of chemical abortion drugs has had potentially serious and life-threatening effects on women and girls. This is especially the case when the effects of chemical abortions are compared to the effects of surgical abortions that rely on medical devices and tools to physically remove a baby from inside the pregnant mother.

52. Endocrine disrupters such as mifepristone could have significant impacts on an adolescent girl's developing body and reproductive system. Despite this

[3] Byron Calhoun, *The maternal mortality myth in the context of legalized abortion*, 80 The Linacre Quarterly 264, 264–76 (2013); James Studnicki & Tessa Longbons, *Pregnancy is Not More Dangerous Than Abortion*, Nat'l Rev. (Aug. 28, 2022), https://www.nationalreview.com/2022/08/pregnancy-is-not-more-dangerous-than-abortion/.

fact, the FDA has never required an assessment that evaluated the safety and effectiveness of chemical abortion drugs on pregnant girls under 18 years of age.

53. Not only has the FDA continued to keep chemical abortion drugs on the market, it has also eliminated the few safeguards it initially established to protect women and girls who receive a chemical abortion drug.

54. In 2016, the FDA made taking chemical abortion drugs even more dangerous for women and girls by (1) allowing pregnant women and girls to take the drug at up to 70 days' gestation rather than only 49 days' gestation; (2) allowing non-doctors to prescribe and administer chemical abortions; (3) reducing the number of required in-person office visits from three to one; (4) changing the dosage and route of drug administration; (5) failing to require a clinical study to determine the safety of these changes on pregnant girls under 18 years old; and perhaps most shocking, (6) eliminating the requirement for prescribers to report nonfatal adverse events from chemical abortion—the natural and probable consequence of which is that the FDA and the public would never learn how many more injuries happen because the prior safeguards were removed.

55. More recently, in 2021, the FDA announced that abortionists could now dispense chemical abortion drugs by mail or mail-order pharmacy, which longstanding federal law expressly prohibits.

56. This Court should 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.

I. Negative effects of chemical abortion drugs and their administration.

57. The administration of chemical abortion drugs requires two drugs: (1) mifepristone (also called "Mifeprex" and "RU-486") and (2) misoprostol.

58. Mifepristone is a synthetic steroid and endocrine disruptor that blocks progesterone receptors in the uterus. Progesterone is necessary for the healthy growth of a baby in utero and the maintenance of a pregnancy. When a woman or girl ingests mifepristone, it blocks her natural progesterone, chemically destroys the baby's uterine environment, prevents the baby from receiving nutrition, and ultimately starves the baby to death in the womb.

59. Mifepristone alone works less than 25 percent of the time to complete the abortion, so the FDA 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.

60. 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 for complications from gastric ulcers and patients at high risk of developing gastric ulceration.[4] Misoprostol's label warns that the drug "should not be taken by pregnant women to reduce the risk of ulcers" by NSAIDs.[5]

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

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[4] *See, e.g.,* Ex. 1, FDA-Approved Label for Misoprostol (Cytotec) (Jan. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf.
[5] *Id.*

62. For example, more than 10% of women who take chemical abortion drugs need follow-up medical treatment for an incomplete or failed chemical abortion,[6] with an average of 39% percent of women requiring surgery if taken in the second trimester.[7] And 20% of females who take chemical abortion drugs experience a related adverse medical event—which is a rate that is four times higher than those who experience surgical abortion. Over 15% of females who take chemical abortion drugs experience hemorrhage, and 2% experience an infection.

63. 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.[8]

64. The number of chemical abortion-related emergency room visits increased by over five hundred percent (500%) between 2002 and 2015.[9]

65. 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,

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[6] Ex. 2, 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.
[7] Ex. 3, 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).
[8] Ex. 4, 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.
[9] *Id.* at 5.

and over six times as many women and girls require surgical abortion after consuming the chemical abortion drugs.[10]

66. Chemical abortion drugs have heightened risks for women and girls with certain blood types. In fact, if a woman or girl with an Rh-negative blood type is not administered certain medication (Rhogam) at the time of her chemical abortion, she could experience isoimmunization, which threatens her ability to have future successful pregnancies. If an Rh-negative woman or girl is left untreated, her future baby will have a fourteen percent (14%) chance of being stillborn and a fifty percent (50%) chance of being born alive but suffering neonatal death or brain injury. Around fifteen percent (15%) of the U.S. population is at risk of this blood condition.[11]

67. 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.[12] 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

[10] Ex. 2, Niinimaki, *supra note* 6, at 5.
[11] 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/.
[12] See, e.g., *Will a doctor be able to tell if you've taken abortion pills*?, Women Help Women (Sept. 23, 2019), https://womenhelp.org/en/page/1093/will-a-doctor-be-able-to-tell-if-you-ve-taken-abortion-pills (last visited Oct. 10, 2023); *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 Oct. 10, 2023).

being at significantly greater risk of needing multiple hospitalizations and follow-up surgery.[13] Ex. 36, Studnicki Affidavit.

68. 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.[14]

69. Some 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."[15]

70. 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.[16] The abortionist misdated the baby's

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[13] Ex. 5, 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.
[14] Ex. 6, 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).
[15] 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/.
[16] 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.

gestational age as six weeks, resulting in the at-home delivery of a "lifeless, fully-formed baby in the toilet," later determined to be around 30-36 weeks old.[17] Because of this chemical abortion, the woman "has endured significant stress, trauma, emotional anguish, physical pain, including laceration and an accelerated labor and delivery unaided by medication, lactation, soreness, and bleeding."[18]

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

71. 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.[19]

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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[17] *Id.* at 10–11.
[18] *Id.* at 11.
[19] For a general overview of the FDA's drug approval process, see *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, Congressional Research Service (May 8, 2018), https://crsreports.congress.gov/product/pdf/R/R41983.

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 to 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.[20] This rule allowed for full or partial

[20] Ex. 7, 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).

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).

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."[21]

99. This final rule established procedures "under which FDA will accelerate approval of certain new drugs and biological products for serious or life-threatening illnesses, with provision for required continued study of the drugs' clinical benefits after approval or for restrictions on distribution or use, where those are necessary for safe use of the drugs."[22]

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."[23]

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

> This subpart applies to certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).

21 C.F.R. § 314.500 (emphasis added).

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[21] Ex. 8, New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58,942 (Dec. 11, 1992).
[22] *Id*. (emphasis added).
[23] *Id*. (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, then 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."[24]

[24] Ex. 8, 57 Fed. Reg. at 58,953.

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

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

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

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

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.[25]

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.[26] Hoechst's resistance and desire to keep a low profile was due, in part, to its corporate history and complicity in previous mass genocide.[27]

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[25] Ex. 9, 2002 Citizen Petition at 7–8.
[26] *Id.* at 8.
[27] 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

120. Nevertheless, on January 22, 1993—his second full day in office—President Bill Clinton directed then-HHS Secretary Donna Shalala to assess initiatives to promote the testing and licensing of RU-486 in the United States.[28]

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.[29]

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."[30]

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.[31]

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

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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.").

[28] Ex. 9, 2002 Citizen Petition at 8.

[29] *Id.*

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

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

organization's first president."[32]

125. The talks between the FDA, the Population Council, and Roussel Uclaf culminated in what HHS called a "donation": Roussel Uclaf transferred, "without remuneration, its United States patent rights to mifepristone (RU-486) to the Population Council."[33]

126. After obtaining the American patent rights to mifepristone, the Population Council conducted clinical trials in the United States.[34]

127. The Population Council then filed a new drug application for "mifepristone 200 mg tablets" on March 18, 1996.[35]

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.[36]

129. On September 18, 1996, the FDA issued a letter stating that the application was "approvable" and requested more information from the Population Council.[37]

130. On February 18, 2000, the FDA issued a second "approvable" letter, setting forth the remaining prerequisites for approval. This letter announced that

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[32] Population Council, https://www.influencewatch.org/non-profit/population-council/ (last visited Oct. 10, 2023).

[33] Ex. 9, 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)).

[34] *Id.* at 9.

[35] *Id.* at 10.

[36] *Id.*

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

the FDA had "considered this application under the restricted distribution regulations contained in 21 C.F.R. § 314.500 (Subpart H) and [had] concluded that restrictions as per [21] CFR § 314.520 on the distribution and use of mifepristone are needed to assure safe use of this product."[38]

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."[39]

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.[40]

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."[41]

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[38] Ex. 10, FDA Letter to Population Council re: NDA (Feb. 18, 2000) at 5.
[39] *Id.*
[40] Ex. 9, 2002 Citizen Petition at 20.
[41] *Id.*

135. The Population Council stated that "[n]either pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable for that reason alone."[42]

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."[43]

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."[44]

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."[45]

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."[46]

140. Despite these last-minute objections, the Population Council ultimately ceased its opposition to the FDA's intention to approve chemical abortion drugs under

[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*

Subpart H on September 15, 2000.[47]

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."[48]

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."[49]

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.[50]

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."[51]

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[47] Ex. 11, 2000 FDA Approval Memo. to Population Council re: NDA 20-687Mifeprex (mifepristone) at 6 (Sept. 28, 2000).
[48] Ex. 12, 2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets at 1 (Sept. 28, 2000).
[49] Ex. 11, 2000 FDA Approval Memo. at 6.
[50] Ex. 13, 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).
[51] Ex. 11, 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."[52]

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."[53]

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.[54]

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."[55]

149. The FDA's Subpart H restrictions included the following requirements

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[52] *Id.* at 2.
[53] *Id.*
[54] *Id.* at 2–3.
[55] *Id.* at 3.

for abortionists: the ability to assess the duration of pregnancy accurately and to diagnose ectopic pregnancies (chemical abortion drugs cannot end an ectopic pregnancy, but the symptoms of these drugs resemble hemorrhaging from a life-threatening ectopic pregnancy[56]); 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.[57]

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.[58]

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

[56] Ex. 14, *AAPLOG Statement on FDA removing Mifepristone safety protocols (REMS)*, at 2, https://aaplog.org/wp-content/uploads/2021/04/AAPLOG-Statement-on-FDA-removing-mifepristone-REMS-April-2021-1.pdf.
[57] Ex. 11, 2000 Approval Memo. at 6.
[58] *Id.*

the FDA acknowledge and address these laws.[59]

152. The FDA also outlined the Population Council's two post-approval study commitments.[60] 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)."[61] The Population Council also agreed "to study ongoing pregnancies and their outcomes through a surveillance, reporting, and tracking system."[62]

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."[63] 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."[64]

154. The FDA nonetheless highlighted the findings of one limited study that included 51 subjects under 20 years of age. The agency explained that the approved labeling states that the safety and efficacy for girls under 18 years of age "have not been studied" because the raw data from this limited study had not been submitted

[59] *Id.*
[60] Ex. 12, 2000 Approval Letter at 2–3.
[61] Ex. 11, 2000 Approval Memo. at 7.
[62] *Id.*
[63] Ex. 12, 2000 Approval Letter at 3.
[64] Ex. 11, 2000 Approval Memo. at 7.

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.[65]

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"[66]—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.[67]

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

158. With the FDA approval in hand, the Population Council then granted Danco Laboratories, LLC ("Danco"), which was incorporated in the Cayman Islands in 1995, an exclusive license to manufacture, market, and distribute Mifeprex in the United States.[68]

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[65] *Id.*
[66] *Id.*
[67] Ex. 15, 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).
[68] Ex. 9, 2002 Citizen Petition at 9.

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, AAPLOG and Christian Medical & Dental Associations, along with the Concerned Women for America, submitted a 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).[69]

161. The 2002 Petitioners requested that the FDA impose an immediate stay of the approval of mifepristone and ultimately revoke the approval, in addition to requesting a full FDA audit of the underlying clinical studies.[70]

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

[69] *Id.* at 1.
[70] *Id.*

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.[71]

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."[72]

164. The 2002 Petitioners similarly pointed out that surgical abortions carry comparatively fewer risks than chemical 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," abortionists are expected to make surgical abortion available for any woman or girl who undergoes chemical abortion.[73]

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."[74]

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[71] *Id*. at 18–23, 41–48.
[72] *Id*. at 19.
[73] Id. at 21–22.
[74] *Id*. at 37.

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.[75]

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."[76]

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

[75] *Id.* at 24–41.
[76] *Id.* at 49–71.

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;

(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.[77]

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.[78]

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).[79]

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[77] *Id.* at 75–76.
[78] *Id.* at 76.
[79] *Id.* at 71–75.

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.[80]

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.[81]

173. The 2002 Citizen Petition next pointed out that the FDA impermissibly reduced the Population Councils' post-approval studies during the final stages of the FDA's review in 2000. "Not only did FDA approve the NDA on the basis of clinical trials so defective with respect to their design and execution as to render them insufficient to establish short-term safety and effectiveness, but FDA also permitted the Population Council to substantially pare down the [post-approval] trials that it would perform."[82]

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

[80] Ex. 9, 2002 Citizen Petition at 75.
[81] *Id*. at 76–83.
[82] *Id*. at 84–85.

as part of another study rather than as a separate [post-approval] study."[83] 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.[84]

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.[85]

VII. Implementation of a REMS for Mifepristone

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

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

178. In a March 27, 2008 Federal Register notice, the FDA identified

[83] *Id*. at 86.
[84] *Id*. at 86, n. 377.
[85] Ex. 13, 2003 Response.

chemical abortion drugs as one of "those drugs that FDA has determined will be deemed to have in effect an approved REMS."[86]

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.[87]

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."[88]

181. The REMS incorporated the previous Subpart H restrictions and consisted of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.[89]

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." [90]

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

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[86] Ex. 16, 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).
[87] Ex. 17, 2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC at 1 (June 6, 2011) (2011 Approval Letter).
[88] *Id*. at 1.
[89] *Id*. at 1; Ex. 18, 2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011) (2011 REMS).
[90] Ex. 17, 2011 Approval Letter at 1; Ex. 30, 2011 REMS.

the advertisement."[91]

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").[92]

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

186. In the 2016 Denial, the FDA asserted that it appropriately approved chemical abortion drugs under Subpart H because "[a]s FDA made clear in the preamble to the final rule for subpart H, the subpart H regulations are intended to apply to serious or life-threatening conditions, as well as to illnesses or diseases."[93]

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."[94]

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."[95]

189. The FDA also asserted that chemical abortion "provides a meaningful therapeutic benefit to some patients over surgical abortion" because chemical

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[91] Ex. 17, 2011 Approval Letter at 2–3.
[92] Ex. 15, 2016 Petition Denial.
[93] *Id.* at 4 (emphasis added).
[94] *Id.*
[95] *Id.*

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."[96]

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."[97]

191. The FDA then asserted that its decision not to require studies of pediatric patients "was consistent with FDA's implementation of the regulations in effect at that time." The agency also asserted that its 2000 Approval "determined that there were sufficient data from studies of mifepristone." Even though the 2000 Approval said the FDA was waiving the requirement for a pediatric assessment, the 2016 Petition Denial stated that the 2000 Approval "should have stated our conclusion that the pediatric study requirements were waived for pre-menarchal patients and that the pediatric study requirements were met for post-menarchal pediatric patients, rather than stating that we were waiving the requirements for all pediatric groups."[98]

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

[96] *Id.* at 5.
[97] *Id.* at 9.
[98] *Id.* at 29.

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."[99]

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."[100] But the FDA did not purport to provide an example of drug labeling where that second drug was not approved for the use of the new indication.

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

194. On the *same day* that the FDA denied the 2002 Citizen Petition—March 29, 2016—the FDA also approved major changes to the mifepristone regimen (2016 Major Changes) in response to an sNDA that Danco had submitted to the FDA on May 28, 2015.[101]

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

[99] *Id*. at 15.
[100] *Id*.
[101] Ex. 19, 2016 FDA Letter to Danco Laboratories re: NDA 020687, Supp 20 (Mar. 29, 2016.

restrictions under which the drug was originally approved."[102] 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.[103]

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

[102] Ex. 20, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020, at 4 (Mar. 29, 2016) (2016 Summary Review).
[103] *Id*. at 6.

after an abortion; and

(g) allowing "healthcare providers" other than physicians to dispense and administer the chemical abortion drugs.[104]

198. Despite these major changes to the regimen, the FDA shockingly *eliminated* the requirement for prescribers to report all nonfatal serious adverse events from chemical abortion drugs. Rather than require future adverse-event reports from abortionists about whether revising the dosages and removing the initial safeguards harmed women and girls, the FDA simply asserted that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged." The FDA at least conceded that "[i]t is important that the Agency be informed of any deaths with Mifeprex to monitor new safety signals or trends."[105]

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

[104] *Id.* at 6–10.
[105] *Id.* at 27.

well-controlled investigation that evaluated the safety and effectiveness of mifepristone and misoprostol under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

202. Instead, the FDA relied on studies that evaluated only one or just a few of the major changes that the FDA enacted in 2016; as the FDA acknowledged, "in some cases data from a given study were relied on to provide evidence to support multiple changes"[106]—but no study supported all the changes.

203. For example, the FDA relied on a study led 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.[107] 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."[108] 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, or (3) an ability of abortionists to personally perform surgical

[106] Ex. 20, 2016 Summary Review at 6.
[107] Ex. 21, Beverly Winikoff et al., *Extending Outpatient Medical Abortion Services Through 70 Days of Gestational Age*, 120 Obstetrics & Gynecology 1070 (2012).
[108] *Id*. at 1071.

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 one or more of the following substantial weaknesses: significant loss to follow-up; safeguards not required under the labeling; small sample size lacking statistical significance; not powered to evaluate safety; and bias.

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

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.[109]

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 premenarcheal females." The FDA then concluded that Danco "fulfilled the remaining PREA requirement in postmenarcheal females by submitting published studies of Mifeprex for pregnancy termination in postmenarcheal females less than 17 years old." The FDA cited three published studies in support of this conclusion.[110]

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.[111]

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

[109] Ex. 20, 2016 Summary Review at 18–20.
[110] *Id.* at 18–19.
[111] *Id.* at 19 (citing Ex. 22, Mary Gatter et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269 (2015).

hospitalized, or experienced other serious adverse events.[112] The authors also recognized that "[l]oss to follow-up was significantly higher among the youngest age group."[113]

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."[114] Despite this significant data gap, the FDA went on to conclude that "age did not adversely impact efficacy outcomes."[115]

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.[116] 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

[112] Ex. 22, Gatter at 4–5.
[113] *Id.* (emphasis added).
[114] Ex. 20, 2016 Summary Review at 19 (emphasis added).
[115] *Id.*
[116] Ex. 22, Gatter at 2.

Gatter[117] and Deborah Nucatola,[118] had significant incentives to increase their income and Planned Parenthood's profits through abortion-related actions outside of performing surgical abortion.[119]

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.[120] 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."[121] 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.[122]

215. The third and final study that the FDA cited in support of its PREA

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[117] *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).

[118] *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").

[119] 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).

[120] Ex. 20, 2016 Summary Review at 19–20 (citing Ex. 2, Niinimaki, *supra* note 6).

[121] Ex. 2, Niinimaki, *supra* note 6 at 3–4.

[122] Ex. 20, 2016 Summary Review at 20.

conclusion was a study of 28 adolescents, ages 14 to 17 years old, with pregnancies under 57 days' gestation.[123] Even though the authors of this study cautioned that a larger study was needed to make any generalizable conclusions for pediatric populations, the FDA likewise found this small study "reassuring."[124]

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

X. 2019 Citizen Petition

217. In response to the 2016 Major Changes, on March 29, 2019, the 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 prescriber."[125]

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

[123] *Id.* at 19.
[124] *Id.* at 20.
[125] Ex. 23, 2019 Citizen Petition of AAPLOG to FDA (Mar. 29, 2019).

of women and girls:

- Reduce the maximum gestational age from 70 days to 49 days;
- Limit the ability to prescribe and dispense chemical abortion drugs to qualified, licensed physicians—not other "healthcare providers";
- Mandate certified abortionists 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.[126]

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.[127]

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."[128]

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

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[126] *Id.*
[127] *Id.* at 13–14.
[128] *Id.*

abortion drug regimen.[129]

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.[130] The 2019 Citizen Petition also raised concerns about dispensing from a pharmacy instead of a clinical facility.[131]

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[132] 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.[133]

225. On the same day, the FDA approved modifications to the existing REMS for chemical abortion drugs to establish a single, shared system REMS for

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[129] *Id.* at 14–25.
[130] *Id.* at 18–20.
[131] *Id.* at 20–23.
[132] GenBioPro, Inc. is located at 3651 Lindell Road, Suite D1041, Las Vegas, Nevada. https://www.dnb.com/business-directory/companyprofiles.genbiopro_inc.f925af03300887aacd053afe151fefb2.html.
[133] Ex. 24, 2019 FDA ANDA Approval Letter to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

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.[134]

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.[135]

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

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

[134] Ex. 25, 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.
[135] Ex. 26, 2020 Letter from ACOG and SMFM, to FDA about Mifepristone REMS (Apr. 20, 2020) (2020 ACOG-SMFM Letter).

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.[136]

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).[137]

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) provided no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to the reported adverse events."[138]

232. The FDA's 2021 Non-Enforcement Decision neither acknowledged nor

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[136] *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).
[137] Ex. 27, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS, at 2 (Apr. 12, 2021) (2021 Non-Enforcement Decision).
[138] *Id.*

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."[139]

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.[140]

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.

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

235. 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.[141]

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[139] *Id*.

[140] Ex. 28, FDA Supplemental Approval Letter to Danco Laboratories, LLC (May 14,2021), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/020687Orig1s024ltr.pdf.

[141] Ex. 29, 2021 FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021).

236. 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."[142]

237. The letter identified specific new modifications to the REMS: "(1) removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals (i.e., the 'in-person dispensing requirement'); and (2) adding a requirement that pharmacies that dispense the drug be specially certified," signaling that the FDA will soon allow pharmacies to dispense chemical abortion drugs.[143]

238. 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.[144]

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).[145]

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[142] *Id.*
[143] *Id.*
[144] *Id.*
[145] Ex. 30, 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.

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.[146]

242. Aside from retaining these two remaining requirements, the FDA denied the 2019 Citizen Petition's requests (1) to restore and strengthen the mifepristone and prescriber requirements approved in 2000 and (2) to continue limiting the dispensing of mifepristone to women in clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber.[147]

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.[148]

244. After providing this regulatory background, the FDA defended its decision in the 2016 Major Changes to reconsider and revise the safeguards codified

16, 2021) (2021 FDA Response).
[146] *Id.* at 21–23.
[147] Ex. 30, 2021 FDA Response.
[148] *Id.* at 2–3.

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."[149]

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."[150]

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.[151]

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

[149] *Id.* at 38.
[150] *Id.* at 25
[151] *Id.* at 25–36.

adverse event"; and thus "FAERS data cannot be used to calculate the incidence of an adverse event . . . in the U.S."[152]

249. The FDA likewise admitted that FAERS "is woefully inadequate to determine the post-marketing safety of mifepristone due to its inability to adequately assess the frequency or severity of adverse events" and the adverse events reported to the FDA "represent a fraction of the actual adverse events occurring in American women."[153] The FDA also agreed that there are reporting "discrepancies [that] render the FAERS inadequate to evaluate the safety of mifepristone abortions." [154]

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.[155] 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.[156]

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[152] Ex. 31, Questions and Answers on FDA's Adverse Event Reporting System (FAERS), https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers.

[153] Ex. 32, 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).

[154] Ex. 33, 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).

[155] Ex. 34, FDA, *FDA Adverse Event Reporting System (FAERS) Electronic Submissions*, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions.

[156] Ex. 35, *Specifications for Preparing and Submitting Electronic ICSRs and ICSR*

251. The FDA also relied on some published studies in making its 2021 decision to deny the 2019 Citizen Petition. The agency, however, noted that "the ability to generalize the results of these studies to the United States population is hampered," "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," and the FDA "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States."[157]

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.[158]

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:

Attachments (April 2021), https://www.fda.gov/media/132096/download.
[157] Ex. 30, 2021 FDA Response at 28.
[158] *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. The FDA's Removal of the In-Person Dispensing Requirement

255. Early in 2021, the FDA "announced that, in connection with the COVID-19 pandemic, the agency would not enforce the in-person dispensing requirement. Effectively, this allowed mifepristone to be prescribed remotely and sent via mail." *AHM*, 78 F.4th at 226.

256. "Later that year, FDA stated that it would adopt the change on a permanent basis. It then amended mifepristone's REMS (which applies to Mifeprex and the generic version) in January of 2023 to formalize the removal of the in-person dispensing requirement." *Id.*

XIX. Injuries to Plaintiffs

A. Injury from 2019 approval of generic mifepristone

257. The same is true of the 2019 Generic Approval. By approving a generic version of the drug, FDA increased supply and availability, lowering cost and thus increasing use of chemical abortions. Ex. 38, Solanky Affidavit.

258. As a direct result of the FDA's decision to approve the 2019 generic version of mifepristone, "third parties [have] react[ed] in predictable ways," increasing the use of chemical abortion compared to surgical abortion. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019).

259. The number of women obtaining chemical abortions has increased as a result of the 2019 generic approval, Ex. 38, Solanky Affidavit, and thus the "the number of women experiencing medical complications after taking mifepristone has risen as a result of the generic" approval, *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 241 (5th Cir. 2023).

260. Because Plaintiff States experience harm, as explained below, from the use of chemical abortions, the 2019 generic approval aggravates and worsens Plaintiff States' harms.

B. Direct Economic Injury to Plaintiffs

261. In addition to the incalculable toll from the loss of human life, the FDA's decisions to increase access to (and demand for) chemical abortions inflict substantial economic injury on Plaintiff States.

262. The FDA does "not dispute that a significant percentage of women who

take mifepristone experience adverse effects." *AHM*, 78 F.4th at 229. "FDA has acknowledged that a certain fraction of patients would require surgery due to miscellaneous complications." *Id.* This fraction is about "5-8" percent, according to the FDA. *Id.*

263. "Some women experience especially severe complications, such as sepsis …." *Id.*

264. "[T]housands of women, and as many as hundreds of thousands, have experienced serious adverse effects as a result of taking the drug, and required surgery or emergency care to treat those effects." *Id.* at 230.

265. Research has conclusively shown that the risks of complications are higher for chemical abortions than for surgical abortions, and also higher for low-income women.

266. A recent study of Medicaid recipients who received abortions from 1999 to 2015 established that "[o]ut of 423,000 confirmed induced abortions, 121,283 abortion recipients, or 28.7%, had an ER [emergency room] visit within 30 days." Ex. 36, Studnicki Affidavit ¶ 18.

267. This rate increased over time. By 2015, "more than 35% of women having any type of induced abortion were having an ER visit for some reason within 30 days of the procedure." *Id.* ¶ 16(g).

268. The rate of ER visits for women who had received a chemical abortion was much higher than the rate of ER visits for women receiving surgical abortions. "[T]he actual number and per-abortion rate of ER visits following any induced

abortion were increasing [from 1999 through 2015], but chemical abortion was consistently associated with more post abortion ER visit morbidity than surgical abortion. While surgical abortions led to ER visits 4% to 5% of the time [within 30 days of an abortion], the percentage for chemical abortions leading to ER visits was 8% to 9% between 2002 and 2013, increasing to a peak of 14.6% from 2014 to 2015," the last year of the study. *Id.* ¶ 11.

269. In other words, "abortion related ER visits as a percentage of total ER visits was consistently about twice as high for chemical abortions as surgical abortions." *Id.* ¶ 16(c).

270. One reason for the higher complication rates and ER rates for women receiving chemical abortions is that, unlike with surgical abortions where complications often occur with a physician present, "adverse events following a mifepristone abortion are more likely to be experienced at home in the absence of a physician." *Id.* ¶ 12. Even when a complication is experienced at a clinic, because abortion drugs are often administered by a person who has no surgical training, a woman experiencing complications is forced to go to an ER. *Id.*

271. Women also are told to "complete the chemical abortion regimen at home," and the FDA has "directed the hundreds of thousands of women who have complications to seek 'emergency care' from" local hospitals near where they live. *All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725, at *8 (5th Cir. Apr. 12, 2023).

272. Beyond emergency room visits, women receiving abortions are also

much more likely to be hospitalized than women receiving surgical abortions are. Ex. 37, Coleman Affidavit ¶ 35(a).

273. "Chemical abortions are significantly more likely (OR 1.80, CL 1.38-2.35) than surgical abortions to result in an RPOC [retained products of conception] admission." Ex. 36, Studnicki Affidavit ¶ 19 (brackets in original).

274. One reason chemical abortions consistently lead to higher hospitalization rates, according to the study, is because they are improperly coded as natural miscarriages at very high rates.

275. Between 1999 and 2015, an average of 30% of Medicaid recipients who obtained chemical abortions and had abortion-related emergency room visits were miscoded as having had natural miscarriages. In 2015, the percent miscoded was 60.9. In other words, between one-third and two-thirds of women who obtained chemical abortions paid for by Medicaid and then had an abortion-related ER visit were improperly coded by ER staff as having had a natural miscarriage instead of an abortion. *Id.* ¶ 13.

276. This miscoding makes hospitalization much more likely. "A patient's decision not to reveal to her treating physician that she obtained a chemical abortion, or the ER staffs' failure to identify the failed abortion attempt, are risk factors for multiple hospital admissions and delayed provision of necessary surgical treatment, compared with care for those whose abortion is not miscoded." *Id.* ¶ 21.

277. These higher complication rates, ER rates, and hospitalization rates for chemical abortions cause direct economic harms on Plaintiff States in several ways.

i. Costs to public insurance associated with medical expenses

278. First, Plaintiff States pay for medical bills related to these complications when women on public insurance (such as Medicaid or insurance provided by the State to government workers) obtain chemical abortions and must go to the emergency room or hospital in Plaintiff States.

279. Even in States that have greatly restricted abortions, women are forced to seek emergency room services after obtaining chemical abortions.

280. For example, abortion is illegal in Missouri (except for medical emergencies), but some Missourians obtain abortion drugs by traveling out of State, only to return to Missouri where they experience the chemical abortion.

281. Last year, at least 2,883 Missourians obtained abortions in Kansas. https://www.kdhe.ks.gov/DocumentCenter/View/29328/KS-Abortions-2022-PDF. A clear majority, 59.6%, of abortions performed in Kansas were chemical abortions. *Id*.

282. Unlike with surgical abortions, complications from chemical abortions typically occur when a woman has returned home. Missouri citizens are told "to complete the chemical abortion regimen at home," and the FDA has "directed the hundreds of thousands of women who have complications to seek 'emergency care' from" local hospitals at home. *All. for Hippocratic Med. v. Food & Drug Admin.*, No. 23-10362, 2023 WL 2913725, at *8 (5th Cir. Apr. 12, 2023).

283. The vast majority of Missourians who obtain chemical abortions in Kansas or other States complete the chemical regimen in Missouri. And if they experience complications, they seek emergency care at facilities in Missouri.

284. Some women in Missouri have also obtained chemical abortion drugs in Missouri. Organizations like "Aid Access" are mailing abortion drugs "to people in all 50 states, even those [like Missouri] that have banned it." Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023).[159]

285. When Aid Access was started in 2018, "FDA regulations prevented licensed US providers from mailing mifepristone, one of the two drugs in the medication abortion regimen, so Aid Access was structured like … telemedicine service." *Id*.

286. But then the "in-person dispensing requirement for mifepristone" was removed. *Id*. "For the first time, legally prescribed medication abortion could be put in the mail. Aid Access used this opportunity to implement a hybrid model: in states where telemedicine abortion was legal, US clinicians handled the prescriptions, while in states where it wasn't, the pills continued to be mailed from India." *Id.*

287. Then, once some States like New York adopted so-called "shield-laws," groups like Aid Access began mailing these pills directly from the United States instead of India, transforming the process from "needing to wait three or four weeks to get it to happen, and not even be sure if those pills are ever going to come" to receiving abortion drugs in the mail in "two-five days." *Id.*

288. The FDA's decision not to require in-person distribution has directly

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159 https://www.theguardian.com/world/2023/jul/23/shield-laws-provide-abortion-care-aid-access

contributed to the decisions of out-of-state companies to mail abortion drugs to people in Plaintiff States. People "feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline" rather than from India. *Id.* (emphasis added).

289. Thus, "third parties [have] react[ed] in predictable ways" to the FDA's decisions, and therefore the actions of third parties are causally tied to the FDA's decisions. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019).

290. Plaintiff States pay for some of the emergency medical costs associated with chemical abortions for women who are on Medicaid or other public insurance, such as insurance programs provided to government employees.

291. For example, Missouri Medicaid (MO HealthNet) covers more than 1 million individuals in the State of Missouri, and 398,945 women and girls between the ages of 14 and 45 are currently eligible for Missouri Medicaid. Ex. 41, Brown Affidavit ¶¶ 5–6.

292. Idaho Medicaid similarly had an average monthly enrollment of 379,954 participants, including 97,055 women and girls between the ages of 14 and 45, in 2020 and 2021. Ex. 40, Charron Affidavit ¶ 15.

293. Between April 28, 2018 and August 23, 2023, Missouri's Department of Health and Senior Services (DHSS) received 438 abortion complication reports, 186 of which (about 42.4%) were submitted following chemical abortions. Ex. 39, Missouri Department of Health and Senior Services Affidavit, at 2.

294. Each year Plaintiff States expend funds covering expenses associated

with medical complications from abortions.

295. "For example, in Calendar Year 2022, Idaho Medicaid provided coverage for a woman presenting with bleeding following a failed medication abortion. The medical intervention that was required and that Idaho Medicaid covered was dilation & curretage." Ex. 40, Charron Affidavit ¶ 12.

296. "In Calendar Year 2022, Idaho Medicaid expended $12,658.05 in total funds ($3,797.42 state funds and $8,860.64 federal funds) covering treatment and follow-up care for abortion medical complications." *Id.* ¶ 9.

297. This was up from 2019, when Idaho Medicaid "expended at least $10,086.47 total funds ($3,025.94 state funds and $7,060.53 federal funds) covering treatment and follow-up care for abortion medical complications." *Id.* ¶ 10.

298. These numbers understate the true cost because chemical abortions routinely are miscoded as miscarriages. In 2015, nearly two-thirds of known chemical abortions among Medicaid recipients were misclassified by ER staff as natural miscarriages. Ex. 36, Studnicki Affidavit ¶ 33. Thus Plaintiff States spend untold sums of money through public insurance treating complications related to chemical abortions without knowing the underlying cause of the complications.

299. Plaintiff States also pay for the cost of medical bills associated with chemical abortion complications when women obtain emergency care out of state. For example, Missouri Medicaid pays for emergency services rendered in other States. https://dss.mo.gov/mhd/providers/pdf/out-of-state-non-bordering-services.pdf.

300. Similarly, government employees can receive payments from

government health insurance programs for government employees out of state.

ii. Costs to public hospitals

301. Second, Plaintiff States operate various public hospitals that serve women who have obtained chemical abortions. The public hospitals act as an arm of the State.

302. In Missouri, for example, each of these public hospitals is ultimately controlled by the State of Missouri and receives state funds.

303. MO HealthNet (Missouri Medicaid) pays a determined rate to public hospitals, which in some circumstances may be lower than the hospital's costs. Per regulations, those public hospitals agree to accept the payment as payment in full, even if it is less than their actual cost. They may not seek further payment from the patient.

304. If MO HealthNet pays only a portion of a medical bill, the public hospital (an instrumentality of the State) will incur as an expense the difference between the full amount of the medical bill and what was paid.

305. If a public hospital provides medical services for complications stemming from chemical abortions, and the State's Medicaid program does not cover the full portion of the bill, the outstanding balance is a loss to the public hospital, which is itself an instrumentality of the State.

306. Between January 2018 and August 16, 2023, 55 of the 438 chemical abortion complication reports (approximately 1 in 8 of all total chemical abortion complication reports) were reported by Missouri's public hospitals. Ex. 39, Missouri

Department of Health and Senior Services Affidavit, at 2.

iii. Costs to public insurance associated with mental health care

307. As with medical complications, Plaintiff States also provide public coverage of certain mental health expenses such as psychiatry, psychology, and counseling, including through Medicaid and public insurance programs for government employees.

308. Studies show that women and girls who receive a chemical abortion suffer from harms to their mental health and psychological conditions at a rate higher than women and girls who receive a surgical abortion. Ex. 37, Coleman Affidavit ¶¶ 18–26(e).

309. According to these studies, women who choose chemical abortion over surgical exhibit significantly higher rates of mental health issues, such as obsessive-compulsive symptoms, guilt, interpersonal sensitivity issues, paranoid ideation, and general psychological/psychiatric symptoms. *Id.* ¶ 19.

310. On top of that, chemical abortion causes greater negative effects on mental health because of its painfulness and disruptiveness. *Id.* ¶ 22.

311. Unlike women who obtain surgical abortions, women who choose chemical abortion often view the unborn child as it is aborted, which is associated with more intrusive events, such as nightmares, flashbacks, and unwanted thoughts related to the experience. *Id.* ¶¶ 22–26(e).

312. Because women are the direct actor when they take abortion pills (unlike with surgical abortions, where the physician is the direct actor) women who

choose chemical abortion report feeling that they have actively participated in their child's death. *Id.* ¶¶ 22–26(e).

313. Women who chose chemical abortion have higher PTSD intrusion scores indicative of nightmares, unwanted thoughts, and images. *Id.* ¶¶ 22(b), 25.

314. Women who choose chemical abortion are more likely to continue associating their homes, or the bathroom, with abortion. The home may become a trigger for uncomfortable emotions rather than a refuge. *Id.* ¶ 26(e).

315. As a result of these and other factors, women who obtain chemical abortions are more likely to seek and need general mental health services, including women who obtain publicly funded mental health services.

C. Injury to Plaintiffs' sovereign interests in the creation and enforcement of their own laws.

316. Doctors who live or work in Plaintiff States will continue to treat women and girls who suffer complications from chemical abortion drugs.

317. Plaintiff States have a number of different statutes regulating and, in certain instances, prohibiting, chemical abortions.

318. For example, Missouri law prohibits any abortion "except in cases of medical emergency." Mo. Rev. Stat. § 188.017.2.

319. Missouri law also states that no provider can administer a chemical abortion drug without first submitting a treatment plan to address complications and obtaining approval from the health department of that plan:

> When the Food and Drug Administration label of any drug or chemical used for the purpose of inducing an abortion includes any clinical study in which more than one percent of those administered the drug or chemical required

> surgical intervention after its administration, no physician may prescribe or administer such drug or chemical to any patient without first obtaining approval from the department of health and senior services of a complication plan from the physician for administration of the drug or chemical to any patient.
>
> Mo. Rev. Stat. § 188.021.2

320. Regulations passed under this law require physicians who perform abortions to prearrange for backup physicians to address complications if needed. 19 C.S.R. 10-15.050.

321. Missouri law also includes an in-person dispensing requirement for abortion drugs. "When RU-486 (mifepristone) or any drug or chemical is used for the purpose of inducing an abortion, the initial dose of the drug or chemical shall be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient." Mo. Rev. Stat. § 188.021.1.

322. The FDA's actions interfere with Plaintiff States' "sovereign interest in 'the power to create and enforce a legal code.'" *Texas Office of Public Utility Counsel v. F.C.C.*, 183 F.3d 393, 449 (5th Cir. 1999) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico,* 458 U.S. 592, 601 (1982)).

323. For example, one federal court has determined that FDA's "2023 REMS reflect a determination by the FDA that when mifepristone is prescribed, it may be prescribed via telemedicine." *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D.W. Va. Aug. 24, 2023). On that basis, the court ruled that West Virginia's law—which, like Missouri's, does not permit telemedicine abortion with chemical abortion drugs—was preempted. *Id.*

324. If sued, Missouri will vigorously dispute that its law is preempted by FDA's REMS, but the *GenBioPro* decision makes clear that the FDA's unlawful REMS creates a substantial risk of injury to Missouri in the form of interference with Missouri's ability to create and enforce a legal code.

325. In addition, as explained above and further below, out-of-state organizations have begun mailing abortion pills directly into Plaintiff States in reliance on the FDA's decision to remove the in-person dispensing requirement. The FDA's decision has thus interfered with the fundamental policy of States like Missouri to prohibit abortions (other than in exceptional circumstances) and to require in-person administration of abortion drugs.

326. In the 2021 Non-Enforcement Decision, the FDA began declining to enforce the in-person dispensing requirement of the REMS for mifepristone.

327. On December 16, 2021, Defendant Cavazonni wrote a letter to Graham Chelius, M.D., of the Society of Family Planning and the California Academy of Family Physicians. The letter stated in part that the FDA was modifying the REMS for mifepristone to remove the in-person dispensing requirement.

328. Since the 2021 Non-Enforcement Decision, abortionists have been mailing mifepristone into Plaintiff States for the purpose of providing abortions to people in states that have laws prohibiting chemical abortions.[160]

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[160] Rachel Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned States*, Wash. Post. (July 20, 2023) https://www.washingtonpost.com/politics/2023/07/20/shield-laws-make-it-easier-send-abortion-pills-banned-states/

329. This continued after the FDA formalized the removal of the in-person dispensing requirement in January 2023.

330. According to just one report, in less than a month, seven U.S.-based providers mailed approximately 3,500 doses of mifepristone and its generic equivalent to states that have banned the use of chemical abortions.[161]

331. Indeed, some States have embraced Defendants' actions and have in fact passed "shield" laws expressly seeking to prevent Plaintiff States from enforcing their own laws.[162] These laws often explicitly name mifepristone and the proponents of those laws openly proclaim that they seek to abrogate the sovereignty of Plaintiff States.[163]

332. Plaintiff States have a sovereign interest in ensuring the enforcement of their duly passed laws and in not being compelled to disregard those laws. *See Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *cf. Abbott v. Perez*, 138 S. Ct. 2305, 2324 n. 17 (2008) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.").

333. By lowering the barriers to obtain mifepristone, including removing the requirement that the drug be administered in-person by a licensed physician, Defendants have unlawfully, arbitrarily, and capriciously removed the restrictions

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[161] *Id.*
[162] Rachel Roubein, *How blue states are responding to the post-Roe world,* Wash. Post (June 21, 2023) https://www.washingtonpost.com/politics/2023/06/21/how-blue-states-are-responding-post-roe-world/
[163] *Id.*

that prevented or limited the ability of third parties to unlawfully provide mifepristone in Plaintiff States.

334. FDA's decisions have similarly deprived Plaintiff States of their sovereign "benefits that are to flow from participation in the federal system." *Alfred L. Snapp*, 458 U.S. at 608. One such benefit is the uniform application of federal law and the ability of States to rely on the backdrop of federal law when enacting their own regulations. *Crow Indian Tribe v. United States*, 965 F.3d 662, 676-677 (9th Cir. 2020).

335. Plaintiff States have relied on federal laws so the States can implement their own policies about in-person administration, protection of human life, and other policies.

336. Defendants' actions—including the 2016 Major Changes and the 2021 Non-Enforcement Decision—have the direct effect of enabling and encouraging third parties to provide, through the mail, mifepristone to citizens of Plaintiff States for the purpose of inducing risky abortions that are expressly contrary to the policies expressed in many of those States' statutes.

337. As a result of Defendants' actions, Plaintiffs have suffered injury to their sovereign interests because they are unable to fully enact and enforce their laws. These harms are distinct (and in addition to) the harms suffered by the citizens of Plaintiffs as a result of the 2016 Major Changes and the 2021 Non-Enforcement Decision.

338. The harms to Plaintiffs' sovereign interests in enforcing their laws are

irreparable. *See, e.g.*, *Kansas v. United States*, 249 F.3d 1213, 1227 (10th Cir. 2001) (holding that Kansas suffered an irreparable harm where a federal agency's decision "places [Kansas'] sovereign interests and public policies at stake.").

339. Absent the relief sought in this lawsuit, the actions of Defendants will continue to encourage the violation of Plaintiffs' laws and harm Plaintiffs' sovereign interests in the enforcement of their laws.

340. Plaintiffs' citizens include women and girls who have suffered and will suffer from complications from the FDA's unlawful approval of chemical abortion drugs and subsequent elimination of the safeguards previously included with the use of chemical abortion drugs.

D. Injury to Plaintiffs' quasi-sovereign interest in protecting the health and wellbeing of its citizens.

341. Plaintiffs' citizens include women and girls who have suffered and will suffer from complications from the FDA's unlawful approval of chemical abortion drugs and subsequent elimination of the safeguards previously included with the use of chemical abortion drugs.

342. Plaintiffs' citizens also include doctors 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.

343. Missouri, Kansas, and Idaho have a quasi-sovereign interest in protecting the health and welfare of women and girls in their states—groups which constitute "a sufficiently substantial segment of [the States'] population[s]." *Alfred L.*

Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 607 (1982). This falls within Plaintiff States' "quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general." *Id*. This injury "suffices to give the State[s] standing to sue" because "the injury" to the health and welfare of women and girls in each State "is one that the State . . . would likely attempt to address." *Id*. Indeed, Plaintiff States have addressed the harms "through [their] sovereign lawmaking powers." *See, e.g.*, Mo. Rev. Stat. § 188.017.2; *Alfred L. Snapp*, 458 U.S. at 607.

i. Injuries to Women and Girls

344. Chemical abortion drugs cause women and girls who are citizens of Plaintiffs to suffer many intense side effects, including cramping, heavy bleeding, and severe pain.

345. Women and girls who are citizens of Plaintiffs and who take chemical abortion drugs experience significantly more complications than those who have surgical abortions.

346. Since the 2016 Major Changes, the number of women and girls who are citizens of Plaintiff States, who have suffered complications from chemical abortion, and who have required critical medical treatment has increased and will continue to increase.

347. The FDA's decision to expand the gestational age for approved mifepristone use to 70 days (10 weeks) harms women and girls.

348. This expansion of the permissible gestational age is especially

dangerous for women and girls when combined with the FDA's elimination of the in-person dispensing and follow-up visit requirements.

349. 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 in-person dispensing requirement exposes women and girls who are citizens of Plaintiffs to increased risk of suffering complications from chemical abortion and requiring further medical attention following the drug regimen.

350. 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 the women and girls 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.

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

352. As more women and girls who are citizens of Plaintiffs 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.

353. 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.

354. The FDA's decision not to require abortionists to report all adverse events for chemical abortion drugs harms women and girls who are citizens of Plaintiffs because it creates an inaccurate and false safety profile for the use of chemical abortion drugs.

355. 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 who are citizens of Plaintiffs from giving informed consent to these providers.

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

357. Abortionists who prescribe or dispense chemical abortion drugs to citizens of Plaintiffs 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 for 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.

358. Women and girls often suffer distress and regret after undergoing chemical abortion, sometimes seeking to reverse the effects of mifepristone. Ex. 37, Coleman Affidavit ¶ 24.

359. A woman or girl can experience these emotions and feelings upon viewing the body of her lifeless baby after taking chemical abortion drugs. *Id.*

360. Even with medical oversight, abortionists can sometimes coerce women into taking chemical abortion drugs—without their true informed consent. *Id.* ¶¶ 44–45(b).

361. The FDA's actions to eliminate in-person dispensing and administration also harm women who are citizens of Plaintiffs 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.

362. Women and girls who are citizens of Plaintiffs will continue to suffer

complications from chemical abortion drugs.

ii. Injuries to Doctors in Plaintiff States

363. Because the FDA's 2000 Approval of chemical abortion drugs legalized an unsafe drug regimen, women and girls, including women and girls who are citizens of Plaintiffs, have suffered many intense side effects and increasing complications—requiring crucial medical attention and treatment.

364. The FDA's 2000 Approval has caused medical professionals, including doctors who live or work in Plaintiff States, to treat women and girls who have suffered complications from mifepristone and misoprostol.

365. Since the 2016 Major Changes and the associated elimination of necessary safeguards for women and girls, medical professionals, including doctors who live or work in Plaintiff States, 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.

366. The FDA's approved regimen for chemical abortion drugs harms not only women and girls but also medical professionals, including doctors who live or work in Plaintiff States, who respond and treat these complications and other effects from chemical abortion drugs.

367. 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, 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 doctors who live or work in Plaintiff States.

368. The same is true of the 2019 Generic Approval. By approving a generic version of the drug, FDA increased supply and availability, lowering cost and thus increasing use of chemical abortions. Ex. 38, Solanky Affidavit.

369. 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. This need for blood transfusions exacerbates the current critical national blood shortage.[164]

370. The increased occurrence of complications related to chemical abortion drugs multiplies the workload of health care providers, including doctors who live or work in Plaintiff States, 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).

371. When there is a complication from chemical abortion drugs, the typical care changes from simple patient management to complicated patient management. Accordingly, a patient who suffers complications from chemical abortion drugs

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

requires significantly more time and attention from providers than most patients require.

372. 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 doctors who live or work in Plaintiff States, especially given that remote abortionists often cannot or do not treat such complications.

373. 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.[165]

374. As more emergency situations arise, emergency room doctors, including doctors who live or work in Plaintiff States, are having to treat more patients, including performing hysterectomies or removing remaining fetal parts. 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.

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[165] 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.

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

376. Doctors who live or work in Plaintiff States experience enormous pressure, stress, and chaos in the emergency situations the FDA created through its approval of chemical abortion drugs and elimination of necessary safeguards.

377. Some of these emergency situations force pro-life doctors, including doctors who live or work in Plaintiff States, into situations in which they feel complicit in an elective chemical abortion because they are required to remove a baby with a beating heart or other pregnancy tissue to save the life or health 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.

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

379. When patients have chemical abortions, their 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.

380. 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, doctors who practice in Plaintiff States cannot effectively practice evidence-based medicine. Healthcare 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.

381. 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.

382. Even when doctors 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.

383. 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 reported complications sent to Danco are ever 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.

384. Because many women and girls suffering complications from chemical abortion drugs tell emergency department doctors that they are experiencing miscarriages, doctors often do not report these incidences as adverse events, leaving these complications significantly underreported or not fully known. In a recent study, as many as 60.9% of chemical abortions were miscoded as miscarriages when patients later were forced to go to the emergency room. Ex. 36, Studnicki Affidavit ¶ 13.

385. 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 doctors who live or work in Plaintiff States, to practice medicine and provide proper treatment to these patients.

386. 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.

387. 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.

388. As this exposure increases, so does the cost to practice medicine, including insurance costs.

389. Doctors who live or work in Plaintiff States 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.

390. Doctors who live or work in Plaintiff States will likely continue to treat women and girls who suffer complications from chemical abortion drugs.

391. FDA's decisions aggravate all these harms. For example, the removal of the pre-2016 REMS, the approval of generic mifepristone, and the 2023 removal of the in-person dispensing requirement increase supply of chemical abortions, thus lowering cost and increasing use of chemical abortions. Ex. 38, Solanky Affidavit. Because chemical abortions are riskier and costlier than surgical ones, that increased use of chemical abortions imposes substantial harms on Plaintiff States.

392. Similarly, by extending the gestational age at which women can obtain the abortion drug, the FDA has increased the risk for women. Chemical abortions at later gestational ages come with greater complication rates and greater risks for mental health. Ex. 37, Coleman Affidavit ¶¶ 27–33, 40–41

CLAIMS FOR RELIEF

CLAIM ONE

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

393. Plaintiffs re-allege and incorporate, as though fully set forth, all previous paragraphs of this complaint.

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

I. FFDCA

395. 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.

396. 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.

397. 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.

398. 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.

399. 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.

400. 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

401. 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.

402. 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.

403. 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

404. 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

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

CLAIM TWO

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**

406. Plaintiffs re-allege and incorporate, as though fully set forth, all previous paragraphs of this complaint.

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

408. Because the FDA relied on the unlawful 2000 Approval of Mifeprex as a means to approve GenBioPro's generic drug, Mifepristone Tablets, 200 mg, the 2019 ANDA Approval needed independently to satisfy the requirements of the FFDCA and PREA.

409. Although Plaintiff States do not challenge the 2000 approval in light of concerns expressed by the Fifth Circuit in the *Alliance for Hippocratic Medicine* case that the statute of limitations may have run, the 2000 approval was arbitrary and capricious and otherwise unlawful.

410. 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).

411. 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).

412. 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.

413. 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).

414. FDA's 2019 ANDA Approval was independently unlawful because FDA lacked a sufficient scientific basis for granting the approval.

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

CLAIM THREE

2016 MAJOR CHANGES, 2019 ANDA APPROVAL, 2021 NON-ENFORCEMENT DECISION, AND 2023 FORMALIZATION OF REMOVAL OF IN-PERSON DISPENSING REQUIREMENT

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

416. Plaintiffs re-allege and incorporate, as though fully set forth, all

previous paragraphs of this complaint.

417. The FDA lacked legal authority when issuing its 2016 Major Changes, 2021 Non-Enforcement Decision, and 2023 Removal of In-Person Dispensing Requirement.

418. 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.

419. 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.

420. The FDA's 2021 Non-Enforcement Decision and 2023 Removal of In-Person Dispensing Requirement 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.

421. Because a federal agency cannot permit what federal law expressly prohibits, the FDA lacked legal authority when issuing its 2016 Major Changes, 2021 Non-Enforcement Decision, and 2023 Removal of In-Person Dispensing Requirement.

422. Therefore, the FDA's 2016 Major Changes, 2021 Non- Enforcement Decision, and 2023 Removal of In-Person Dispensing Requirement 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 FOUR

2023 REMOVAL OF IN-PERSON DISPENSING REQUIREMENT

**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;
VIOLATION OF 18 U.S.C. §§ 1461–62**

423. Plaintiffs re-allege and incorporate, as though fully set forth, all previous paragraphs of this complaint.

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

425. FDA lacked data to justify removing the in-person dispensing requirement.

426. Removal of the in-person dispensing requirement authorizes delivering abortion drugs by mail or common carrier, which is plainly illegal under federal law, 18 U.S.C. §§ 1461–62.

427. Therefore, the FDA's 2023 Removal of In-Person Dispensing Requirement must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

PRAYER FOR RELIEF

For these reasons, Plaintiff States respectfully request that the Court enter an order and judgment against Defendants, including their employees, agents, successors, and all persons in active concert or participation with them, in which it:

A. Issues a preliminary injunction ordering Defendants

i. to reinstate the REMS that were in place before 2016;

ii. to rescind the 2019 generic approval; and

iii. to restore the in-person dispensing requirement;

B. Issues a 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.

C. Holds unlawful, sets aside, and vacates the 2016 Major Changes.

D. Holds unlawful, sets aside, and vacates the 2019 ANDA Approval.

E. Holds unlawful, sets aside, and vacates the 2023 Removal of In-Person Dispensing Requirement.

F. Declares 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."

G. Declares 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.

H. Declares 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.

I. Declares 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.

J. Declares 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.

K. Retains jurisdiction of this matter for the purpose of enforcing this Court's order.

L. Awards Plaintiffs' costs, attorneys' fees, and other disbursements for this action.

M. Grants any other relief this Court deems equitable, just, and appropriate.

Dated: November 3, 2023

Respectfully submitted,

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* *pro hac vice applications forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that, on November 3, 2023, the foregoing was filed electronically through the Court's electronic filing system and served by email on all parties.

/s/ *Joshua M. Divine*