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

State of Missouri; **State of Kansas**; **State of Idaho**, *Intervenor Plaintiffs*, v. **U.S. Food and Drug Administration**; **Robert M. Califf**, in his official capacity as Commissioner of Food and Drugs, 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**

AMENDED COMPLAINT

1. Women face severe, even life-threatening, harm because the federal government has disregarded their health and safety.

2. Defendant U.S. Food and Drug Administration (FDA) has the statutory responsibility to protect the health, safety, and welfare of all Americans by putting commonsense safeguards on high-risk drugs.

3. But the FDA has failed in this responsibility by removing many of the safety standards it once provided to women using abortion drugs.

4. Abortion drugs are dangerous—the FDA's own label says that an estimated roughly one in 25 women who take abortion drugs *will* visit the emergency room.

5. But the FDA has enabled online abortion providers to mail FDA-approved abortion drugs to women in states that regulate abortion—dispensing abortion drugs with no doctor care, no exam, and no in-person follow-up care. These dangerous drugs are now flooding states like Missouri and Idaho and sending women in these States to the emergency room.

Women prepare in-home abortion kits at a 'pill-packing party' at the MAP's offices; Patient packages include two abortion medications, instructions and additional information.[1]

6. Women face severe bleeding, ruptured ectopic pregnancies, and life-threatening infections because the FDA recklessly removed in-person safety standards that it once provided.

7. Women should have the in-person care of a doctor when taking high-risk drugs. The States of Missouri, Kansas, and Idaho thus challenge the FDA's actions

[1] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

to remove commonsense safety measures for abortion drugs and ask that the Court hold these actions unlawful, stay their effective date, set them aside, and vacate them.

8. In rolling back safeguard after safeguard, the FDA has turned a blind eye to the known harms of abortion drugs to the detriment of women and girls.

9. The FDA has taken the following agency actions that harm women and girls: (1) the 2016 rollback of most of the safety precautions that the FDA had put in place when it approved mifepristone in 2000, including three in-person doctor visits and limits to ensure these drugs were not taken later in pregnancy; (2) the 2019 approval of a single, shared system Risk Evaluation and Mitigation Strategy (REMS) for the brand and generic versions of mifepristone; and (3) the 2021 and 2023 decisions to allow these drugs to be sent by mail and dispensed online or at pharmacies.

10. In March 2016, the FDA made "interrelated," "major changes" to the abortion drug regimen but failed to explain why it was unnecessary to consider any study that evaluated the cumulative effects of the changes as a whole.

11. Major changes that occurred in 2016 included (1) extending the permissible gestational age of the baby from seven weeks to ten weeks; (2) reducing the number of required in-person office visits from three to one; and (3) expanding who could prescribe and administer abortion drugs beyond medical doctors.

12. Each of these regimen changes carries its own risks. And combining them only increases those risks. For example, numerous studies show that there are increased risks from abortion drugs to pregnant women as the baby's age advances from seven to ten weeks, due in part to significant growth of the placenta and the baby during that period. The risks of harm to women are also exacerbated without follow-up visits, during which a doctor can assess whether a mother is suffering complications from the older gestational age of her baby.

13. But despite the FDA itself characterizing these changes as "interrelated," the FDA made them without any studies that evaluated the impact of removing all of these interrelated safeguards at once.

14. On top of removing these safeguards, the FDA also eliminated the safeguard under which abortion providers must report non-fatal complications. But this elimination was based on past data collected under the originally approved safety standards, not the new deregulated regime. This was unreasonable.

15. In 2016, the agency also ignored the potential impacts that the removal of commonsense safeguards would have on adolescent girls, a violation of the Pediatric Research and Equity Act (PREA). It improperly relied on extrapolation in lieu of any safety assessment of the new regimen's safety and effectiveness on pediatric populations. And the FDA needed to classify pregnancy as a "disease" to avoid such a safety assessment. But pregnancy is not a disease.

16. In addition, the studies on which the FDA did rely included safety measures like ultrasound screenings and follow-up visits that were stripped from the new regimen.

17. The FDA's major changes failed to satisfy the rigorous scientific standards of the Federal Food, Drug, and Cosmetic Act (FDCA) and violated PREA's requirement for a specific safety assessment of these changes on pregnant girls who undergo the revised regime.

18. In 2019, several organizations filed a citizen petition challenging the 2016 changes and asserting that the agency violated the law by ignoring the growing and substantial evidence that these high-risk drugs harm women. *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 226 (5th Cir. 2023), *rev'd*, 602 U.S. 367 (2024) (*AHM*).

19. One month later, the FDA approved a generic version of Mifeprex based on the flawed and unlawful 2016 Major Changes.

20. When the FDA approved generic mifepristone, it also approved a single, shared system risk evaluation and mitigation strategy (REMS) for mifepristone products for "the medical termination of intrauterine pregnancy" through 70 days (known as the "Mifepristone REMS Program").

21. In April 2021, the FDA, under new management installed by the Biden-Harris Administration, issued a "Non-Enforcement Decision" under which the agency would not enforce the in-person dispensing protection but instead would temporarily allow abortion drugs to be shipped by mail during the COVID-19 public health emergency despite a statute expressly disallowing that conduct. 18 U.S.C. § 1461.

22. In December 2021, the FDA rejected almost all the relief sought in the citizen petition and, on the same day, the Biden-Harris FDA announced that it would permanently allow abortion providers to send abortion drugs through the mail, in blatant violation of statutory law. 18 U.S.C. § 1461.

23. And in 2023, the FDA formalized its 2021 removal of the in-person dispensing protection and expanded the program to allow mifepristone to be dispensed by retail pharmacies. The agency relied on the same basis for its 2021 decision, adding only that it had not observed a significant difference in adverse event reporting during the COVID-19 public health emergency.

24. The FDA's decision to eliminate the in-person dispensing protection failed to account for or address the federal laws that prohibit the distribution of abortion drugs by postal mail, express company, or common carrier and by interactive computer service. *See* 18 U.S.C. §§ 1461, 1462. Instead, through its words and actions FDA permitted and sometimes even encouraged these illegal activities. But a federal agency cannot authorize unlawful actions. *FCC v. Next Wave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) ("The Administrative Procedure Act requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U.S.C.

§ 706(2)(A)—which means, of course, any law, and not merely those laws that the agency itself is charged with administering.") (citation omitted).

25. The FDA has consistently identified emergency medical care—including State emergency medical care—as the backstop for abortion drug complications. Its current label directs women to emergency rooms if one of many adverse complications arise.

26. The FDA has acted unlawfully. Now, the State Plaintiffs ask the Court to protect women by holding unlawful, staying the effective date of, setting aside, and vacating the FDA's actions to eviscerate crucial safeguards for those who undergo this dangerous drug regimen.

JURISDICTION AND VENUE

27. 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 FDCA, 21 U.S.C. § 301 *et seq*.

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

29. 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.

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

31. 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).

32. 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.

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

34. 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.

35. Plaintiff States brought this intervention action in the same district and division in which an action involving the same subject matter is already pending.

36. Defendants are United States officers or agencies sued in their official capacities.

37. Therefore, this Court has personal jurisdiction over Defendants for purposes of this action because their immunity has been abrogated by 5 U.S.C. § 702, and they have "submit[ted]" to such jurisdiction "through contact with and" regulatory "activity directed at" Plaintiff States and their respective medical providers and health plans. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881 (2011).

PARTIES

Intervenor Plaintiffs

38. 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, including its interests in protecting its citizens.

39. Andrew Bailey, the Attorney General of Missouri, is authorized to "institute, in the name and on the behalf of the state, all civil suits and other

proceedings at law or in equity requisite or necessary to protect the rights and interests of the state." Mo. Rev. Stat. § 27.060.

40. 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, including its interests in protecting its citizens.

41. Kansas brings this suit through its attorney general, Kris W. Kobach. He is the chief legal officer of the State of Kansas and has the authority to represent Kansas in federal court. Kan. Stat. Ann. 75-702(a).

42. 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, including its interests in protecting its citizens.

Defendants

43. Defendant the 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 FDCA for approving new drug applications and authorizing REMS for dangerous drugs. FDA's headquarters is located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

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

45. Defendant Patrizia Cavazzoni, M.D., named 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.

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

47. Defendant Xavier Becerra is the Secretary of HHS and is named 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.

48. 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.

49. 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

I. Background

50. This action challenges the FDA's failure to abide by its legal obligations to protect the health, safety, and welfare of women and girls and comply with statutory law when eliminating necessary safeguards for pregnant women who undergo the high-risk abortion drug regimen of mifepristone and misoprostol.

51. The FDA no longer even requires an in-person visit to protect women's health and well-being when taking abortion drugs.

52. Abortion drugs are high-risk. Endocrine disrupters such as mifepristone could have significant impacts on an adolescent girl's developing body and reproductive system. Despite this fact, the FDA failed to require an assessment that evaluated the safety of the 2016 Major Changes on pregnant girls under 18 years of age.

53. The FDA has also eliminated the few safeguards it initially established to protect women who receive mifepristone.

54. In 2016, the FDA made changes (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; and (3) eliminating crucial in-person follow-up office visits to check women for life-threatening complications after taking high-risk abortion drugs.

55. The agency also eliminated the safeguard under which prescribers must report nonfatal adverse events from chemical abortion based on past data collected when original standards were still in place. This last change meant that the FDA and the public would never learn how many more happened due to the removal of the prior safeguards.

56. These changes were not only "major" but "interrelated."[2] Yet the FDA never explained why no study it relied on to make the changes assessed their collective impact on the safety and effectiveness of the drug.

57. Then, in 2021, the FDA announced that abortion providers could dispense abortion drugs by mail or mail-order pharmacy, despite longstanding federal law prohibiting mailing abortion drugs.

[2] Ex. 2, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020 (Mar. 29, 2016) (2016 Summary Review).

58. In 2023, the FDA formalized its decision to remove any in-person dispensing protection and to permit abortion providers to prescribe abortion drugs without an initial office visit or confirming that a woman does not have a life-threatening complication, such as an ectopic pregnancy, that would preclude her from taking abortion drugs.

59. The FDA relied on the same basis for its 2023 decision as its 2021 decision but added that "[t]he number of adverse events reported to FDA during the COVID-19 PHE with mifepristone use for medical termination of pregnancy is small, and the data provide no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to these reported adverse events."[3] It also noted that the format of the REMS document would not be changed "[t]o avoid the misperception that this REMS modification is making major changes to the REMS document that go beyond our December 16, 2021, determination that the REMS must be modified to remove the in-person dispensing protection and add pharmacy certification," and that the "[c]hanges are in line with the REMS Modification Notification letters sent December 16, 2021."[4]

II. The Harms of Abortion Drugs

60. A chemical abortion requires administering two drugs: (1) mifepristone (also called "Mifeprex" and "RU-486") and (2) misoprostol.

61. 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 ingests mifepristone, it blocks her natural progesterone, chemically destroys the baby's

[3] Ex. 3, FDA, Center for Drug Evaluation and Research, Mifepristone Summary Review, dated Jan. 3, 2023 at 21 (FDA 2023 Summary Review).

[4] *Id.* at 8–9, 16.

uterine environment, prevents the baby from receiving nutrition, and ultimately starves the baby to death in the womb.

62. The second drug, misoprostol, induces cramping and contractions to expel the baby from the mother's womb.

63. Women who take abortion drugs experience many intense side effects, including cramping and heavy bleeding.[5]

64. The use of these two drugs can cause significant injuries and harms to pregnant women, and studies of the real-world use of mifepristone concluded that significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient.[6]

65. For example, the FDA's own label states that roughly one in 25 women who take abortion drugs will end up in the emergency room, with up to 7 percent requiring a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding."[7]

66. Of those women who end up in the emergency room after taking abortion drugs, many suffer severe injuries. A recent study testing the severity of emergency department visits for Medicaid-eligible women following various pregnancy outcomes found that "an [emergency department] visit following a chemical abortion was significantly more likely to have a severe or critical acuity rating than a visit following surgical abortion, live birth, or an ED visit at any time by a woman who was never

---

[5] Ex. 4, Harrison Compl. Decl. ¶ 23.

[6] *Id.* ¶ 16.

[7] Ex. 5, FDA-Approved Label for Mifepristone (Mifeprex) (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf (Mifeprex 2023 Label).

pregnant."[8] The study also found that ED visits coded severe or critical for women who underwent a chemical abortion increased by 4,041.1% between 2004 and 2015, compared to a 450.6% increase for surgical abortion subjects and 20.9% for live birth subjects.[9]

67. Many women also do not understand the nature of chemical abortion or the risks associated with taking abortion drugs, resulting in an increase in the frequency of women seeking emergency medical care for side effects such as cramping, heavy bleeding, and severe pain even if they are not suffering an adverse event.[10]

68. The complications of abortion drugs increase as the baby's gestational age increases. One study found that, after nine weeks' gestation, almost four times as many women and girls experience an incomplete abortion, nearly twice as many suffer an infection, and over six times as many women and girls require surgical abortion after consuming the abortion drugs than at before nine weeks gestation.[11] The FDA's own label notes that the percentage of surgical interventions for ongoing pregnancy is just over ten times higher for women at 64–70 days gestation than for women at less than or equal to 49 days gestation.[12]

---

[8] James Studnicki et al., *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004-2015*, Int'l J. Epidemiology & Pub. Health Rsch., Apr. 2024.

[9] *Id.* at 2.

[10] Ex. 4, Harrison Compl. Decl. ¶ 31.

[11] Ex. 6, 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 5.

[12] *Supra* note 7, Mifeprex 2023 Label at Table 4.

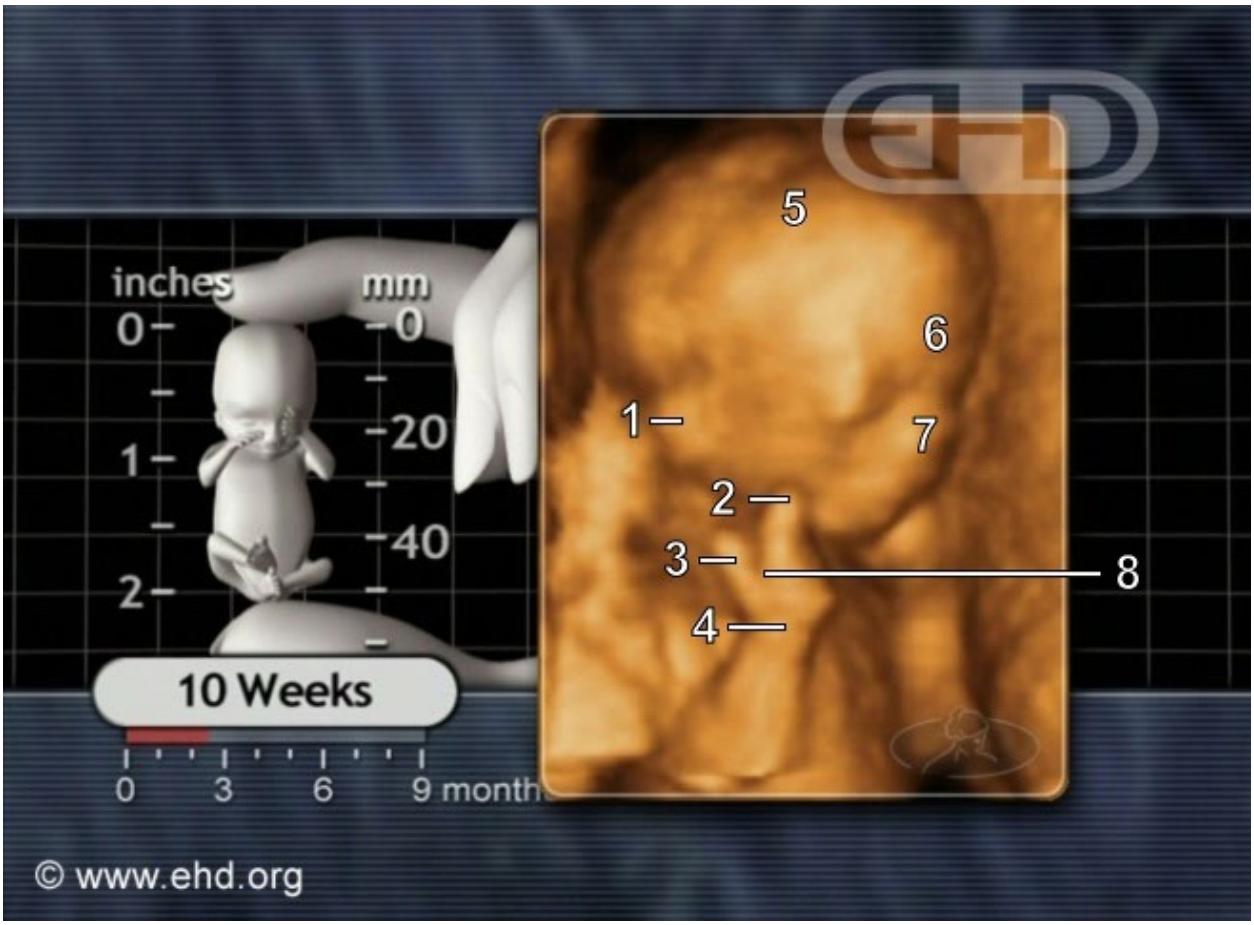
69. At seven weeks, the embryo has already developed significantly, as shown in this image:

7½-Week Embryo[13]

70. By ten weeks, the fetus is even more developed, as the following image shows.

[13] Endowment for Human Development, 7 ½ week embryo, https://www.ehd.org/gallery/477U/7%C2%BD-Week-Embryo#content.

Ten-Week Fetus[14]



71. Abortion drugs present heightened risks for women with an Rh-negative blood type. If these women are not administered Rhogam at the time of their chemical abortion, they may experience isoimmunization, which threatens their ability to have future successful pregnancies. If an Rh-negative woman is left untreated, her future baby will have a fourteen percent (14%) chance of being stillborn and a fifty percent (50%) chance of suffering neonatal death or a brain injury. Around fifteen percent (15%) of the U.S. population has this blood type.[15]

---

[14] Endowment for Human Development, I am Pointing, https://www.ehd.org/gallery/424/I-am-Pointing%21.

[15] *See* Ex. 9, *Am. Coll. of Obstetricians and Gynecologists Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, 130 Obstetrics & Gynecology 481 (Aug. 2017).

72. Without any in-person examination, abortion providers can misdate the gestational age of a baby or fail to detect an ectopic pregnancy, with serious consequences. It is undisputed that an ultrasound is the most accurate method to determine gestational age and identify ectopic pregnancy.[16]

73. Some abortion activists encourage women to lie to emergency room staff by saying they are having a miscarriage if they suffer complications requiring urgent care.[17]

74. The risk of chemical abortions is not only physical: women have described that their chemical abortion experiences harmed their mental health and left them feeling unprepared, silenced, regretful, or left with no other choice.[18]

75. Some abortion providers exacerbate this mental health harm by failing to inform a woman what she will see when she self-administers abortion drugs at home. For example, one woman was surprised and saddened to see that her aborted

---

[16] Ex. 10, *Am. Coll. of Obstetricians & Gynecologists Practice Bulletin No. 193: Tubal Ectopic Pregnancy*, 131 Obstetrics & Gynecology 91, 92 (Mar. 2018), https://perma.cc/3AA3-CNQX ("The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."); *see also* Ex. 4, Harrison Compl. Decl. ¶ 16 (recommending pre-abortion ultrasound to rule out ectopic pregnancy and confirm gestational age).

[17] *See, e.g.*, Ex. 11, *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; Ex. 12, *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 Aug. 28, 2024).

[18] Ex. 13, 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).

baby "had a head, hands, and legs" with "[d]efined fingers and toes."[19] Indeed, due to "seeing [the] aborted child once it passes," women who chemically abort their child especially "experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion." *All. for Hippocratic Medicine v. U.S. Food and Drug Admin.*, 668 F.Supp.3d 507, 527 (N.D. Tex. 2023), *rev'd*, 2024 WL 4196546 (5th Cir. Sept. 16, 2024).

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

76. The FDA's modification of a drug approval must comply with the FDCA, PREA, and the agency's regulations. When taking regulatory action on new and existing drugs, the FDA must also meet the requirements of other federal laws restricting distribution.[20]

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

77. Under the FDCA, anyone seeking to introduce into commerce and distribute a 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).

78. 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.

79. 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

---

[19] Ex. 14, 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/.

[20] 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.

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).

80. 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).

81. The FDA must refuse an application if 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).

82. 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).

83. "Substantial evidence" is "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).

84. 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.

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. A generic drug manufacturer may submit an abbreviated new drug application (ANDA) 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 identical to the approved drug, allowing it to rely on the FDA's previous finding of safety and effectiveness. The route of administration, dosage form, and strength for the generic also identical to the approved drug. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94.

B. Assessments on Pediatric Populations.

89. PREA was enacted in 2003 to require 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.

90. In general, PREA requires a drug application or supplement to an application to include a safety and effectiveness assessment 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).

91. 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(a)(2)(B)(i) (emphasis added).

92. But 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(a)(2)(B)(iii) (emphasis added).

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

93. Originally, abortion drugs were subject to a safety regimen commonly referred to as Subpart H. Subpart H allowed the FDA to accelerate approval of drugs for serious and life-threatening illnesses and authorized the FDA to require post-approval studies and distribution limitations.

D. Drugs Approved with Previous Subpart H Restrictions Deemed to have REMS.

94. In 2007, Congress codified Subpart H. 21 U.S.C. § 355-1. The Food and Drug Administration Amendments Act of 2007 (FDAAA) authorized 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).

95. 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.

96. For example, drugs like mifepristone previously approved with added safeguards were temporarily "deemed to have in effect an approved [REMS]." Pub. L. No. 110-85 at § 909(b)(1). And in 2011, the FDA approved a REMS for mifepristone that "incorporated the restrictions under which the drug was originally approved."[21]

97. 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).

98. 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).

99. The FDA may 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).

---

[21] Ex. 2, 2016 Summary Review at 4.

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

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

E. Federal Laws Restrict Distribution of Abortion Drugs to Women.

102. Two federal laws restrict the distribution of abortion-inducing drugs. 18 U.S.C. §§ 1461–62.

103. *First*, 18 U.S.C. § 1461 prohibits the use of postal "mails" to convey or deliver abortion drugs to women. 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 … drug…advertised or described in a manner calculated to lead to another to use or apply it for producing abortion."

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

IV. The FDA's Review and Approval of the Population Council's Application to Market Abortion Drugs in the United States.

105. 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.[22]

[22] Ex. 15, 2002 Citizen Petition of AAPLOG to FDA at 7–8 (Aug. 8, 2002).

106. After obtaining the American patent rights to mifepristone, the Population Council, a not-for-profit organization, conducted clinical trials in the United States.[23]

107. The Population Council then filed a new drug application for "mifepristone 200 mg tablets" on March 18, 1996.[24] It received priority review.[25]

108. The FDA approved mifepristone in 2000. The FDA said it had considered the drug under Subpart H because "restrictions ... on the distribution and use of mifepristone are needed to assure safe use of this product."[26]

109. 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."[27]

110. Given the known dangers of abortion drugs, the FDA approved the Population Council's application under Subpart H because this was the only means "to assure safe use." 21 C.F.R. § 314.520.

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

---

[23] *Id.* at 9.

[24] *Id.* at 10.

[25] *Id.*

[26] Ex. 16, FDA Letter to Population Council re: NDA (Feb. 18, 2000) at 5.

[27] *Id.*

[28] Ex. 17, 2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets at 1 (Sept. 28, 2000).

112. 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."[29]

113. The FDA could not approve mifepristone without invoking Subpart H, as it was the only authority under which it could apply postmarketing restrictions on abortion drugs.[30]

114. The FDA stated that mifepristone "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."[31]

115. 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."[32]

116. It also 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;

---

[29] Ex. 18, 2000 FDA Approval Memo. to Population Council re: NDA 20-687 Mifeprex (mifepristone) at 6 (Sept. 28, 2000) (2000 FDA Approval Memo).

[30] Ex. 19, 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).

[31] *Supra* note 29, 2000 FDA Approval Memo at 2.

[32] *Id.*

and (3) the Day 14 return to the doctor's office to confirm no fetal parts or tissue remain.[33]

117. 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."[34]

118. The FDA's Subpart H restrictions included the safeguard under which any hospitalization, transfusion, or other serious events must be reported.[35]

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

- In-person dispensing;
- 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.[36]

120. The Population Council granted Danco Laboratories, LLC ("Danco")—incorporated in the Cayman Islands in 1995—an exclusive license to manufacture, market, and distribute Mifeprex in the United States.[37]

---

[33] *Id.* at 2–3.

[34] *Id.* at 3.

[35] *Id.* at 6.

[36] *Id.*

[37] Ex. 15, 2002 Citizen Petition at 9.

V. 2002 Citizen Petition

121. In August 2002, the American Association of Pro-Life OBGYNs (AAPLOG) and Christian Medical & Dental Associations (CMDA), 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 FDCA (21 U.S.C. § 355).[38]

122. Before litigants may seek court intervention, the FDA's regulations require them to submit 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).

123. Following the procedure outlined in 21 C.F.R. § 10.45(b), 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.[39]

124. The 2002 Petitioners challenged the FDA's 2000 Approval because Danco's studies included safeguards not included in the approved label.[40]

---

[38] *Id.* at 1.

[39] *Id.*

[40] *Id.* at 76.

VI. Implementation of a REMS for Mifepristone.

125. After receiving the 2002 Citizen Petition, the FDA followed Congress's mandate under the FDAAA to convert Subpart H postmarketing restrictions for previously approved drugs into a REMS under Section 909(b)(1).

126. In a March 27, 2008 Federal Register notice, the FDA identified mifepristone as one of "those drugs that FDA has determined will be deemed to have in effect an approved REMS."[41]

127. In 2011, the FDA then approved a REMS for mifepristone.[42]

128. The FDA "determined that a REMS is necessary for MIFEPREX (mifepristone) to ensure the benefits of the drug outweigh the risks of serious complications."[43]

129. The REMS incorporated the previous Subpart H restrictions (including a black-box warning on the label for special problems, in-person dispensing, post-abortion office visits, the ability to assess gestational age and diagnose ectopic pregnancies, adverse event reporting, and the ability to provide surgical intervention or ensure patient access to other qualified physicians or medical facilities). The new REMS consisted of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.[44]

---

[41] 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).

[42] Ex. 20, 2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC at 1 (June 6, 2011) (2011 Approval Letter).

[43] *Id.* at 1.

[44] *Id.* at 1; Ex. 21, 2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011) (2011 REMS).

130. 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."[45]

131. The FDA also instructed Danco that, "[a]s part of the approval under Subpart H, as required by 21 CFR § 314.550, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days before the intended time of initial distribution of the labeling or initial publication of the advertisement."[46]

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

132. Almost fourteen years after receiving the 2002 Citizen Petition—on March 29, 2016—the FDA denied the 2002 Citizen Petition ("2016 Denial").[47]

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

133. On the *same day* that the FDA denied the 2002 Citizen Petition, it 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.[48]

134. The FDA acknowledged that "these major changes are interrelated," demonstrating the agency's awareness that each change impacted the others.[49]

---

[45] Ex. 20, 2011 Approval Letter at 1; Ex. 21, 2011 REMS.

[46] Ex. 20, 2011 Approval Letter at 2–3.

[47] Ex. 22, 2016 FDA Letter to AAPLOG, Christian Medical & Dental Associations, and Concerned Women for America denying 2002 Citizen Petition, Docket No. FDA-2002-P-0364 (Mar. 29, 2016) (2016 Petition Denial).

[48] Ex. 23, 2016 FDA Letter to Danco Laboratories re: NDA 020687, Supp 20 (Mar. 29, 2016).

[49] Ex. 2, 2016 Summary Review at 6.

135. Among other things, the 2016 Major Changes included the following revisions:

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

B. removing the requirement for any in-person follow-up examination after an abortion (including follow-up examinations on Days 3 and 14);

C. allowing "healthcare providers" other than physicians to dispense and administer the abortion drugs.[50]

136. Despite these three major changes to the regimen, the FDA eliminated the safeguard under which prescribers must report all nonfatal serious adverse events from mifepristone. Rather than require future adverse-event reports from abortion providers, the FDA simply asserted that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged." The FDA conceded that "[i]t is important that the Agency be informed of any deaths with Mifeprex to monitor new safety signals or trends."[51]

137. The 2016 Major Changes also included changes to dosing, route of administration, and timing of administration, which are not challenged here.

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

138. Despite acknowledging that the 2016 changes were interrelated, the FDA's review and approval did not include a single study that evaluated the safety and effectiveness of mifepristone and misoprostol under the conditions prescribed, recommended, or suggested in the proposed labeling. In particular, it did not assess

[50] *Id.* at 6–10.

[51] *Id.* at 27.

the cumulative effects of increasing the gestational age from 7 to 10 weeks, eliminating follow-up visits to check for complications, and requiring the supervision of a physician capable of treating complications.

139. Instead, the FDA relied on studies that evaluated only one or some of the changes. And many studies included *additional* safeguards not required under the new REMS, such as an ultrasound to confirm gestational age and pregnancy location.

140. The FDA never explained why it could rely on studies assessing only some of the interrelated changes.

141. For example, the FDA relied on three studies that "closely mirrored" the 2016 changes,[52] but all of them included in-person, post-abortion follow-up visits—one of the safeguards the agency removed despite previously calling it "very important."[53] Yet the FDA provided no explanation for why it could rely on this study for amending the gestational age, physician requirement, *and* follow-up visits.

142. Additionally, increasing the maximum gestational age by three full weeks indisputably increases rates of abortion failures, surgical interventions, and complications.[54] Simultaneously removing the two in-person follow-up visits that afford the opportunity to diagnose and treat complications before they result in an

---

[52] *See* Brief for the Federal Petitioners at 38–39, *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (No. 23-235).

[53] Ex. 24, 2000 Mifeprex Label 15, https://perma.cc/3V7C-SU6Q.

[54] Ex. 25, Mifeprex (mifepristone) Prescribing and Label information (Jan. 2023); Ex. 26, Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with Buccal Misoprostol for Medical Abortion: A Systematic Review*, 126 Obstetrics & Gynecology 12 (Jul. 2015); Ex. 27, *Am. Coll. of Obstetrics & Gynecology Practice Bulletin No. 225: Medication Abortion up to 70 days of Gestation*, 136 Obstetrics & Gynecology 31 (Oct. 2020), https://perma.cc/52KQ-HYF9 (ACOG Gestation Bulletin).

emergency only compounds these risks. But the FDA did not assess the impacts of doing both in *any* study.[55]

143. As the Fifth Circuit noted, such variations between the study conditions and the approved labeling and the collective impact of all the 2016 changes as a whole are "unquestionably an important aspect of the problem" that the FDA had a statutory duty to address. *AHM*, 78 F.4th at 246. It therefore held: "[t]he problem is not that [the] FDA failed to conduct a clinical trial that included each of the proposed changes as a control," but that the "FDA failed to address the cumulative effect at all." *Id*.

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

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

145. The FDA did not require Danco to submit an assessment on the safety and effectiveness of the drug for the claimed indications in 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.[56]

146. Under PREA, "[i]f 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

[55] *See* Ex. 2, Harrison Reply. Decl. ¶ 16.

[56] Ex. 2, 2016 Summary Review at 18–20.

patients, such as pharmacokinetic studies." 21 U.S.C. § 355c(a)(2)(B)(i) (emphasis added).

147. PREA also requires the drug sponsor to include "[a] brief documentation of the scientific data supporting the conclusion" that extrapolation is warranted "in any pertinent review for the application under section 355 of this title[.]" 21 U.S.C. § 355c(a)(2)(B)(iii).

148. Pregnancy is not a disease.[57] The FDA therefore lacked authority under § 355c(a)(2)(B)(i) to extrapolate pediatric effectiveness.

149. The FDA then concluded that Danco fulfilled its PREA obligations "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.[58] None of them satisfied the PREA requirement for a specific assessment of safety for pediatric populations.

150. The FDA must also consider "data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—(1) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and (2) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective." 21 U.S.C. § 355c(a)(2)(A). The studies relied upon by the FDA did not do either of these two things.

151. The primary study on which the FDA relied, *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, by Mary

---

[57] *California by & through Becerra v. Azar*, 950 F.3d 1067, 1090 n.20 (9th Cir. 2020) (en banc) ("Pregnancy is not a disease, and a nontherapeutic abortion is not a treatment option.").

[58] Ex. 2, 2016 Summary Review at 18–19.

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.[59]

152. 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.[60] 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."[61] 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.[62]

153. The third and final study that the FDA discussed was a study of 28 adolescents, ages 14 to 17 years old, with pregnancies under 57 days' gestation.[63] The authors of this study cautioned that a larger study was needed to make any generalizable conclusions for pediatric populations.

154. The FDA did not require any studies on the long-term effects of mifepristone in pediatric populations with developing reproductive systems.

---

[59] *Id.* at 19 (citing Ex. 28, Mary Gatter et al., *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days*, 91 Contraception 269 (2015)).

[60] Ex. 2, 2016 Summary Review at 19–20 (citing Ex. 6, Niinimaki, *supra* note 11).

[61] Ex. 6, Niinimaki, *supra* note 11 at 3–4.

[62] Ex. 2, 2016 Summary Review at 20.

[63] *Id.* at 19.

155. Given the limitations with the three cited studies, FDA needed to extrapolate the safety of the 2016 Major Changes for adolescent girls. But the agency could not avail itself of the extrapolation exception because pregnancy is not a "disease."

IX. 2019 Citizen Petition

156. In response to the 2016 Major Changes, on March 29, 2019, AAPLOG and American College of Pediatricians (ACPeds) (collectively, the 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 FDCA (21 U.S.C. § 355).

157. 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."[64]

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

A. Reducing the maximum gestational age from 70 days to 49 days;

B. Limiting the ability to prescribe and dispense abortion drugs to qualified, licensed physicians—not other "healthcare providers";

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

C. Mandating certified abortion providers be physically present when dispensing abortion drugs;

D. Requiring 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;

E. Restoring the requirement for in-person administration of misoprostol;

F. Restoring the requirement for an in-person follow-up visit to confirm abortion and rule out life-threatening infection through clinical examination or ultrasonographic scan;

G. Restoring the 2000 label language that stated that abortion drugs are contraindicated if a woman lacks adequate access to emergency medical care; and

H. Restoring 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.[65]

159. 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.[66]

---

[65] *Id.*

[66] *Id.* at 13–14.

160. 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."[67]

161. At a minimum, 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, it requested the FDA do no further harm to the few remaining safeguards for women who undergo the abortion drug regimen.[68]

162. In particular, the 2019 Petitioners explained that eliminating or relaxing the REMS to facilitate internet or telephone prescriptions would be dangerous to women.[69] The 2019 Citizen Petition also raised concerns about dispensing from a pharmacy instead of a clinical facility.[70]

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

---

[67] *Id.*

[68] *Id.* at 14–25.

[69] *Id.* at 18–20.

[70] *Id.* at 20–23.

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

164. On April 11, 2019, the FDA approved GenBioPro, Inc.'s[71] generic version of Mifeprex, "Mifepristone Tablets, 200 mg" (2019 ANDA Approval) since the agency "concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling."[72] 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.[73] GenBioPro sells the only generic mifepristone and misoprostol, and these sales are the company's only product and sole source of revenue.[74]

165. On the same day, the FDA approved modifications to the existing REMS for mifepristone to establish a single, shared system REMS for mifepristone products for the "medical termination of intrauterine pregnancy," thus allowing the FDA to have a uniform REMS for the abortion drugs that two companies were now

---

[71] GenBioPro, Inc. is located at 3651 Lindell Road, Suite D1041, Las Vegas, Nevada. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=4179736a-1cb2-4661-8c50-3d68ec7f4025&type=display.

[72] Ex. 30, 2019 FDA ANDA Approval Letter to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

[73] *Id.*

[74] Am. Compl. at ¶ 23, *GenBioPro, Inc. v. Raynes*, No. 3:23-cv-0058 (S.D.W. Va. Oct. 19, 2023), ECF No. 75.

marketing. The FDA did not make any substantive modifications to the REMS approved in 2016.[75]

XI. 2020 ACOG-SMFM Letter to the FDA.

166. 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 the in-person dispensing protection for mifepristone during the COVID-19 pandemic and instead allow dispensing by mail or mail-order pharmacy.[76]

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

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

169. The FDA then filed for an emergency stay of the injunction with the U.S. Supreme Court. Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 (U.S. Aug. 26, 2020) ("2020 FDA Stay Appl."). In that filing, the agency affirmed that the initial and only remaining in-person office visit was both "minimally burdensome" and "necessary" to preserve the safety of the women who

---

[75] Ex. 30, 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

[76] Ex. 31, 2020 Letter from ACOG and SMFM, to FDA about Mifepristone REMS (Apr. 20, 2020) (2020 ACOG-SMFM Letter).

take abortion drugs. *Id.* at 4, 13. The FDA also explained that it had reviewed "thousands of adverse events resulting from the use of Mifeprex," determined that abortion drugs continue to cause "serious risks for up to seven percent of patients," and concluded that an in-office visit was "necessary to mitigate [those] serious risks." *Id.* at 4, 7, 21. The U.S. Supreme Court granted the requested stay. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

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

170. Just three months after the Supreme Court granted FDA's request for a stay, on April 12, 2021, the FDA stated that it "intends to exercise enforcement discretion" of the in-person dispensing protection during the COVID pandemic (2021 Non-Enforcement Decision).[77]

171. The FDA's 2021 Non-Enforcement Decision relied, in part, on a supposed lack of reported adverse events occurring between January 2020 and January 2021—despite the agency's elimination of non-fatal reporting requirements for abortion providers 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."[78] But given the limitations of the FDA's adverse-event reporting, the agency could not—and did not—conclude that these reported events showed that removing the in-person dispensing protection was safe for women's health.[79]

---

[77] Ex. 32, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS, at 2 (Apr. 12, 2021).

[78] *Id.*

[79] *Id.*

172. The FDA's 2021 Non-Enforcement Decision neither acknowledged nor addressed the federal laws expressly prohibiting the distribution of mifepristone by mail, express company, common carrier, or interactive computer service—despite explicitly recognizing that this action would allow "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy."[80]

XIII. The FDA's December 2021 Decision to Permanently Remove the In-Person Dispensing Protections.

173. In a December 16, 2021 letter, the FDA "determined that the Mifepristone REMS Program continues to be necessary to ensure that the benefits of the drug outweigh the risks," but 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."[81]

174. 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 would soon allow pharmacies to dispense abortion drugs.[82]

175. The Letter acknowledged that the FDA had answered the "related" 2019 Citizen Petition and would post the agency's response in the public docket.[83]

---

[80] *Id.*

[81] Ex. 33, 2021 FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021).

[82] *Id.*

[83] *Id.*

XIV. The FDA's Denial and Grant of the 2019 Citizen Petition.

176. That same day—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).[84]

177. 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.[85]

178. The FDA otherwise 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.[86]

179. The FDA defended its decision to remove safeguards in the 2016 Major Changes and repeated its previous justifications not to require studies in the pertinent pediatric population in the 2016 Major Changes. The agency again asserted that "the safety and efficacy were expected to be the same for postpubertal (i.e., post-menarchal) adolescents."[87]

180. The FDA further 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

---

[84] Ex. 34, 2021 FDA Letter to AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 (Dec. 16, 2021) (2021 FDA Response).

[85] *Id.* at 21–23.

[86] Ex. 34, 2021 FDA Response.

[87] *Id.* at 38.

requirement is no longer necessary to ensure that the benefits of the drug outweigh the risks."[88]

181. 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 before removed the requirement for abortion providers to report nonfatal adverse events.[89]

182. The FDA relied on the FAERS database despite conceding these facts: "FAERS data does have limitations"; the "FDA does not receive reports for every adverse event"; and thus "FAERS data cannot be used to calculate the incidence of an adverse event . . . in the U.S."[90]

183. The 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."[91] Reporting "discrepancies [that] render the FAERS inadequate to evaluate the safety of mifepristone abortions."[92]

---

[88] *Id.* at 25.

[89] *Id.* at 25–36.

[90] Ex. 35, 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.

[91] Ex. 36, 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).

[92] Ex. 37, 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).

184. The complicated FAERS electronic submission process further hinders the reporting of adverse events and exacerbates the unreliability of the number of adverse event reports.[93] Doctors or other interested individuals seeking to submit an adverse event report must navigate a confusing, complicated, acronym-laden webpage.[94] 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.[95]

185. In addition to FAERS data, the FDA evaluated "assessment data" concerning healthcare provider certification, program utilization, and non-compliance. It noted that the eight reported cases of adverse events from these data were also identified in the FAERS database.[96]

186. The FDA also claimed support from published literature evaluating mail-order dispensing by pharmacies and clinics.[97] Yet the agency conceded that it was unable to "generalize" the results to the United States population, and that "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes."[98] The FDA thus acknowledged that "the studies [it] reviewed are *not adequate on their own* to establish the safety of the model

---

[93] Ex. 4, Harrison Compl. Decl. ¶¶33–34.

[94] Ex. 38, 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.

[95] Ex. 39, *Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments* (April 2021), https://www.fda.gov/media/132096/download.

[96] Ex. 34, 2021 FDA Response at 25.

[97] *Id.*; Ex. 32, 2021 FDA Letter to ACOG and SMFM about Mifepristone REMS at 2.

[98] Ex. 34, 2021 FDA Response at 28.

of dispensing mifepristone by mail."[99] Instead, the studies were merely "not inconsistent with" FDA's conclusion that removing the initial in-person visit would be safe.[100]

187. The FDA reviewed three studies for "mail order pharmacy dispensing."[101]

188. One (Hyland) reported that 3 percent of the participants needed to be hospitalized—a 330 percent increase over the rate on the approved label.[102] The FDA disregarded this dramatic increase, saying it could not make any "conclusions on [that study's] safety findings."[103]

189. Another study (Upadhyay) had certain "deviations" from abortion practices in the United States, "limited follow-up information, and small sample size"—all of which "limit[ed] [its] usefulness."[104]

190. The third study, an "interim analysis" (Grossman), was largely inapplicable because it evaluated outcomes for "dispens[ing] by mail-order pharmacy after in-person clinical assessment."[105]

191. The FDA also cited five studies that "evaluated clinic dispensing by mail."[106]

---

[99] *Id.* at 35 (emphasis added).

[100] *Id.* at 28.

[101] *Id.* at 30.

[102] *Id.* at 31. (The FDA-approved mifepristone labeling includes a baseline hospitalization rate of less than one percent.)

[103] *Id.*

[104] *Id.* at 30–31.

[105] *Id.* at 30.

[106] *Id.* at 31.

192. In one (Raymond), "7 percent of participants had clinical encounters in [emergency department (ED)]/urgent care centers."[107]

193. In another (Chong), "6 percent of participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical interventions were required in 4.1 percent to complete abortion."[108]

194. A third study (Anger) revealed that "12.5 percent had an unplanned clinical encounter."[109]

195. In the fourth study (Kerestes), 5.8 percent in the "telemedicine plus mail group" had "ED visits," a rate exceeding the range on the label (2.9 to 4.6 percent) and almost three times higher than its 2.1 percent comparator figure for women who had an "in-person" visit.[110]

196. The final study (Aiken) had "significant limitations" because "investigators were unable to verify the outcomes" and "the study's design did not capture all serious safety outcomes."[111]

197. After reviewing these studies, the FDA conceded that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic."[112] The agency similarly acknowledged that the Anger study "suggests a pre-abortion examination may

---

[107] *Id.* at 32.

[108] *Id.*

[109] *Id.* at 32–33.

[110] *Id.* at 33.

[111] *Id.* at 34.

[112] *Id.* at 35; *accord id.* at 33–34.

decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care."[113]

198. Nevertheless, the FDA concluded that "these studies overall support that dispensing by mail from the clinic is safe,"[114] and that mifepristone would "remain safe and efficacy [would] be maintained" if it removed the in-person dispensing protection from the REMS program.[115]

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

200. In January 2023, the FDA rejected a similar petition submitted on December 13, 2022, by Students for Life of America and other signatories (SFLA Petition).

201. The SFLA Petition requested that the FDA reverse its 2021 and 2016 modifications and restore the 2011 mifepristone REMS. The FDA noted that the relief requested by SFLA was "the same or substantially the same as" the 2019 Citizen Petition and directed SFLA to its "December 16, 2021 response to that petition."[116]

---

[113] *Id.* at 33.

[114] *Id.* at 34.

[115] *Id.* at 28.

[116] Ex. 40, 2023 FDA Letter to Students for Life of Am. denying 2022 SFLA Petition, Docket No. FDA-2022-P-3209, at 2 (Jan. 3, 2023), https://www.regulations.gov/document/FDA-2022-P-3209-0003.

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

Regulation	2000 Approval	2016 Major Changes	2021/2023 Decision
Maximum Gestational Age	49 days	70 days	70 days
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
In-person administration of misoprostol	Yes	No	No
Follow-up in-person evaluation post-abortion	Yes	No	No
Requiring prescribers to report all non-fatal serious adverse events	Yes	No	No

XV. The FDA's 2021/2023 Removal of the In-Person Dispensing Protection.

203. In April 2021, prior to the agency's denial of almost all of the 2019 Citizen Petition, the FDA "announced that, in connection with the COVID-19 pandemic, the agency would not enforce the in-person dispensing protection. Effectively, this allowed mifepristone to be prescribed remotely and sent via mail." *AHM*, 78 F.4th at 226. The FDA's April 2021 action expressly allowed "dispensing []

mifepristone through the mail ... or through a mail-order pharmacy" during the applicable time period.[117]

204. In December 2021, the FDA decided to permanently remove the in-person dispensing protection.[118]

205. Pursuant to its December 2021 decision, the FDA "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." *AHM*, 78 F.4th at 226.

206. The FDA acknowledged in 2023 that it had "determined" on "12/16/2021" that "the REMS must be modified to remove the in-person dispensing requirement."[119]

207. It added in its 2023 Summary Review that, following its 2021 decision, "[t]he number of adverse events reported to FDA during the COVID-19 PHE with mifepristone use is small." And that this additional data "provide[d] no indication that any program deviation or noncompliance with the Mifepristone REMS Program contributed to these reported adverse events."[120]

208. The FDA also noted that the format of the REMS document would not be changed "[t]o avoid the misperception that this REMS modification is making major changes to the REMS document that go beyond our December 16, 2021, determination that the REMS must be modified to remove the in-person dispensing

---

[117] Ex. 32, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS at 2.

[118] Ex. 34, 2021 FDA Response at 6.

[119] Ex. 3, FDA 2023 Summary Review at 6.

[120] *Id.* at 38.

requirement and add pharmacy certification," and that the "[c]hanges are in line with the REMS Modification Notification letters sent December 16, 2021."[121]

209. The FDA's January 2023 REMS permanently "[r]emov[ed] 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 expanded the program to allow mifepristone to be dispensed by certified pharmacies, including retail pharmacies.[122]

210. These actions comprise the 2021/2023 Removal of the In-Person Dispensing Protection.

211. By March 2024, one year after the modified REMS took effect, Walgreens and CVS announced they had completed certification requirements and would begin dispensing mifepristone in their stores.[123]

212. The current Mifeprex Prescriber Agreement Form also requires such healthcare providers to have the "[a]bility to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[124]

213. And the current Mifepristone Patient Agreement acknowledges that "[m]y healthcare provider has told me that these symptoms listed above could require

---

[121] *Id.* at 8–9, 16.

[122] Ex. 41, REMS Single Shared System for Mifepristone 200 mg (Jan. 2023), https://perma.cc/MJT5-35LF (the "2023 Mail-Order Decision").

[123] Ex.42, Pam Belluck, *CVS and Walgreens Will Begin Selling Abortion Pills This Month*, New York Times (March 1, 2024), https://www.nytimes.com/2024/03/01/health/abortion-pills-cvs-walgreens.html.

[124] Ex. 43, Mifeprex Prescriber Agreement Form at 1.

emergency care. If I cannot reach the clinic/office/provider right away, my healthcare provider has told me who to call and what to do."[125]

214. Dispensing mifepristone by mail also poses potential problems for maintaining the appropriate level of active ingredient under uncontrolled shipping conditions. One 2018 study of mifepristone from India found that 18 mifepristone-misoprostol combination drugs shipped over a range of three to 21 business days contained within 8% of the labeled 200 mg amount of active mifepristone by the time they reached their destination.[126] The study did not control for humidity, heat, or other conditions affecting active ingredient degradation, posing concerns for individuals receiving abortion drugs exposed to even harsher weather conditions. Indeed, the researchers projected that the 35 percent of packages that did not arrive within the advertised shipping time "may have been delayed because of *winter* weather."[127]

215. FDA's own label for mifepristone requires a storage temperature of "25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]."[128] These conditions cannot be guaranteed during standard shipping transit, particularly in summer or winter weather conditions. But the FDA's decision to allow mail-order abortion drugs neither acknowledged nor addressed this known issue.

216. What's more, the study noted that none of the sites on which the abortion drugs were procured "required a prescription or any medical documents.

---

[125] Ex. 44, Mifepristone Patient Agreement at 1.

[126] Chloe Murtagh et al., *Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet*, 97 Contraception 287 (2018).

[127] *Id.* at 288 (emphasis added).

[128] *Supra* note 7, Mifeprex 2023 Label at 13.

Two required completion of an online medical history questionnaire; none of the questions asked about gestational age or any of the specific contraindications listed on the label for Mifeprex®, the brand of mifepristone approved for abortion by the US Food and Drug Administration."[129]

XVI. The FDA's Recognition that Emergency Rooms would be the Backstop for Abortion Drug Harm.

217. The FDA has consistently identified emergency rooms as the backstop for abortion drug harms. ER visits are the predictable consequence of its removal of safeguards.[130]

218. Given the potential for serious adverse events, the FDA recognized that "access to ... emergency services *is critical* for the safe and effective use of the drug."[131] The FDA required and still requires doctors "to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[132] The drug was also "contraindicated" where "access to emergency services" was "[in]adequate."[133] And the FDA required prescribing physicians without the ability to perform emergency services to "direct" women "to a hospital for emergency services."[134]

219. Danco, in consultation with FDA, also issued a "Dear Emergency Room Director" letter in 2004 to "assist [ER Directors] in taking care of patients who may

---

[129] Murtagh, *supra* note 126 at 288.

[130] *See* Ex. 4, Harrison Compl. Decl. ¶¶ 18–19, 26–30.

[131] Ex. 18, 2000 FDA Approval Memo at 3 (emphasis added).

[132] *Id.* at 6; see also Ex. 44, Mifepristone Patient Agreement Form at 1.

[133] Ex. 18, 2000 FDA Approval Memo at 5.

[134] *Id.*

present in an emergency room setting" after taking abortion drugs.[135] The letter warned that "there may be some women who present to an emergency room with serious and sometimes fatal infections and bleeding" or ruptured ectopic pregnancies.[136]

220. In its 2011 REMS materials, the FDA warned that women should not take mifepristone if they "cannot easily get emergency medical help [for] 2 weeks" after taking the drug.[137] The REMS required prescribers "to assure patient access to appropriate medical facilities" that were "equipped to provide blood transfusions and resuscitation, if necessary."[138] And the agency instructed women to take the medication guide with them "[w]hen [they] visit an emergency room."[139]

221. In its 2016 denial of the 2002 Citizen Petition, the FDA said it would continue to rely on emergency rooms as a backstop to "ensure that women have access to medical facilities for emergency care" to manage the expected complications.[140]

222. The agency did the same in its 2021 petition denial, noting prescribers were required to "ensure that mifepristone is prescribed [only] to women for whom emergency care is available."[141] And prescribers were not themselves required to be able to treat life-threatening complications, just "assure patient access to medical facilities equipped to provide blood transfusions and resuscitation."[142] Recognizing

---

[135] Ex. 45, Letter from Danco Labs. to Emergency Room Doctors 1 (Nov. 12, 2004) https://perma.cc/734R-LLSQ.

[136] *Id.*

[137] Ex. 21, 2011 REMS at 5.

[138] *Id.* at 1, 7.

[139] *Id.* at 4.

[140] Ex. 22, 2016 Petition Denial at 21.

[141] Ex. 34, 2021 FDA Response at 39.

[142] *Id.* at 9.

that this care would frequently come from emergency rooms, the FDA observed that "[i]t is common practice for healthcare providers to provide emergency care coverage for other healthcare providers' patients, and in many places, hospitals employ 'hospitalists' to provide care to all hospitalized patients."[143]

223. In evaluating mail-order dispensing, the FDA relied on five studies. In one, "7 percent of participants had clinical encounters in [emergency department (ED)]/urgent care centers."[144] In another, "6 percent of participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical interventions were required in 4.1 percent to complete abortion."[145] A third study revealed that "12.5 percent had an unplanned clinical encounter."[146] In the fourth study, 5.8 percent in the "telemedicine plus mail group" had "ED visits," which was almost three times higher than "the in-person group."[147] And the last study had "significant limitations" because "investigators were unable to verify the outcomes" and "the study's design did not capture all serious safety concerns."[148]

224. Finally, the FDA's current label for mifepristone also directs women to emergency rooms if one of many adverse events arises.[149] It says that an estimated 2.9 to 4.6 percent of women will visit the emergency room after taking mifepristone

---

[143] *Id.* at 12.

[144] Ex. 34, 2021 FDA Response at 32.

[145] *Id.*

[146] *Id.* at 32–33.

[147] *Id.* at 33.

[148] *Id.* at 34.

[149] *Supra* note 7, Mifeprex 2023 Label at 2.

on the label.[150] That's roughly one in 25 women who will end up in the emergency room if they take abortion drugs as directed.

225. The use of emergency rooms to treat abortion harms was a predictable consequence of removing safeguards around Mifepristone.[151] For example, the predictable consequence of removing the requirement that physicians dispense abortion drugs is the "explosion of Mifeprex complications including hemorrhage."[152]

XVII. Defendants' actions seek to undermine state abortion laws and state law enforcement.

226. Defendants' actions undermine state abortion laws and frustrate state law enforcement.

227. By removing REMS restrictions, the FDA fostered the creation of out-of-state abortion drug markets—and it facilitated the creation of abortion-drug markets that operate by mail, common carrier, and interactive computer service.

228. The FDA loosened the prior safeguards that prevented mifepristone from being mailed to any state or being dispensed other than in-person.

229. The FDA has done nothing to prevent mifepristone from being mailed to any particular state, regardless of federal or state law.

230. Evading state abortion laws has been the FDA's overarching regulatory purpose for mifepristone—even at the cost of harm to women's health and safety.

231. When the FDA began its approval and regulation of abortion drugs, the agency admitted that the reason to approve mifepristone was to undermine state abortion laws. Ruth B. Merkatz, PhD, RN, FAAN served as the Director of the Office of Women's Health from 1994-1996, and later became a director at the Population

---

[150] *Id.* at 8.

[151] Ex. 4, Harrison Compl. Decl. ¶¶ 18, 26.

[152] Ex. 4, Harrison Compl. Decl. ¶ 19.

Council. In her oral history of the approval of mifepristone, she explained the FDA's intent to use mifepristone to evade state abortion laws: "It was really a revolutionary decade in the '90s. We knew RU-486 was going to be very important especially in states where surgical abortions are not permitted. And if they overturn *Roe v. Wade*, it's going to be really important. What's interesting if you look through the panels in this program [referring to conference program], these are the topics that I thought were important to discuss. This is in 1994. It includes a panel on RU-486."[153]

232. A letter to the FDA in 2016 signed by 30 pro-abortion organizations stated, "[a]lthough the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the *current conditions* surrounding patient *access to abortion* care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU)." [154] The letter urged the FDA to "[c]onsider the current *legal* and social climate," explaining that "[t]he overall *legal* and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[155]

233. Early in the Biden-Harris administration, Vice President Kamala Harris promised that the administration would "fight to protect access" to abortion[156]

---

[153] FDA, Oral History Interview with Ruth B. Merkatz at 39 (Oct. 16, 2019), https://www.fda.gov/media/165295/download?attachment.

[154] Ex. 46, Letter from Soc'y of Fam. Plan. et al., to Stephen Ostroff, Acting Comm'r of Food & Drugs, Robert M. Califf, Deputy Comm'r for Med. Prods. & Tobacco & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin. 2, 5 (Feb. 4, 2016) (emphasis added).

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

[156] White House, Statement by Vice President Harris on Texas Law SB8 (Sept. 1, 2021), https://perma.cc/6TXB-8ENU.

and "use every lever of our Administration to defend the right to safe and legal abortion—and to strengthen that right."[157]

234. The President tasked HHS and the Department of Justice (DOJ) to explore steps to "ensure access to safe and legal abortion."[158] Officials were to "use every lever at their disposal to ensure … access" for "every woman … across the country."[159]

235. HHS would be a key part of this "whole-of-government approach."[160] HHS was "to look for ways to make sure we are providing access to healthcare to women" and the FDA would make a decision about lifting the REMS on mifepristone.[161]

236. In *Dobbs v. Jackson Women's Health Organization*, on June 24, 2022, the Supreme Court returned the regulation of abortion "to the people and their elected representatives." 597 U.S. 215, 259 (2022). This decision recognized that the States may regulate and prohibit abortion drugs.

---

[157] White House, Statement by Vice President Kamala Harris on Supreme Court Ruling on Texas Law SB8 (Sept. 2, 2021), https://perma.cc/7VDJ-MKZB.

[158] White House, Readout of White House Roundtable Meeting with Women's Rights and Reproductive Health Leaders (Sept. 3, 2021), https://perma.cc/CN85-AZM2.

[159] White House, Press Briefing by Press Secretary Jen Psaki and Deputy National Security Advisor for Cyber and Emerging Technologies Anne Neuberger, September 2, 2021 (Sept. 2, 2021), https://perma.cc/6CVF-3MMQ.

[160] White House, Press Gaggle by Principal Deputy Press Secretary Karine Jean-Pierre (Sept. 3, 2021), https://perma.cc/4AWK-DQQW.

[161] White House, Press Briefing by Press Secretary Jen Psaki, Secretary of Agriculture Tom Vilsack, and National Economic Council Director Brian Deese, September 8, 2021 (Sept. 8, 2021), https://perma.cc/HJ77-7KFR.

237. In response, President Biden called *Dobbs* "an extreme decision"[162] by "not a normal Court."[163]

238. Rather than wait for Congress to heed his call to codify *Roe v. Wade*, President Biden "committed to doing everything in his power" to "protect access" to abortion.[164] He noted, "Some states are saying that they'll try to ban or severely restrict access to these medications."[165]

239. So he issued multiple executive orders mandating access to abortion.[166]

240. The day *Dobbs* was issued, "[i]n the face of threats from state officials saying they will try to ban or severely restrict access to medication for reproductive health care, the President directed the Secretary of Health and Human Services to identify all ways to ensure that mifepristone is as widely accessible as possible in light of the FDA's determination that the drug is safe and effective—including when prescribed through telehealth and sent by mail."[167] President Biden specifically

---

[162] White House, Remarks by President Biden Before Meeting with His Task Force on Reproductive Healthcare Access (Jan. 22, 2024), https://perma.cc/N9KR-TKX9.

[163] White House, Remarks by President Biden on the Supreme Court's Decision on Affirmative Action (June 29, 2023), https://perma.cc/7XU8-3KL4.

[164] White House, FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services (July 8, 2022), https://perma.cc/F5ZZ-XGL8.

[165] White House, Remarks by President Biden on the Supreme Court Decision to Overturn Roe v. Wade (June 24, 2022), https://perma.cc/B8Y3-EWUZ.

[166] Exec. Order No. 14,076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053 (July 8, 2022); Exec. Order No. 14,079, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49,505 (Aug. 3, 2022); *see also* Presidential Memorandum, Further Efforts To Protect Access to Reproductive Healthcare Services, 88 Fed. Reg. 4895 (Jan. 26, 2023) ("My Administration remains committed to supporting safe access to mifepristone...").

[167] White House, FACT SHEET: President Biden Announces Actions In Light of Today's Supreme Court Decision on Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://perma.cc/66T6-BL87.

directed HHS Secretary Becerra to ensure women have "access" to abortion drugs "no matter where they live."[168]

241. The same day, Secretary Becerra accordingly announced HHS's "commitment to ensure every American has access to … medication abortion" and promised, "we will double down and use every lever we have to protect access to abortion."[169]

242. Secretary Becerra explained in a written statement, "At the Department of Health and Human Services, we stand unwavering in our commitment to ensure every American has access to health care and the ability to make decisions about health care -- including the right to safe and legal abortion, such as medication abortion that has been approved by the FDA for over 20 years. I have directed every part of my Department to do any and everything we can here. As I have said before, we will double down and use every lever we have to protect access to abortion care."[170]

243. At a press conference the same day, Secretary Becerra repeated: "HHS will take steps to increase access to medication abortion," and that "We will leave no stone unturned."[171]

---

[168] White House, FACT SHEET: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion (Jan. 22, 2023), https://perma.cc/S6R9-AT7W.

[169] Press Release, HHS, HHS Secretary Becerra's Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), https://perma.cc/89AZ-RFL4.

[170] *Id.*

[171] Press Release, HHS, Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of Roe v. Wade (June 28, 2022), https://perma.cc/KW6H-KF7D.

244. President Biden's then issued a follow-up executive order again directing HHS "to protect and expand access to abortion care, including medication abortion."[172]

245. In due course, HHS promoted "access" to abortion drugs through the FDA REMS process. In section 1 of its post-*Dobbs* "action plan," entitled "Access to Medication Abortion and Contraception," HHS said that "HHS will continue its work to protect access to FDA-regulated products for abortion that have been found to be safe and effective." It continued, the "FDA will continue the REMS modification process and review the applicants' proposed changes to the REMS related to removing the in-person dispensing requirement."[173]

246. After the FDA modified the REMS for mifepristone, HHS issued a report called *Marking the 50th Anniversary of Roe: Biden-Harris Administration Efforts to Protect Reproductive Health Care*. In this report, HHS identified the January 2023 REMS change as one of the actions HHS took since *Dobbs* to protect access to abortion.[174] In an accompanying press release, HHS highlighted the FDA's

---

[172] Exec. Order No. 14,076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053, 42,053 (July 8, 2022).

[173] Press Release, HHS, HHS Takes Action to Strengthen Access to Reproductive Health Care, Including Abortion Care (Aug. 26, 2022) https://perma.cc/JH79-NBEB; Secretary's Report, HEALTH CARE UNDER ATTACK, An Action Plan to Protect and Strengthen Reproductive Care (Aug. 2022), https://perma.cc/2SYF-G624.

[174] HHS, Marking the 50th Anniversary of Roe: Biden-Harris Administration Efforts to Protect Reproductive Health Care (Jan. 19, 2023), https://perma.cc/8EB4-P7US (HHS "continue[s] to activate all divisions of the Department in service to [its] commitment to ensuring" access to abortion).

modification of the REMS for mifepristone as one of the Department's "six core priorities" to "protect and expand access" to abortion post-*Dobbs*.[175]

247. As Secretary Becerra explained shortly thereafter, "We're using our authority as well to secure reproductive health care access for every American who needs it—wherever they are, whenever they need it."[176]

248. The White House likewise identified the FDA's 2023 permanent removal of the in-person dispensing protection as an action taken in response to President Biden's July 8, 2022 executive order directing HHS to "protect and expand access to abortion care, including medication abortion."[177]

249. Another part of the White House's whole-of-government response to *Dobbs* included enlisting DOJ in support of HHS's actions to undermine state laws by creating a 50-state mail-order abortion economy.

250. When *Dobbs* was decided, Attorney General Merrick Garland, the nation's chief law enforcement officer and head of DOJ, promised that DOJ will "work tirelessly to protect and advance" abortion and will "use every tool at our disposal."

---

[175] Press Release, HHS, HHS Releases Report Detailing Biden-Harris Administration Efforts to Protect Reproductive Health Care Since Dobbs (Jan. 19, 2023), https://perma.cc/6CE3-J7DD.

[176] Press Release, HHS, HHS Secretary Xavier Becerra Urges Nation to Shift from an "Illness-Care System" to a "Wellness-Care System" at National Press Club Luncheon (Feb. 9, 2024), https://perma.cc/R9SF-3VKC.

[177] White House, FACT SHEET: The Biden-Harris Administration's Record on Protecting Access to Medication Abortion (Apr. 12, 2023), https://perma.cc/78TT-3J2G (citing Exec. Order No. 14,076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053 (July 8, 2022), and HHS, Secretary's Report, Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care (Aug. 2022), https://perma.cc/WWV5-CSFY).

Garland warned that "States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy."[178]

251. HHS soon reported that it had been working with DOJ "to help ensure access to care and preserve [the] FDA's role in determining what is safe and effective for patients."[179] HHS said that, "The Attorney General of the United States made clear that states may not ban mifepristone based on disagreement with [the] FDA's expert judgment about its safety and efficacy."[180] These announcements came in a formal HHS report entitled *Secretary's Report Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care*, in a section entitled Federal Preemption—Protecting Access to Medication Abortion

252. Later, the White House confirmed that this purported preemption was another step that "the Biden-Harris Administration has taken…to protect access to medication abortion."[181] "[P]reserving access" to abortion drugs, the White House reiterated, is "one of two key priorities" after *Dobbs*.[182]

XVIII. The FDA actions created a 50-state abortion drug mailing economy, undermining state abortion laws.

253. Defendants' actions had their predictable and intended effect.

254. *First*, the FDA's 2016 actions resulted in the dispensing of abortion drugs to women from Plaintiff States later in pregnancy, without follow-up care, and

---

[178] Press Release, DOJ, Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://perma.cc/E6DY-59LK.

[179] HHS, Secretary's Report Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care 8 (Aug. 2022), https://perma.cc/WWV5-CSFY.

[180] *Id*.

[181] White House, FACT SHEET: The Biden-Harris Administration's Record on Protecting Access to Medication Abortion (Apr. 12, 2023), https://perma.cc/78TT-3J2G.

[182] *Id*.

without doctor supervision—leaving harmed women to seek emergency care in Plaintiff States.

255. *Second*, the FDA's 2021/2023 actions removed all in-person dispensing protections and enabled the creation of out-of-state abortion-drug distributors that dispense FDA-approved drugs by mail, common carrier, and interactive computer service—all to evade state abortion laws.

256. These actions caused a nationwide increase in chemical abortions, the widespread taking of abortion drugs up to 10 weeks of pregnancy, and the resulting cascading medical complications for women.

A. Defendants' deregulatory actions resulted in women receiving abortion drugs out-of-state and returning home to Plaintiff States with no continuous in-person care.

257. The FDA's actions enabled abortion providers to dispense abortion drugs to residents of Plaintiff States later in pregnancy and without follow-up care—causing women to seek emergency services in Plaintiff States for treatment of resulting complications.

258. This is confirmed by another case concerning the 2016 and 2023 REMS, *Whole Woman's Health Alliance v. FDA*, in which abortion providers in Virginia, Montana, and Kansas confirmed that they now dispense abortion drugs to residents of Plaintiff States who travel to them outside of Plaintiff States and then leave follow-up care to Plaintiff States' emergency providers—all because the FDA enabled these abortion providers not to provide continuous follow-up care or three in-person doctor visits.[183]

---

[183] Ex. 47, Complaint, ECF No. 1, *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM, ¶1 (W.D. Va. May 8, 2023) (hereinafter *Whole Woman's Health* Compl.) This complaint is supported by sworn declarations from the plaintiff abortion providers. *See* Ex. 48, Rebecca Tong Decl., ECF No. 10-1, *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM (W.D. Va. May 8, 2023) (hereinafter Tong Decl.); Ex.

259. Each provider in *Whole Woman's Health Alliance v. FDA* uses both Danco's Mifeprex and GenBioPro's generic mifepristone.[184] One of those providers, Trust Women, spent $20,000 on brand name mifepristone alone in early 2023.[185]

260. These abortion providers dispense FDA-approved drugs to women from Plaintiff States in order to evade state abortion laws. These providers have made what they describe as "herculean efforts to provide" abortion drugs "not only for residents of their states, but also for the thousands of patients forced to travel hundreds of miles for basic healthcare from the 13 states and counting where abortion is now banned, and the many others where it remains severely restricted."[186]

261. The FDA's decision to remove follow-up visit protections enabled Whole Woman's Health (WWH), an abortion provider with locations across the country and in Virginia, to provide abortion drugs in one state and then leave follow-up care to emergency medical professionals in other states.

262. For example, WWH of Alexandria provides FDA-approved abortion drugs up to 11 weeks to many women from Plaintiff States with no in-person follow-up visits.[187] "Because WWH of Alexandria is close to a large airport, many of our patients travel to us by plane from states where abortion [is] banned ... WWH of

---

49, Nicole Smith Decl., ECF No. 10-2, *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM (May 8, 2023) (hereinafter Smith Decl.); Ex. 50, Helen Weems Decl., ECF No. 10-3, *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM (May 8, 2023) (hereinafter Weems Decl.); Ex. 51, Amy Hagstrom Miller Decl. ¶¶ 9, 12, 19, ECF No. 10-4, Whole *Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM (May 8, 2023) (hereinafter Miller Decl.).

[184] Whole Woman's Health Compl. ¶ 60; Smith Decl. ¶ 23; Weems Decl. ¶19; Tong Decl. ¶¶ 27–28.

[185] Tong Decl. ¶ 28.

[186] Whole Woman's Health Compl. ¶ 1.

[187] Miller Decl. ¶ 16.

Alexandria provides abortion care to approximately 2,300 patients per year, and approximately 64% of those receive medication abortion."[188]

263. Another of these providers, Trust Women, operates a clinic in Wichita, Kansas that has provided abortion drugs since it opened in 2013 and that currently provides abortion drugs up to 11 weeks.[189] The clinic has "18 doctors, and 16 of them fly in to Kansas to provide care."[190] In 2021, almost half of its patients received FDA-approved abortion drugs as their method of abortion.[191]

264. As the provider explained, Trust Women Wichita "experienced a huge surge in patients seeking care following" the *Dobbs* decision.[192] In 2022, the Kansas clinic saw patients start coming from hundreds of miles away.[193] "Trust Women Wichita, as one of the few remaining clinics somewhat close to Texas, Oklahoma, and other ban states, has seen a massive increase in patients seeking care due to abortion bans.[194] Specifically, "In 2021, Trust Women Wichita saw around 1500 patients. In 2022, we saw around 3500 patients. For the first 4 months of 2023, we have seen *2000 patients already*—on pace for 6,000 for the year. Around two-thirds of our patients are coming from out of state."[195] Since Texas's abortion law "S.B. 8 took effect, it is not uncommon for us to receive tens of thousands of calls a day."[196]

---

[188] *Id.* ¶ 19 (emphasis added).

[189] Tong Decl. ¶¶ 1, 6.

[190] *Id.* ¶ 30.

[191] *Id.* ¶ 35.

[192] Whole Woman's Health Compl. ¶ 103.

[193] Tong Decl. ¶ 19.

[194] *Id.*¶ 19.

[195] *Id.* ¶ 19.

[196] *Id.* ¶ 21.

265. Montana's Blue Mountain Clinic likewise considers itself and Montana to be "a critical site of access to abortion for people in the greater Northern Rockies and Plains regions" as "access" in other states "has grown exponentially worse" since *Dobbs*.[197] Each of Montana's neighboring states—North Dakota, South Dakota, Wyoming, and Idaho—restrict abortion.[198] And "[a]bout 25% of Blue Mountain Clinic's patients travel more than 50 miles" for abortions. Smith Decl. ¶10. Blue Mountain Clinic provides FDA-approved abortion drugs up to 10 weeks of pregnancy to patients physically present in Montana.[199] In 2022, "Blue Mountain Clinic provided about 400 abortions. Almost 40% of those abortions were for patients who are insured through Medicaid (which covers abortion care in Montana)."[200]

266. All these providers send women from Plaintiff States home without ongoing care or in-person follow-up visits for abortion drug complications.

267. The FDA's lack of required in-person follow-up visits results in women traveling across the country to pick up abortion drugs from these providers (and many more like them) before returning home to complete the abortion regimen—leaving women to seek emergency care in Plaintiff States for the inevitable complications.

268. These abortion providers—the WWH entities, Blue Mountain Clinic, All Families, and Trust Women Wichita continue to provide abortion drugs in-person to this day.

269. In another case, *Washington v. FDA*, abortion providers similarly explained in sworn declarations how their use of abortion drugs under Defendants'

---

[197] Smith Decl. ¶ 7.

[198] *Id.* ¶ 7.

[199] *Id.* ¶ 13.

[200] *Id.* ¶ 15.

actions have enabled them to evade state laws and leave follow-up care to Plaintiff States.[201]

270. Cedar River Clinic in Renton, Seattle, Tacoma, and Yakima, Washington provides abortion drugs to residents and non-residents.[202] This clinic is "only one of a small handful of full-service abortion clinics in Eastern Washington," near the Idaho border.[203] FDA-approved abortion drugs "make up approximately 40% of all the abortions Cedar River Clinics perform." Cantrell Decl. ¶10. The clinic provides abortion drugs in clinic and via telemedicine to "those traveling from out of state or internationally."[204]

271. As Cedar River Clinic explained, "Many of those patients had to travel due to restrictive laws. Since the *Dobbs v. Jackson Women's Health Organization* decision in June 2022 and subsequent abortion bans, Cedar River Clinics are experiencing a rising tide in the volume of individuals coming to Washington from other states to seek an abortion. It is not limited to our region; we are serving patients from across the country *especially the South and Midwest* who are being impacted by the abortion bans in their states."[205]

272. In this case, *Washington v. FDA*, Planned Parenthood of Greater Washington and Northern Idaho (PPGWNI) likewise explained how the current FDA REMS enables it to provide FDA-approved abortion drugs to Idaho and other out-of-

---

[201] *Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. filed Feb. 23, 2023).

[202] Ex. 52, Declaration of Connie Cantrell, ECF 4-1, Ex. 2, *Washington v. FDA*, No. 1:23-cv-03026, at ¶¶ 4,7 (E.D. Wash. Feb. 24, 2023) (hereinafter Cantrell Decl.).

[203] Cantrell Decl. ¶ 6.

[204] *Id.* ¶¶ 7, 10.

[205] *Id.*¶ 7 (emphasis added).

state residents without follow-up care.[206] PPGWNI provides abortion drugs through 11 clinics throughout central and eastern Washington, with locations in Spokane, Spokane Valley, Pullman, Walla Walla, Moses Lake, Sunnyside, Pasco, Kennewick, Wenatchee, Yakima, and Ellensburg.[207] PPGWNI's abortion drugs cost $700.[208] "PPGWNI sees a high percentage of patients on Medicaid."[209]

273. PPGWNI historically has provided abortion drugs to Idaho residents and since 2022 has had an increase in other out-of-state residents seeking abortion drugs. As the provider explained, "With three of our clinics (Spokane, Spokane Valley, and Pullman) so close to the border, PPGWNI has long seen patients from Idaho. But since *Dobbs*, we have seen a significant increase in out-of-state patients."[210] "In January 2023, PPGWNI saw an increase of 25% in total abortion patient visits compared to January 2022. We saw a 75% increase in Idaho patients from January 2023 compared to January 2022."[211] "This includes a 36% increase for procedural abortion patient visits and 90% increase for medication abortion visits from Idaho."[212] "In our Pullman clinic, we now have an outright majority of patients—53% in 2022 and likely higher in 2023—coming from Idaho."[213] "This is up from 39% in 2021."[214] "Further, with the closure of PPGWNI's Boise clinic, we have started to see an influx

---

[206] Ex. 53, Declaration of Paul Dillon, ECF 4-1, Ex. 5, *Washington v. FDA*, No. 1:23-cv-03026, at ¶¶ 4, 7 (E.D. Wash. Feb. 24, 2023) (hereinafter Dillon Decl.).

[207] Dillon Decl. ¶ 4.

[208] *Id.* ¶ 21.

[209] *Id.* ¶ 7.

[210] *Id.* ¶ 9.

[211] *Id.* ¶ 10.

[212] *Id.* ¶ 10.

[213] *Id.* ¶ 11.

[214] *Id.* ¶ 11.

of out-of-state patients at our Kennewick and Walla Walla clinics."[215] "These clinics have not historically treated many out-of-state patients, but they are now the closest clinics for many people in southern Idaho."[216] "Since Dobbs, We [sic] have also started to see patients come from as far away as Texas and Florida."[217]

274. In the same case, *Washington v. FDA*, the Washington State Department of Health confirmed that Washington abortion providers like Cedar River Clinic and PPGWNI dispense abortions to non-Washington residents.[218] "In 2021, there were 15,968 abortions among Washington residents" and "998 abortions were provided to non-residents who traveled from out of state."[219] "Non-residents seeking abortion care in Washington came from 41 states, as well as Guam and Canada, with the majority coming from Idaho (406), Oregon (330), and Alaska (51)."[220] Abortion sites "in the eastern and southern parts of Washington are most likely to serve patients from Idaho and Oregon respectively based on geographic location."[221] "In 2021, 59% of the abortions provided in Washington were medication abortions."[222]

275. Cedar River Clinic and PPGWNI continue to dispense abortion drugs in person to this day.

---

[215] *Id.* ¶ 12.

[216] *Id.*

[217] *Id.* ¶ 13.

[218] Ex. 54, Declaration of Cynthia Harris, ECF 4-1, Ex. 10, *Washington v. FDA*, No. 1:23-cv-03026, at ¶¶4, 7 (E.D. Wash. Feb. 24, 2023) (hereinafter Harris Decl.).

[219] Harris Decl. ¶ 4.

[220] *Id.*

[221] *Id.* ¶ 11.

[222] *Id.*¶ 4.

276. Other abortion providers confirm that they provide abortion drugs to women from Plaintiff States in single appointments—without three doctor visits or other in-person follow-up care. For example, Emily Wales, CEO and president of Planned Parenthood Great Plains, said, "In a matter of months [after *Dobbs*], we started serving patients from Texas and Arkansas and Oklahoma … Missourians had to really compete for too few appointments" for abortion drugs.[223]

277. The FDA's actions removing the protection of three doctor visits enabled these abortion providers to provide abortion drugs to so many women—and enabled them to redirect all emergency care to Plaintiff States.

278. Without these prior FDA safeguards, these providers have increased their in-person provision of abortion drugs since 2016 (surging after *Dobbs*) which increases complications for women from Plaintiff States.

B. Defendants' removal of any doctor safeguards also contributed to women receiving abortion drugs out-of-state and then returning home with no continuous in-person follow-up care.

279. The removal of the safeguard of a doctor prescriber for FDA-approved abortion drugs was likewise a key step in allowing them to be dispensed to women in one state while leaving follow-up care to the woman's home state.

280. Three of the plaintiff providers in *Whole Woman's Health v. FDA* (Whole Woman's Health, Blue Mountain Clinic, and All Families) employ advanced practice clinicians (APCs) to provide chemical abortion drugs.[224]

---

[223] Ex. 55, Anna Spoerre, *2 Years After Missouri Banned Abortion, Navigating Access Still Involves Fear, Confusion*, Missouri Independent (June 24, 2024), https://missouriindependent.com/2024/06/24/2-year-anniversary-missouri-abortion-ban/.

[224] Whole Woman's Health Compl. ¶ 101; Miller Decl. ¶ 18; Smith Decl. ¶ 31.

281. WWH of Alexandria employs a nurse practitioner to dispense abortion drugs in-clinic, and it employed other advanced practice clinicians in the past.[225] The clinic estimates that its "nurse practitioners have provided around 1,500 medication abortions, which is more than 40% of the total medication abortions."[226]

282. WWH of Alexandria credits the FDA's removal of the prior doctor protections for its ability to provide more abortions. WWH of Alexandria "only has physicians providing abortion Thursday through Saturday, so employing APCs allows the clinic to offer abortions for the rest of the week and frees up clinic space and resources for later abortion cases over the weekend."[227] Reinstating the physician-only certified prescriber requirement would complicate WWH's operations and recruiting of APCs..."[228]

283. One provider in Montana, All Families (which is close to the border with Idaho) says that this FDA deregulation is the only way that it can provide abortion drugs. "In the case of All Families, the sole clinician prescribing and providing abortion is an advanced practice clinician. Reinstating the REMS' physician-only requirement for certified prescribers will thus eliminate the sole mifepristone provider from the northwest region of Montana."[229] In Montana the next closest provider, Blue Mountain Clinic, is a three-hour drive away.[230]

---

[225] Miller Decl. ¶ 18.

[226] *Id.* ¶ 18.

[227] *Id.* ¶ 36. "

[228] *Id.* ¶ 37.

[229] Whole Woman's Health Compl. ¶ 102; Weems Decl. ¶¶ 1–2.

[230] Weems Decl. ¶¶ 25, 28; Smith Decl. ¶ 33.

284. All Families provides abortion drugs up to 11 weeks of pregnancy.[231] In 2022, it provided approximately 260 abortions, and providing abortion drugs "makes up well over half" of these abortions.[232] The next year, abortion drugs made up "between 65% and 90%" of total monthly abortions in 2023 at All Families.[233]

285. For All Families, restoring the pre-2016 REMS would be "devastating" for its operations.[234] Reinstating "the physician-only certified prescriber requirement would mean [it] could no longer prescribe mifepristone."[235] "Advanced practice clinicians have been critical to maintaining or restoring access to abortion in this region—including access to mifepristone—and this requirement would once again cut off that access."[236]

286. At Blue Mountain Clinic, two physician assistants likewise dispense abortion drugs, and Blue Mountain Clinic brought suit to maintain this status quo.[237]

287. The other providers in *Whole Woman's Health Alliance v. FDA* similarly seek to use non-doctors to provide abortion drugs. WWH of Charlottesville does not currently have any advanced practice clinicians providing abortion care but is actively recruiting for such providers.[238] Trust Women in Kansas likewise "would want to use advanced practice clinicians to mail chemical abortion drugs if they are ultimately able to start their telehealth program."[239]

---

[231] Weems Decl. ¶ 6.

[232] *Id.*

[233] *Id.*

[234] *Id.* ¶ 24.

[235] *Id.* ¶ 25.

[236] *Id.* ¶ 26.

[237] Smith Decl. ¶ 31.

[238] Miller Decl. ¶ 11.

[239] Whole Woman's Health Compl. ¶ 101; Tong Decl. ¶ 27.

288. The FDA's actions directly led to the ability of these abortion providers to dispense abortion drugs or to dispense more abortion drugs to women from Plaintiff States, and the FDA's action directly increased harm to women and girls.

C. The FDA's pharmacy deregulation likewise leads to abortions with no in-person follow-up care.

289. Defendants' pharmacy dispensing deregulation also has major implications for Plaintiff States. This action also enabled abortion providers in other States to dispense abortion drugs (or dispense more abortion drugs) to women from Plaintiff States and then send them home for follow-up care in Plaintiff States.

290. The FDA's permission for pharmacies to dispense abortion drugs led major pharmacy chains to start stocking abortion drugs in many states—without providing in-person follow-up care.

291. Walgreens and CVS each swiftly announced that they "will sell the prescription abortion pill mifepristone after the Food and Drug Administration this week dropped a long-standing rule that prevented drug stores from doing so."[240] As one article explained, "This means patients in many parts of the U.S. will effectively be able to obtain mifepristone like other prescription medications, either in-person at a retail pharmacy or through the mail."[241] In early 2024, both "major pharmacy chains CVS and Walgreens announced they had been certified to begin dispensing mifepristone at select locations in states where abortion is legal."[242]

---

[240] Ex. 56, Spencer Kimball & Bertha Coombs, *CVS and Walgreens Plan to Sell Abortion Pill Mifepristone at Pharmacies after FDA Rule Change*, CNBC (Jan. 5 2023), https://www.cnbc.com/2023/01/05/abortion-cvs-and-walgreens-will-sell-mifepristone-in-pharmacies.html.

[241] *Id.*

[242] Ex. 57, Patrick Adams, *In Washington State, Pharmacists* are *Poised to Start Prescribing Abortion Drugs*, NPR (March 1, 2024),

292. In March 2024, Walgreens announced that "it will begin dispensing mifepristone pills within a week — consistent with state laws — in select locations in California, Illinois, Massachusetts, New York and Pennsylvania."[243]

293. GenBioPro's website reports that CVS Pharmacy now likewise provides abortion drugs in California, Colorado, Connecticut, DC, Delaware, Hawai'i, Illinois, Massachusetts, Maryland, Maine, Michigan, Minnesota, New Hampshire, New Jersey, Nevada, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Virginia, Vermont, and Washington.[244]

294. Another national pharmacy dispensing abortion drugs is Honeybee Health, which GenBioPro reports provides abortion drugs by mail "in multiple states."[245]

295. Smaller pharmacies are now dispensing abortion drugs, too. GenBioPro identifies smaller or regional pharmacies that dispense its abortion drugs in Arizona, California, Connecticut, Maryland, Nevada, New York, Rhode Island, South Carolina, Texas, Washington, and Wisconsin.[246]

296. As NPR has reported, "Over the past several months, a handful of community pharmacies in states where abortion remains legal have begun to take advantage of a new rule that allows them to fill prescriptions for the abortion pill mifepristone. Prior to the rule change, which was finalized last January by the Food

---

https://www.npr.org/sections/health-shots/2024/01/22/1225703970/pharmacists-prescribe-dispense-abortion-pill-mifepristone.

[243] Ex. 58, Chloe Atkins, *CVS and Walgreens to Start Dispensing the Abortion Pill Mifepristone*, NBC (Mar. 1, 2024), https://www.nbcnews.com/health/health-news/cvs-walgreens-dispense-abortion-pill-mifepristone-rcna141396.

[244] Ex. 59, GenBioPro, Pharmacy Directory, https://genbiopro.com/roster.

[245] *Id.*

[246] *Id.*

and Drug Administration, pregnant people had to get the drug directly from their doctor or by mail if using telemedicine, depending on the laws in their state."[247] The lack of a prescriber dispensing protection now means, for example, that anyone could travel to Washington to pick up a mifepristone prescription filled by a pharmacy in Washington for a woman in Idaho—with no in-person care. This will likely increase further the number of women with no follow-up care who seek emergency services in Plaintiff States.

297. In fact, in Washington, pharmacists "go a step further than that" and "pharmacists themselves [now] prescribe the abortion medication, without a physician."[248] In Washington, "efforts are underway to open up access to medication abortion in a radical new way: by training pharmacists not only to dispense abortion pills but also to prescribe them to their walk-in patients."[249] NPR reports that "[t]here are 10 pharmacists in the first cohort," expected to start prescribing in early 2024.[250]

298. Without the FDA's in-person dispensing protection or without any doctor safeguards, a pharmacist in Washington can now conduct a telehealth appointment with an Idaho resident in Washington and prescribe mifepristone. As NPR concludes, "Pharmacist prescribing of mifepristone puts the drug a step closer to over-the-counter."[251]

---

[247] *Id.*

[248] Ex. 57, Patrick Adams, *In Washington State, Pharmacists are Poised to Start Prescribing Abortion Drugs*, NPR (March 1, 2024), https://www.npr.org/sections/health-shots/2024/01/22/1225703970/pharmacists-prescribe-dispense-abortion-pill-mifepristone.

[249] *Id.*

[250] *Id.*

[251] *Id.*

299. The new ability of pharmacists to prescribe and dispense abortion drugs shows how women from Plaintiff States will be harmed by the FDA's actions and seek follow-up care from providers at home.

D. Defendants' actions resulted in the creation of a 50-state mail-order abortion-drug economy.

300. Lifting any in-person dispensing protections —no matter the risk to women's health and safety—was the final step in the FDA's plan to limit any effect from *Dobbs* and undermine state abortion laws.

301. Removing the in-person dispensing protections enabled a 50-state mail-order abortion drug economy—a world where countless women in Plaintiff States receive abortion drugs by mail later in pregnancy with no in-person care and go the emergency room in Plaintiffs' States.

302. According to one report, in less than a month after *Dobbs* was decided, seven U.S.-based providers mailed approximately 3,500 doses of mifepristone and its generic equivalent to states that prohibit the use of abortion drugs.[252]

303. Eight States have embraced Defendants' actions and passed "shield" laws expressly seeking to facilitate these providers conducting out-of-state mail-order abortions and to prevent Plaintiff States from enforcing their own laws.[253]

---

[252] Ex. 60, Rachel Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned State*s, Wash. Post. (July 20, 2023) https://www.washingtonpost.com/politics/2023/07/20/shield-laws-make-it-easier-send-abortion-pills-banned-states/.

[253] *Id.*; Ex. 61, 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/.

304. These shield laws often explicitly name mifepristone and the proponents of those laws openly proclaim that they seek to abrogate the sovereignty of Plaintiff States.[254]

1. Aid Access

305. Many abortion providers, like Aid Access, have explained to the press how Defendants' actions have enabled them to frustrate state abortion restrictions and mail FDA-approved abortion drugs "to people in all 50 states, even those [like Missouri] that have banned it."[255]

306. Mailing FDA-approved abortion drugs is new for Aid Access. In the past, Aid Access did not mail FDA-approved abortion drugs.

307. When Aid Access was started in 2018, it operated as a black-market provider of abortion drugs from India. "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."[256]

308. But then in 2021 the "in-person dispensing requirement for mifepristone" was removed.[257] Aid Access responded to the FDA's 2021 change by entering the U.S. market as a provider of FDA-approved abortion drugs by mail in certain states. "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

---

[254] *Id.*

[255] Ex. 62, Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023), https://www.theguardian.com/world/2023/jul/23/shield-laws-provide-abortion-care-aid-access.

[256] *Id.*

[257] *Id.*

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."[258]

309. Later, after the FDA's 2023 permanent removal of in-person dispensing safeguards, Aid Access expanded its scope and began providing FDA-approved abortion drugs by mail to all states.

310. Once some States like New York adopted shield-laws, Aid Access began mailing FDA-approved abortion drugs directly from the United States instead of black-market abortion drugs from India.

311. This change transformed 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." [259]

312. The FDA's decision not to require in-person distribution directly 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.[260]

313. In an NBC news story, Dr. Linda Prine, a New York City-based shield law provider for Aid Access explained the scale of its new FDA-enabled mailing operations by mid-2024. "Before we had the shield law, we were mailing pills to the blue states, and only [pills from] overseas could be sent to the restricted states." After New York's shield law passed, Aid Access began sending FDA-approved abortion

---

[258] *Id.*

[259] *Id.*

[260] *Id.*

drugs to every state: "the first month we sent about 4,000 pills into restricted states, and now we're up to around 10,000 pills a month."[261]

314. Another Aid Access provider, located in "a basement in upstate New York" also "underscored the importance of sending these pills from the U.S., rather than overseas. 'Sometimes they got stuck in customs,' the provider explained as more than 100 prescriptions were being packaged around them, preparing to be shipped into states with bans."[262]

315. Aid Access moreover benefits from Defendants' removal of the safeguard that women receive a doctor's care when receiving FDA-approved abortion drugs. Alongside doctors, Lauren Jacobson, a nurse practitioner, prescribes abortion medication through Aid Access—helping make Aid Access the largest of the current shield law abortion drug providers.[263]

316. The NBC story provided images of New York's Aid Access providers mailing GenBioPro's generic mifepristone to women in Plaintiff States—the images show that next to pill bottles and mailing envelopes, these abortion providers have stacks of white boxes of mifepristone with GenBioPro's distinctive purple and pink circular logo.[264]

---

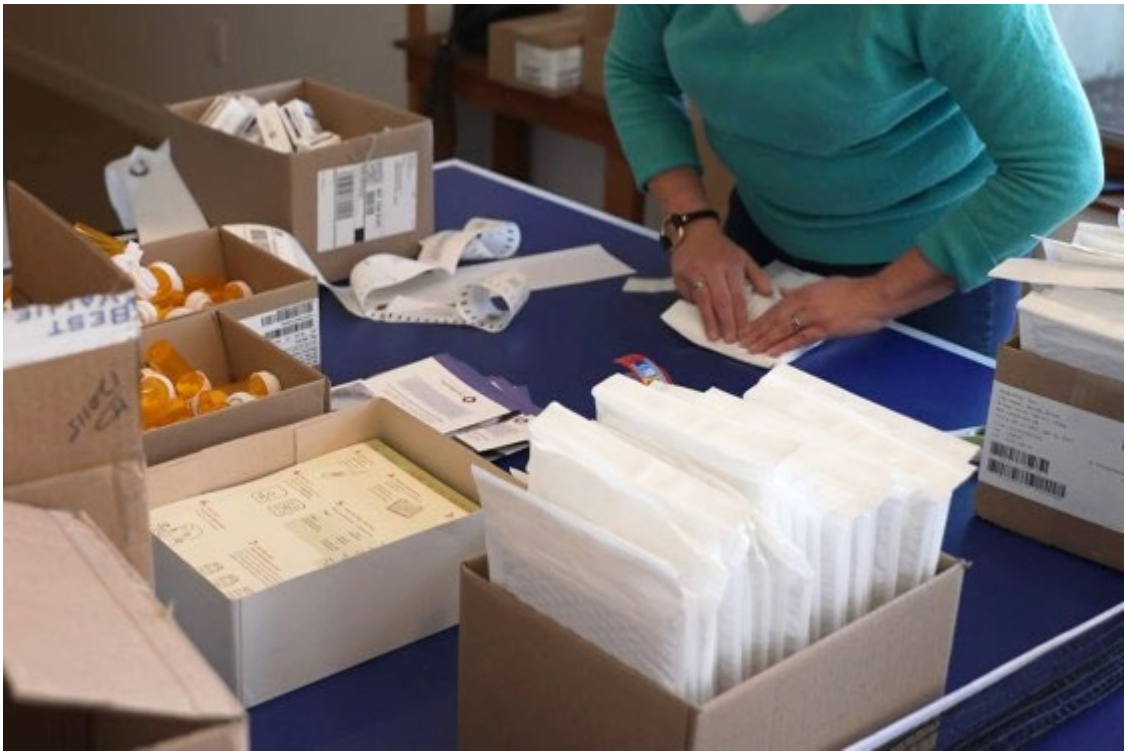
[261] Ex. 63, Abigail Brooks and Dasha Burns, How A Network of Abortion Pill Providers Works Together in the Wake of New Threats, NBC News (April 7, 2024), https://www.nbcnews.com/health/health-news/network-abortion-pill-providers-works-together-wake-new-threats-rcna146678.

[262] *Id.*

[263] Ex. 64, Elissa Nadworny, *Inside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024), https://www.npr.org/2024/08/06/nx-s1-5037750/abortion-pills-bans-telehealth-mail-mifepristone-misoprostol.

[264] Ex. 63, Abigail Brooks and Dasha Burns, *How a Network of Abortion Pill Providers Works Together in the Wake of New Threats*, NBC News (April 7, 2024),

A shield law provider packs abortion pills into envelopes to be sent from New York to states with bans. Callan Griffiths / NBC News



https://www.nbcnews.com/health/health-news/network-abortion-pill-providers-works-together-wake-new-threats-rcna146678.

Boxes of pills will be packed into envelopes to ship around the country. Callan Griffiths / NBC News

Envelopes filled with abortion pills. Callan Griffiths / NBC News

Empty pill bottles in the basement of a shield law provider in New York will be filled with abortion medication. Abigail Brooks / NBC News

317. Aid Access and Ms. Jacobson interviewed with the *Washington Post* in June 2023 when they first began their "new pipeline of legally prescribed abortion pills flowing into states with abortion bans." This "small group" mailed 3,500 doses of FDA-approved abortion drugs in the first month and aimed to "facilitate at least 42,000 abortions" in its first year.[265]

318. The article described one Hudson Valley doctor whose "family's ping-pong table [was] covered with abortion pills bound for the South and Midwest, where abortion has been largely illegal since the Supreme Court overturned *Roe v. Wade* in

[265] Ex. 65, Caroline Kitchener, *Blue-State Doctors Launch Abortion Pill Pipeline Into States With Bans*, Wash. Post (July 19, 2023), wapo.st/3M29JUq.

June 2022." This doctor "arrives at the post office with dozens of new packages every afternoon."[266]

319. In another interview with the *Washington Post*, Dr. Prine said that "[a]nxiety and uncertainty are common even among patients who receive the medication at an abortion clinic in a state where abortion is legal ... because they're at home by the time they start feeling the full effects."[267] "People from anywhere can be freaking out because everyone is taking these pills at home alone."[268] And "[i]n states with abortion bans, the emergency room is often the only option for women who want in-person care during their medication abortions."[269]

320. Dr. Prine said that when someone calls her by phone for advice, she tells women who call concerned about complications "that their experiences are nothing out of the ordinary, and that they almost certainly don't need to go to the emergency room."[270]

321. Dr. Prine "said she's felt the need to send someone to the emergency room only once in nearly five years … 'Your uterus knows what to do,' Prine told a woman who called that January morning with reports of unexpectedly heavy bleeding. 'It's going to take care of itself.'"[271]

---

[266] *Id.*

[267] Ex. 66, Caroline Kitchener, *Alone in a Bathroom: The Fear and Uncertainty of a Post-Roe Medication Abortion* (April 11, 2024), https://www.washingtonpost.com/politics/interactive/2024/abortion-pill-experience-stories/?itid=ap_carolinekitchener.

[268] *Id.*

[269] *Id.*

[270] *Id.*

[271] *Id.*

322. The Washington Post shared Dr. Prine's comments with other doctors. It reported, "A woman in that situation could have hemorrhaged or become septic, according to five OB/GYNs interviewed for this article."[272]

323. Keri Garel, an OB/GYN at Boston Medical Center, said, "Whenever there is something inside the uterus that is trying to come out and won't come out, the risk of bleeding and infection gets higher with every passing moment," and so she would advise someone in [this woman's] situation to go to the hospital immediately. "At that point, your life is the most important thing."

324. Aid Access will provide abortion drugs to a woman or girl of any age.[273]

325. Dr. Prine described how once a "quiet and scared" girl who was 15 years old called her from "an area code in a state with an abortion ban" desperate for help after she "had taken pills and passed a fetus larger than she'd expected." The article relates, "Unable to flush the fetus down the toilet, the girl asked about throwing it away." Dr. Prine's main response: "There's nothing in there that's traceable back to you … As long as you don't tell anybody."[274]

326. Ms. Jacobson conceded to the *Washington Post* "that this system is far from perfect." And she admitted to "occasions her patients in restricted states require in-person care" that she would not provide.[275]

327. In February 2024, the *New York Times* profiled Ms. Jacobson and her Boston-based mailing operations. The *New York Times* likewise reported that these

---

[272] *Id.*

[273] Ex. 67, Plan C, Texas, https://www.plancpills.org/abortion-pill/texas#telehealth.

[274] Ex. 66, Caroline Kitchener, *Alone in a Bathroom: The Fear and Uncertainty of a Post-Roe Medication Abortion* (April 11, 2024), https://www.washingtonpost.com/politics/interactive/2024/abortion-pill-experience-stories/?itid=ap_carolinekitchener.

[275] *Id.*

abortion drugs were "prescribed by licensed Massachusetts providers, packaged in the little room and mailed from a nearby post office, arriving days later in Texas, Missouri and other states where abortion is largely outlawed."[276]

328. At the time of publication in February 2024, Aid Access mailed 7,000 sets of abortion drugs a month, or 50 orders a day, "nearly 90 percent of them in states with bans or severe restrictions."[277]

329. The *New York Times* confirmed that Aid Access provided no in-person exams or in-person follow-up care. "Patients contact this service and others online and fill out forms providing information about their pregnancy and medical history.… Patients and providers can communicate by email or phone if needed."[278]

330. The *New York Times* article profiled two Texas women who received FDA-approved abortion drugs through this service.[279] One of the *Washington Post* articles likewise profiled a Houston, Texas woman who received abortion drugs from Aid Access, took them, and ended her pregnancy.[280]

331. The *New York Times* article quotes Rachel Rebouché, the dean of Temple University Law School, who has worked with shield law advocates and legislators. "This might be the most important event since *Dobbs* on so many levels … Thousands and thousands of pills are being shipped everywhere across the United States from a

---

[276] Ex. 68, Pam Belluck, *Abortion Shield Laws: A New War Between the States, New York Times* (Feb. 22, 2024), https://www.nytimes.com/2024/02/22/health/abortion-shield-laws-telemedicine.html.

[277] *Id.*

[278] *Id.*

[279] *Id.*

[280] Ex. 66, Caroline Kitchener, *Alone in a Bathroom: The Fear and Uncertainty of a Post-Roe Medication Abortion* (April 11, 2024), https://www.washingtonpost.com/politics/interactive/2024/abortion-pill-experience-stories/?itid=ap_carolinekitchener.

handful of providers. That alone speaks to the nature of what mailed medication abortion can do."[281]

2. Massachusetts Abortion Project (MAP)

332. A second new abortion provider operating under a similar model is the Massachusetts Abortion Project (MAP).

333. NPR reported in August 2024 that MAP is "a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion."[282]

334. MAP launched last fall as a project of Cambridge Reproductive Health Consultants, a nonprofit.[283]

335. MAP mails FDA-approved abortion drugs to women and girls who are up to 10 weeks pregnant and who are 16 or older.[284]

336. MAP is one of "four organizations in the U.S. operating under recently enacted state shield laws, which circumvent traditional telemedicine laws requiring out-of-state health providers to be licensed in the states where patients are located."[285]

---

[281] Ex. 68, Pam Belluck, *Abortion Shield Laws: A New War Between the States*, New York Times (Feb. 22, 2024), https://www.nytimes.com/2024/02/22/health/abortion-shield-laws-telemedicine.html.

[282] Ex. 64, Elissa Nadworny, *Inside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024), https://www.npr.org/2024/08/06/nx-s1-5037750/abortion-pills-bans-telehealth-mail-mifepristone-misoprostol.

[283] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

[284] Ex. 64, Elissa Nadworny, *Inside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024), https://www.npr.org/2024/08/06/nx-s1-5037750/abortion-pills-bans-telehealth-mail-mifepristone-misoprostol.

[285] *Id.*

337. MAP harnesses websites like plancpills.org to get the word out to women nationwide."[286] Patients use third-party payment services like Cash App or PayPal to pay MAP $250 for mailing the two-drug regimen, although some low-income patients pay as little as $5.[287]

338. MAP does not conduct in-person exams on patients or provide in-person follow-up care. Instead, women "can fill out an online form, connect with a doctor via email or text and, if approved, receive the pills within a week, no matter which state they live in."[288] MAP's review of a woman's online submission can occur "within an hour" and the whole process can take only three hours before MAP mails the abortion drugs at the post office. [289] Occasionally some women "talk by phone with [Dr. Angel] Foster or a prescriber."[290]

339. MAP's abortion drugs "cannot be picked up in person."[291]

340. On its website, MAP states that if a woman needs follow up care, they should turn to local providers in home states. In response to the question, "I am worried that something went wrong with the abortion. What do I do?" MAP says, "People only need some kind of help, like a suction procedure or more medication, in

---

[286] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

[287] Ex. 64, Elissa Nadworny, *Inside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024), https://www.npr.org/2024/08/06/nx-s1-5037750/abortion-pills-bans-telehealth-mail-mifepristone-misoprostol.

[288] *Id*.

[289] *Id*.

[290] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

[291] Ex. 67, Plan C, Texas, https://www.plancpills.org/abortion-pill/texas#telehealth.

about 2 in 100 cases. However, if you are worried, you can get an ultrasound at an emergency department or through a primary care doctor or gynecologist. If you do not feel safe telling them you used abortion pills, tell them you are pregnant and had some bleeding and want to know if everything is OK."[292]

341. On the day of NPR's visit, MAP's four OB-GYNs "signed off on prescriptions for nearly two dozen women — in Texas, Florida, Tennessee, Georgia, Alabama, Oklahoma and South Carolina." [293]

342. On average, "MAP currently sends out about 500 prescriptions a month."[294] NBC reports in its own story about MAP that this "rise of telehealth is part of why the number of abortions in the U.S. has continued to go up since the Supreme Court overturned *Roe v. Wade* in 2022 — even though 14 states have near-total abortion bans…In those states, shield law providers represent the only legal way people can access abortions within the established health care system."[295]

343. According to the Society of Family Planning's WeCount project, in 2024 shield law practices account "for about 10% of abortions nationwide," including "9,200 abortions a month provided under shield laws from January to March" of 2024.[296] But NPR noted that "some researchers estimate that this number has risen since then and could be as high as 12,000 per month."[297]

---

[292] Ex. 69, MAP, Frequently asked questions, https://www.cambridgereproductivehealthconsultants.org/map

[293] Ex. 64, Elissa Nadworny, *Inside a Medical Practice Sending Abortion Pills to States Where They're Banned*, NPR (Aug. 7, 2024), https://www.npr.org/2024/08/06/nx-s1-5037750/abortion-pills-bans-telehealth-mail-mifepristone-misoprostol.

[294] *Id.*

[295] *Id.*

[296] *Id.*

[297] *Id.*

344. NPR provided images of MAP mailing abortion drugs to women in Plaintiff States. These images show that MAP packing abortion drug mailers using Danco's well-known orange boxes of Mifeprex.[298]

Mifepristone, a drug used in abortion care, at the MAP's office in Massachusetts. Elissa Nadworny/NPR

[298] *Id.*

"Welcome to modern abortion care," says Angel Foster, who leads operations at what's known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion. Elissa Nadworny/NPR

A staff member of the MAP brings the boxes containing abortion medication to the local post office. Elissa Nadworny/NPR

345. In August 2024, the *Wall Street Journal* reported that MAP now hosts "pill-packing parties to help strangers in faraway states circumvent strict laws."[299]

346. At these pill-packing parties, volunteers help "mail abortion medication to women in states with strict limits."[300] For example, on "a recent Monday evening, the group filled 350 boxes—in-home abortion kits ready for mailing to women in states such as Texas and Florida with near-total or six-week abortion bans….Retirees and professionals ate pizza, sipped Chardonnay in red plastic cups and chatted while

[299] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

[300] *Id.*

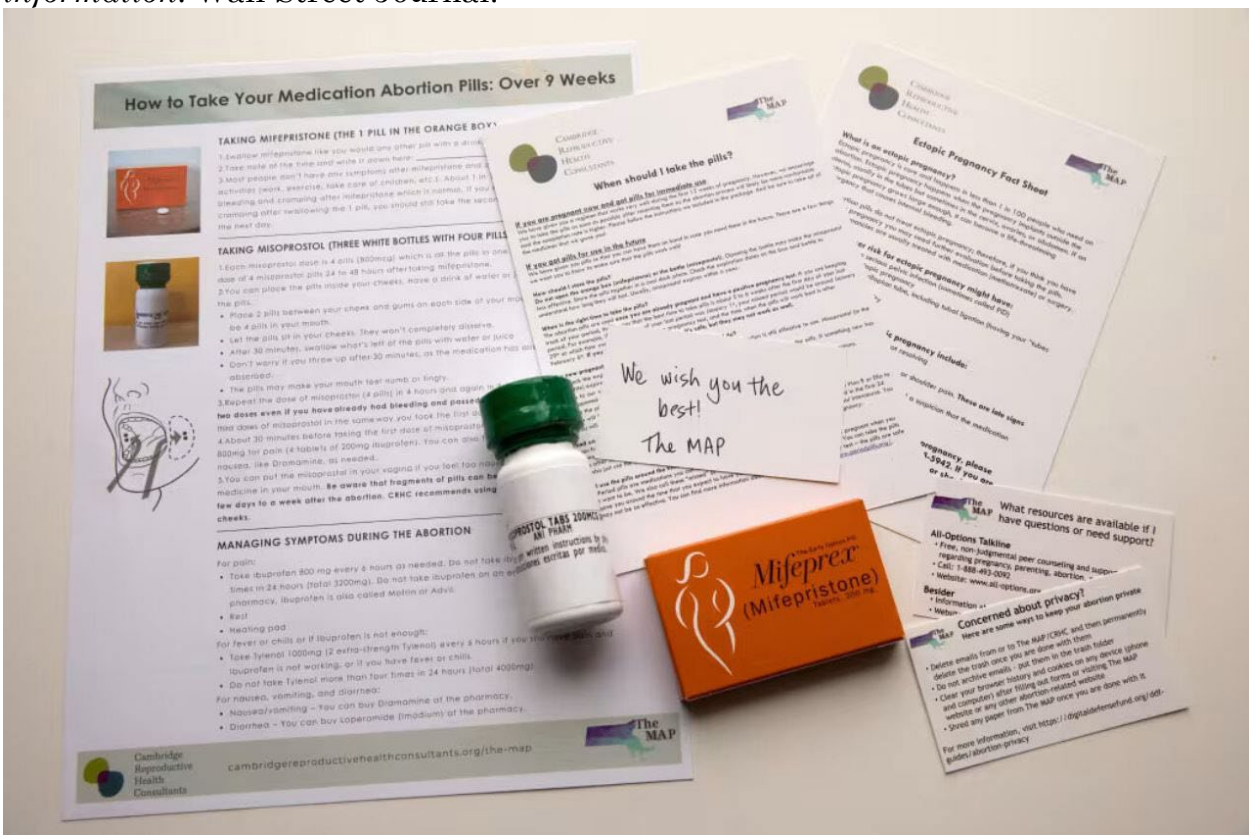
working purposefully….Nearby, a MAP staffer printed address labels for 45 boxes of pills before packing them into tote bags for the trip to the post office. They were bound for 19 states, including Texas, Georgia and Florida…The gatherings jumped from monthly to twice-monthly in July, the MAP's busiest month with 560 boxes shipped, and are set to go weekly this fall." [301]

347. The *Wall Street Journal* photographed MAP's mailing operations. These images likewise show MAP's pill-packing party attendees mailing Danco's brand-name version of Mifeprex straight from Danco's orange boxes.

Women prepare in-home abortion kits at a 'pill-packing party' at the MAP's offices. Wall Street Journal.

[301] Ex. 1, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall Street Journal (Aug. 12, 2024), https://www.wsj.com/us-news/abortion-pill-parties-shipping-148e3c15.

Patient packages include two abortion medications, instructions, and additional information. Wall Street Journal.



Tote bags containing the MAP's patient packages are carried to a post office for mailing. Wall Street Journal.

348. The *Wall Street Journal* also reported on the high number of FDA-approved abortion drugs mailed by these groups at that time to states that restrict abortion drugs.

349. From July 2023 to March 2024, these "shield-law groups provided more than 68,000 abortion kits by mail to residents in states with tight limits on the procedure or telemedicine.... Shield-law providers accounted for about 9,500 medication abortions in March, up from 5,620 in July 2023."[302] That month, "Abortions reached nearly 100,000 nationwide in March [2024], up from 84,000 in May 2022, according to WeCount, despite 18 states imposing near-total or six-week

[302] *Id.*

bans.…Nearly 20% of all abortions are via drugs sent by mail, including from bricks-and-mortar clinics."[303]

3. Abuzz

350. A third similar shield-law service is Abuzz, which serves some states with abortion bans.[304]

351. Abuzz provides abortion drugs to Missouri, Idaho, and Kansas addresses, and it mails to every State except Texas, Mississippi, Alabama, and Georgia.[305] It provides abortion drugs through 10 weeks of pregnancy and beyond.[306]

352. Abuzz's website states that it does not provide in-person care. Instead, Abuzz says, "In most cases, providers do not require a phone call or video visit. After you fill in the form, a clinician will arrange payment with you and review your information. If you're approved to receive abortion pills by mail, your pills will be shipped out in 1-2 business days."[307] "Your FDA-approved medications (mifepristone and misoprostol) will be sent by mail."[308]

353. On its FAQs page, Abuzz advises patients that they need not tell emergency room doctors that they have taken abortion drugs. In response to the question, "If I have to go to the hospital, what should I say?" Abuzz says, "The treatment for a miscarriage and abortion are the same, so you can just say something like 'I'm bleeding but it doesn't feel like my usual period. I'm afraid something is

---

[303] *Id.*

[304] Ex. 68, Pam Belluck, *Abortion Shield Laws: A New War Between the States, New York Times* (Feb. 22, 2024), https://www.nytimes.com/2024/02/22/health/abortion-shield-laws-telemedicine.html.

[305] Ex. 70, Abuzz, https://www.abuzzhealth.com/.

[306] Ex. 71, Abuzz, FAQs, https://www.abuzzhealth.com/faqs/

[307] Ex. 70, Abuzz, https://www.abuzzhealth.com/.

[308] Ex. 71a, Abuzz, How it works, https://www.abuzzhealth.com/how-it-works/.

wrong' or 'I'm pregnant and bleeding. I'm scared there's something wrong' and you should get the care you need."[309]

4. Armadillo Clinic

354. A fourth major shield-law provider is Armadillo Clinic.[310] Plan C reports that Armadillo Clinic provides abortion drugs to women aged 18+.[311]

355. On its website, Armadillo Clinic says it "specializes in abortion pills by telemedicine" and, after a patient fills out a ten-minute form, the clinic will "send abortion pills confidentially by mail, in 2-5 days."[312]

356. Armadillo Clinic does not provide in-person exams or follow-up care. Instead, it provides patients with "information you need to manage the process, start to finish," and its providers will only answer questions "by live chat or phone."[313]

5. We Take Care of Us

357. A fifth provider of FDA-approved abortion drugs is We Take Care of Us.

358. Plan C reports that We Take Care of Us will provide abortion drugs to a woman or girl of any age.[314]

---

[309] Ex. 71, Abuzz, FAQs, https://www.abuzzhealth.com/faqs/

[310] Ex. 72, Shira Stein, *Thousands of Out-of-State Abortion Seekers Rely on Two Dozen Doctors from Telehealth Shield States*, San Francisco Chronicle (June 12, 2024), https:/www.sfchronicle.com/politics/article/telehealth-abortion-providers-california-19508548.php.

[311] Ex. 67, Plan C, Texas, https://www.plancpills.org/abortion-pill/texas#telehealth.

[312] Ex. 73, Armadillo Clinic, https://www.armadilloclinic.org/.

[313] *Id.*

[314] Ex. 67, Plan C, Texas, https://www.plancpills.org/abortion-pill/texas#telehealth.

359. We Take Care of Us describes itself as "a cooperative run by Certified Nurse Midwives (CNMs)," indicating that the FDA's removal of any doctor involvement has enabled this platform.[315]

360. We Take Care of Us tells patients that a "video visit is not required" and so it offers to communicate by "secure messaging app, text and email."[316] We Take Care of Us requires only a "10-15 minute online intake request."[317]

361. We Take Care of Us accepts payment by Venmo and "can arrange shipment to any U.S. state, Guam, Puerto Rico and APO addresses."[318]

6. The effect on Plaintiff States

362. These providers send abortion drugs to Plaintiff States by mail, common carrier, and interactive computer service.

363. The website Plan C lists websites that will ship FDA-approved abortion drugs to Plaintiff States. Plan C says, "Abortion access in Missouri is restricted, but abortion pills are still available by mail from providers outside of Missouri. Options below."[319] Under a section entitled, "How people get abortion pills in Missouri," Plan C lists six abortion drug providers who provide "FDA-approved medications," describing each as "online clinics that mail pills."

364. Plan C identifies as providers of FDA-approved abortion drugs Abuzz, Aid Access, Armadillo Clinic, Cambridge Reproductive Health Consultants (MAP), We Take Care of Us, and A Safe Choice.[320] In addition, Plan C specifically notes that

---

[315] Ex. 74, We Take Care of Us, FAQs, https://www.wetakecareof.us/faqs.

[316] *Id.*

[317] Ex. 74a, We Take Care of Us, Care, https://www.wetakecareof.us/care.

[318] *Id.*

[319] Ex. 75, Plan C, Missouri, https://www.plancpills.org/abortion-pill/missouri.

[320] *Id.*

Aid Access's abortion drugs "are prescribed by clinicians licensed in the US and the FDA-approved abortion pills are mailed to all states."[321]

365. Of these six providers, Abuzz and MAP will mail FDA-approved abortion drugs to Missouri residents aged 16+.[322]

366. Plan C identifies Abuzz, Aid Access, MAP, We Take Care of Us, and A Safe Choice as "online clinics that mail pills" to Idaho[323] and Kansas residents, and it also identifies Abortion on Demand as a provider for Kansas residents.[324] Abuzz and MAP will mail FDA-approved abortion drugs to Idaho and Kansas residents aged 16+.[325]

367. The FDA has thus facilitated violations of many States' laws—and has left many women to face complications from abortion drugs with no required in-person care.

368. The FDA has also created a method to violate many States' laws regarding age restrictions (like Kansas's) and allowed rapists to hide their actions and avoid criminal laws because many drug shippers (A Safe Choice, Aid Access, MAP, and We Take Care of Us) do not have a verification mechanism, and those who do (Armadillo Clinic and Abuzz) have only a minimal screening process that are unlikely to stop a perpetrator from obtaining chemical abortion drugs.

369. Of course, other organizations mail or dispense FDA-approved abortion drugs to Plaintiff States, too.

---

[321] *Id.*

[322] *Id.*

[323] Ex. 76, Plan C, Idaho, https://www.plancpills.org/abortion-pill/idaho#telehealth.

[324] Ex. 77, Plan C, Kansas, https://www.plancpills.org/abortion-pill/kansas#telehealth.

[325] *Id.*; Ex. 76, Plan C, Idaho, https://www.plancpills.org/abortion-pill/idaho#telehealth.

370. For example, Plan C identifies six abortion providers located in Kansas that may provide FDA-approved abortion drugs: Planned Parenthood - Wichita Health Center, Aria Medical, Center for Women's Health, Planned Parenthood - Kansas City Health Center, Planned Parenthood - Comprehensive Health Services, and Trust Women Wichita.[326]

E. The lack of in-person dispensing results in women receiving pills by mail in one state from brick-and-mortar abortion providers before returning to Plaintiff States for follow-up care.

371. The FDA's lifting of the in-person dispensing protection also enabled providers with brick-and-mortar in-person locations to remotely dispense abortion drug.

372. Using the mail or common carrier, abortion providers at these brick-and-mortar locations now could add virtual options to their offerings. The FDA's actions enabled them to mail abortion drugs to women up to 10 weeks pregnant from Plaintiff States who traveled to the brick-and-mortar provider's virtual service area—and then send the women home to Plaintiff States without in-person follow-up care.

373. No brick-and-mortar abortion provider mails to all states. Most mail only to states without abortion restrictions—and they allow any person temporarily in those states to order abortion drugs by telehealth and mail before returning to their home states.

374. For example, NBC reported, "After the FDA eased restrictions on mifepristone prescriptions during pandemic, allowing women to get the abortion pill through the mail, Hey Jane [a self-described "virtual reproductive and sexual health

[326] Ex. 78, Plan C, Kansas Abortion Clinic Guide from Plan C Pills, https://abortion-clinic.plancpills.org/kansas.

care haven"][327] took off. The company has shipped abortion pills to at least 50,000 patients" with mailing addresses in states without abortion restrictions.[328]

375. The brick-and-mortar providers in *Whole Woman's Health v. FDA*, No. 3:23-cv-00019 (W.D. Va. filed May 8, 2023) and *Washington v. FDA*, No. 1:23-cv-03026 (E.D. Wash. filed Feb. 23, 2023) likewise now provide abortion drugs by mail, common carrier, and interactive computer service in many states to women from Plaintiff States—expanding the number of women receiving abortion drugs with no in-person care who seek emergency rooms in Plaintiff States. (This virtual option is in addition to their in-person option for women who receive abortion drugs in person at their brick-and-mortar locations.)

376. For example, WWH of Alexandria operates via telehealth, and Whole Woman's Health of the Twin Cities, LLC, has operated a virtual program since August of 2021 that provides abortion drugs by telehealth in Virginia, Maryland, Minnesota, New Mexico, and Illinois.[329] This virtual brick-and-mortar program provides medication abortion to approximately 2,400 patients per year, and the majority of those patients seek telehealth in Virginia. It estimates that "[a]round half of our virtual patients live in the states where we provide telehealth, while the other half travel to those states from other places."[330] "Many patients require funding to

---

[327] Ex. 79, Hey Jane, About Us, https://www.heyjane.com/about-us.

[328] Ex. 63, Abigail Brooks and Dasha Burns, *How a Network of Abortion Pill Providers Works Together in the Wake of New Threats*, NBC News (April 7, 2024), https://www.nbcnews.com/health/health-news/network-abortion-pill-providers-works-together-wake-new-threats-rcna146678.

[329] Ex. 51, Miller Decl. ¶ 20.

[330] *Id.*¶ 22.

pay for their telehealth abortion, both for the visit and any associated travel to the states where telehealth is available."[331]

377. Whole Woman's Health is clear that FDA deregulation is essential to this mail-order brick-and-mortar business model: "The optimal use of telehealth in the provision of abortion care, however, depends on the ability to dispense mifepristone remotely. Because the REMS still prohibit clinicians from writing a prescription for mifepristone, the only remote option for distribution of mifepristone is by mail."[332] "If clinicians are required to dispense mifepristone in person, their patients are forced to travel to the clinic to pick up the medication, even if doing so requires significant travel and other logistical challenges."[333] So, when the FDA removed in-person dispensing protection, "[f]or WWH and our patients, this change in the REMS was huge. It allowed us to build out our telehealth practice and begin working with a mail order pharmacy to dispense mifepristone."[334]

378. The lack of an in-person dispensing protection allowed Whole Woman's Health to dispense drugs to women from States that prohibit abortion. As Whole Woman's Health explains, after the REMS change, "WWH's Virtual Program has been critical in allowing WWH to meet the demand for abortions from patients traveling from states where abortion is now banned."[335]

379. The 2023 REMS change allows Whole Woman's Health to dispense abortion drugs from New Mexico to Texas women. "[E]xpanding our virtual program to New Mexico allowed us to continue seeing patients traveling from Texas, even after

---

[331] *Id.*

[332] *Id.*¶ 38.

[333] *Id.* ¶ 39.

[334] *Id.* ¶¶ 40–41.

[335] *Id.* ¶ 42.

our Texas clinics were forced to close."[336] "Even though we now have a clinic site in New Mexico, almost all of our patients seeking telehealth in New Mexico travel from out of state."[337] "The virtual program allows patients to reduce their travel time and expense and helps ease clinic congestion."[338] "This is particularly important because the New Mexico clinics, who have been inundated with patients traveling from out of state since *Roe v. Wade* was overturned, often have a 3-week wait for appointments."[339] The 2023 REMS change thus "is critical to the care of our patients, the sustainability of our medical clinics, and the retention of our clinicians and staff."[340] "Telehealth has been instrumental in allowing clinics to meet the demand for abortions."[341]

380. Blue Mountain Clinic similarly credits the FDA's actions with its ability to dispense drugs from its brick-and-mortar location remotely and by mail so long as a person comes within Montana's borders. It explains: "Accessing medication abortion via direct-to-patient telehealth can be the difference between accessing abortion care or not. Reinstating a ban on dispensing mifepristone by mail would take mifepristone off the table as an option for these patients, who otherwise may be unable to make the in-person visit for a procedural abortion."[342]

---

[336] *Id.* ¶ 43.

[337] *Id.*

[338] *Id.*

[339] *Id.*

[340] *Id.* ¶ 47.

[341] *Id.* ¶ 32.

[342] Ex. 49, Smith Decl. ¶ 30.

381. All Families also dispenses abortion drugs remotely and by mail from its brick-and-mortar location to patients physically present in Montana.[343] More than half of its abortions are by abortion drugs and more than half of its abortion drugs are dispensed by mail.[344]

382. Just like the other providers, All Families points to the FDA as responsible for this virtual "expansion," which it said "opened up when a court order blocked the FDA from enforcing the in-person dispensing requirement in 2020" and when the "FDA then temporarily suspended the requirement in 2021 and solidified that by updating the REMS in 2023 to eliminate this requirement."[345]

383. In much the same way, PPGWNI dispenses abortion drugs via telehealth and by mail to patients in Washington, allowing it to expand its operations for Idaho residents and other non-Washington residents.[346] PPGWNI was thus "grateful for the removal of the in-person requirement with the FDA's recent updates to REMS for mifepristone."[347]

384. The above abortion providers from *Whole Woman's Health v. FDA*[348] and *Washington v. FDA*[349] continue to provide abortion drugs by telehealth, mail, common carrier, or other remote means to this day from their brick-and-mortar locations—further increasing the harms caused by abortion drugs.

---

[343] Ex. 50, Weems Decl. ¶ 6.

[344] *Id.* ¶ 31.

[345] *Id.*

[346] Ex. 53, Dillon Decl. ¶ 20.

[347] *Id.* ¶ 23.

[348] No. 3:23-cv-00019-NKM, ¶1 (W.D. Va. May 8, 2023).

[349] No. 1:23-cv-03026 (E.D. Wash. filed Feb. 23, 2023).

385. Trust Women Wichita furthermore now intends to provide abortion drugs through the Internet and by mail or common carrier.[350] Until 2018, Trust Women Wichita offered a telemedicine clinic for medication abortion," but it was "forced to stop that practice due to a Kansas state law."[351] But "[t]hat law was very recently enjoined."[352] So it is "particularly interested in pursuing the option to mail mifepristone, which would greatly expand our ability to help patients."[353] "We would start as soon as we can if mifepristone remains available and possible to dispense by direct to patient telehealth."[354]

386. In sum, in the words of all the brick-and-mortar abortion providers in *Whole Woman's Health Alliance v. FDA*, "Medication abortion, and specifically, provision of mifepristone by advanced practice clinicians (including nurse practitioners and physician assistants) and the availability of medication abortion by mail ('direct to patient telehealth') has been critical" to their ability to dispense abortion drugs without follow-up care. Complaint, ECF No. 1, *Whole Woman's Health All. v. FDA*, No. 3:23-cv-00019-NKM, ¶ 2 (May 8, 2023) (hereinafter Whole Woman's Health Compl.).

F. The FDA predictably enabled this 50-state abortion drug economy.

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

---

[350] Ex. 48, Tong Decl. ¶ 9.

[351] *Id.*

[352] *Id.*

[353] *Id.*

[354] *Id.*

388. The FDA enabled the remote dispensing of abortion drugs into all 50 States. When the FDA unlawfully removed its prohibition against mailing abortion drugs, it was predictable that private parties would start mailing those drugs.

389. A decision from this Court would redress this effect. As several abortion providers explained in *Whole Woman's Health v. FDA*, "reinstating the REMS requirement that mifepristone be dispensed only in a clinic, medical office, or hospital—and not via mail-order pharmacy—will eliminate abortion access for the large number of patients who have come to rely on direct to patient telehealth services." Whole Woman's Health Compl. ¶103. Likewise, as GenBioPro itself explained in this case, "under the pre-2016 conditions … telemedicine providers and mail-order pharmacies constituting a substantial proportion of GenBioPro's customer base will no longer be able to prescribe or dispense GenBioPro's product."[355]

390. At issue in this case are organizations mailing FDA-approved abortion drugs; they differ from so-called black-market organizations that mail non-FDA-approved drugs.

391. Plan C for instance identifies 14 websites that sell pills to Missouri, Idaho, and Kansas residents without a clinician as well as community networks that mail pills to Missouri, Idaho, and Kansas residents: Pill Pulse, Life Easy on Pills, Home AbortionRx, Private Emma, Medside 24, Home Abortion PillsRx, YBYCMeds, Privacy Pill RX, Safe Pharmacy, Abortion Pills Rx, Generic Abortion Pills, Abortion Rx, Online Abortion Pill Rx, and Abortion Privacy.[356] Others exist, too. These smaller-scale black-market groups each provide abortion pills that Plan C does not describe

---

[355] Amic. Br. GenBioPro, Inc., *FDA v. All. for Hippocratic Medicine*, No. 23-235 at *2 (Jan. 30, 2024).

[356] Ex. 80, Plan C, Websites That Sell Pills, https://www.plancpills.org/websites-that-sell-pills.

as FDA-approved from manufacturers who "are not certified or inspected by the FDA."[357]

392. Just as Aid Access used to mail abortion drugs that were not FDA-approved, these providers still mail drugs from other countries like India or Kazakhstan from manufacturers based in China, Russia, Vietnam, Africa, or other unknown locations.[358]

393. The mailing of drugs that are not FDA-approved is not at issue in this case as these drugs are not attributable to the challenged FDA actions.

XIX. Plaintiff States' residents are receiving abortion drugs in the absence of FDA's past safeguards.

394. Defendants' actions have resulted in abortion drugs being given to women in Plaintiffs' States by abortion providers—just as the abortion providers report and as the FDA intended.

A. Harm to women in Plaintiff States from the FDA's deregulation of abortion drugs

395. Many women in Plaintiff States have been harmed by the FDA's deregulation of abortion drugs.

1. Harms caused by the FDA's deregulation of abortion drugs

396. Dr. Ingrid Skop has "often treat[ed] patients who are admitted through the hospital's emergency department with complications from chemical abortions."[359]

---

[357] *Id.*

[358] Ex. 81, Dominique Mosbergen and Vibhuti Agarwal, *Websites Selling Unapproved Abortion Pills Are Booming*, Wall Street Journal (Aug. 21, 2022), https://www.wsj.com/articles/websites-selling-unapproved-abortion-pills-are-booming-11661079601.

[359] Ex. 82, Skop Decl. ¶ 12.

397. Dr. Skop is a board-certified OB/GYN with privileges in the Baptist Hospital System and a 25-year career in clinic and hospital care.[360]

398. In her words, she has "cared for several dozen women in the emergency department who were totally unprepared for the pain and bleeding they experienced due to chemical abortion."[361]

399. She has "treated patients who have experienced trauma and emotional distress because of complications from chemical abortion."[362] From what she observed, "[t]hose women were not anticipating that complications were possible[.]"[363] At least a dozen patients have expressed to her significant emotional distress "when they viewed the body of their unborn child in the toilet after the chemical abortion."[364]

400. In her experience, "the doctors who prescribed or administered chemical abortion drugs to these women often did not adequately prepare them for the drugs' effects, so these women could not have truly achieved informed consent."[365]

401. Dr. Skop has "cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion. Sometimes this includes the embryo or fetus, and sometimes it is placental tissue that has not been completely expelled."[366]

---

[360] *Id.* ¶¶ 2, 6.

[361] *Id.* ¶ 13.

[362] *Id.* ¶ 16.

[363] *Id.*

[364] *Id.* ¶ 15.

[365] *Id.* ¶ 14.

[366] *Id.* ¶ 17.

402. Dr. Skop has "cared for approximately five women who, after a chemical abortion, have required admission for a blood transfusion or intravenous antibiotics or both."[367]

403. She reports that the "FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion. Given my experience, I expect to see and treat more patients presenting with complications from chemical abortion."[368]

404. "For example, in one month while covering the emergency room, my group practice admitted three women to the hospital. Of the three women admitted in one month due to chemical abortion complications, one required admission to the intensive care unit for sepsis and intravenous antibiotics, one required a blood transfusion for hemorrhage, and one required surgical completion for the retained products of conception (i.e., the doctors had to surgically finish the abortion with a suction aspiration procedure)."[369]

405. In another example, in her office, Dr. Skop "treated one young woman who had been bleeding for six weeks after she took the chemical abortions drugs given to her by a doctor at a Planned Parenthood clinic. After two follow-ups at Planned Parenthood, during which she was given additional misoprostol but not offered surgical completion, she presented to me for help. I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication." [370]

---

[367] *Id.* ¶ 18.

[368] *Id.* ¶¶ 20–21.

[369] *Id.* ¶ 22.

[370] *Id.* ¶ 23.

406. Dr. Skop has also cared for minor women below the age of 18 who have obtained abortion drugs.[371]

407. In Dr. Skop's experience, "[t]he FDA's actions harm women, including [her] patients, because without proper oversight, chemical abortions can become even more dangerous than when they are supervised."[372]

408. The many "clinics and physicians prescribing or dispensing chemical abortion drugs, or websites that provide these drugs through mail order delivery without any physician involvement, often underprepare women for the severity and risks of chemical abortion, and they often provide insufficient or no follow-up care to those women."[373]

409. "Many women are inadequately prepared for the effects of the drugs, the severity of the pain and bleeding they will experience, the human tissue they will expel, and some are unaware that they have complicating factors such as ectopic implantation, more advanced gestation than estimated, and Rh-negative blood type. These patients are being abandoned because in many cases there is no doctor-patient relationship, so they often present to overwhelmed emergency rooms in their distress, where they are usually cared for by physicians other than the abortion prescriber."[374]

410. In particular, Dr. Skop notes that "approximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the

---

[371] *Id.* ¶ 24.

[372] *Id.* ¶ 26.

[373] *Id.* ¶ 27.

[374] *Id.*

uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death."[375]

2. Care provided by Dr. Shaun Jester demonstrates harms caused by the FDA's deregulation of abortion drugs

411. Dr. Shaun Jester has likewise witnessed harm caused by the lack of follow-up care for women given abortion drugs.[376]

412. Dr. Jester is a board-certified obstetrician and gynecologist and the Medical Director of Moore County Ob/Gyn.[377]

413. He has seen firsthand the harm the FDA caused by removing the protection that an in-person follow-up visit provides.

414. The FDA hurt one of his patients by allowing for abortion drugs to be dispensed to her in another state without mandatory follow-up care. As he related, "I treated a woman who traveled from Texas to obtain chemical abortion drugs from Planned Parenthood New Mexico to complete an abortion at 10 weeks' gestation. The woman returned to Texas, suffered from two weeks of moderate to heavy bleeding, and then developed a uterine infection. At the hospital, I provided her with intravenous antibiotics and performed a dilation and curettage procedure. If she had waited a few more days before receiving care, she could have been septic and died. I reported this adverse event to the FDA."[378]

415. The FDA's actions caused this patient to seek care from Dr. Jester in her home state of Texas, as there was no requirement for in-person follow-up care from the abortion provider in New Mexico. As he explains, "In the chemical abortion

---

[375] *Id.* ¶ 29.

[376] Ex. 83, Jester Decl. ¶¶ 2, 17.

[377] *Id.* ¶ 2.

[378] *Id.* ¶ 17.

case that I reported as an adverse event to the FDA, I had no existing patient relationship or prior knowledge of the patient's medical history."[379] And "it disturbed me that she was not informed that it was not normal to bleed for multiple weeks and that if she had a routine follow-up visit, as required by past REMS, this situation could have been avoided before requiring overnight hospitalization and her being at risk for developing sepsis."[380]

416. In his experience, "the requirement for an in-person, postabortion office visit, which is when a physician determines whether any fetal parts or other products of conception remain [is] essential to ensure that women experience no complications after chemical abortion."[381] "The elimination of mandatory follow-up visits after chemical abortion drugs have been administered is … dangerous … Without follow-up visits, physicians cannot identify potential complications like sepsis and hemorrhage, lingering products of conception, and others until the patient is at a critical time or it is too late to help the patient."[382]

B. State governmental data on women in Plaintiff States receiving abortion drugs due to the FDA's deregulation

417. Data show how many of Plaintiff States' residents have been receiving abortion drugs in the absence of the FDA's safeguards.

418. At oral argument before the Fifth Circuit, Defendants were asked about the Supreme Court's ruling that state plaintiffs in *Department of Commerce* v. *New York*, 139 S. Ct. 2551 (2019), had standing. The Federal Government responded that, in *Department of Commerce*, "the plaintiffs were states," meaning "the effects [of

---

[379] *Id.* ¶ 20.

[380] *Id.* ¶ 27.

[381] *Id.* ¶ 10.

[382] *Id.* ¶ 25.

challenged federal action] on them happened at the population level," and the States could thus "rely on population-wide statistics and probabilities." Oral Arg. Rec. at 17:16–17:42 (May 17, 2023), *All. for Hippocratic Med.*, No. 23-10362.[383]

419. Just as in *Department of Commerce*, population-wide information shows the number of women affected by Defendants' actions.

420. Under state abortion reporting laws, Plaintiff States' agencies collect data on abortions performed on state residents. These estimates are likely an undercount due to reporting inadequacies and missing data, especially in light of the high rates of chemical abortions nationwide and the known refusal of out-of-state providers to submit information to Plaintiff States or comply with Plaintiffs' abortion laws. In addition, non-governmental organizations have begun collecting abortion drug data for the years after *Dobbs*.

1. Missouri's state abortion data

421. The Missouri Department of Health and Senior Services collects data on abortions performed on Missouri residents in Missouri and Illinois and it estimates the total abortions per year on Missouri residents.[384]

422. The Missouri Department of Health and Senior Services reports the number of chemical abortions per year on Missouri residents, broken down by age of gestation.[385]

---

[383] https://www.ca5.uscourts.gov/OralArgRecordings/23/23-10362_5-17-2023.mp3

[384] Mo. Dep't of Health & Senior Services, Missouri Vital Statistics Annual Reports, Graph D, Resident Abortion Ratios per 1,000 Live Births: Missouri, https://health.mo.gov/data/vitalstatistics/data.php. Data is not available beyond 2022.

[385] Mo. Dep't of Health & Senior Services, Missouri Vital Statistics Annual Reports, Table 12A, Resident Abortions by Race, Age, and Type of Procedure by Weeks of Gestation, https://health.mo.gov/data/vitalstatistics/data.php.

423. The following table shows the number of chemical abortions from 2016 to 2022 as the market for abortion drugs shifted out-of-state to evade increasing state abortion regulations enacted from 2016 onwards.

Total Estimated Missouri Abortions by Year and Total Reported Chemical Abortions by Year and for FDA-Approved Gestational Age Ranges

Year	2016	2017	2018	2019	2020	2021	2022
Total estimated Missouri resident abortions	8,946	9,029	9,271	9,254	10,018	11,185	10,255
Total estimated Missouri chemical abortions	2,931	2,893	2,529	2,189	2,298	2,503	1,792
-under 9 weeks	2,434	2,423	2,191	1,910	1,940	2,086	1,334
-9-10 weeks	485	453	313	268	320	374	417

424. The large number of abortions on Missouri residents by abortion drugs in this table includes abortions for Missouri residents who obtained the drugs by from out-of-state providers, such as providers in Kansas or Illinois, who were enabled by the FDA's removal of the requirement for three in-person doctor visits. Before 2022, Missouri was one of the only states to successfully defend laws requiring abortion providers to undertake safety measures that abortionists arrange for a physician to always be available to treat complications caused by abortion drugs, and (2) that abortionists obtain admitting privileges at a nearby hospital. *Comprehensive Health of Planned Parenthood Great Plains v. Williams*, No. 2:17-cv-04207 (W.D. Mo. 2017); *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, No. 2:16-cv-04313 (W.D. Mo. 2016)

425. By sometime in 2019, Missouri's only abortion clinic (Planned Parenthood in St. Louis) performed *no* in-state abortions with chemical abortion drugs, and by the end of 2020, the number of surgical abortions that it performed

monthly was either in the single digits or zero.[386] As the press reported at the time, "Dr. Colleen McNicholas, a Planned Parenthood chief medical officer, said the number of abortions performed at the St. Louis clinic has dropped since a clinic opened 18 miles (28 kilometers) away in Fairview Heights, Illinois, in October 2019. Patients at that clinic can avoid Missouri's 72-hour mandatory waiting period, which requires two appointments three days apart to receive an abortion."[387] In addition, "More patients are also seeking medication abortions, which the St. Louis facility has not provided in more than two years because of Missouri's requirement that patients wanting that procedure must undergo a pelvic exam."[388]

426. Consequently, although the baseline for Missouri residents' abortions via abortion drugs should be zero from 2019 onwards, these figures show that Missouri residents received at least some abortions from out-of-state providers who dispensed abortion drugs in a single visit and then sent women home to Missouri with no in-person follow-up care—all enabled by the FDA's lack of a requirement for three in-person doctor visits, including a follow-up visit.

---

[386] Ex. 84, Associated Press, *Planned Parenthood in Missouri Disputes Report State No Longer Performs Abortions, But Number of Procedures Fell Due to New Regulations*, Chicago Tribune (Jan. 20, 2021), https://www.chicagotribune.com/2021/01/20/planned-parenthood-in-missouri-disputes-report-state-no-longer-performs-abortions-but-number-of-procedures-fell-due-to-new-regulations/ ("No surgical abortions were performed at the clinic in December, with only seven in November, Planned Parenthood said, compared with nine and five during those months in 2019").

[387] *Id.*

[388] *Id.*

2. Idaho's state abortion data

427. The Idaho Department of Health & Welfare collects data on abortions performed on Idaho residents.[389]

428. The following table summarizes this data.

[389] Idaho Dep't of Health & Welfare, Induced Termination, https://publicdocuments.dhw.idaho.gov/WebLink/browse.aspx?id=5657&dbid=0&repo=PUBLIC-DOCUMENTS (collecting annual reports from 2019 to 2022).

Total Reported Idaho Abortions and Chemical Abortions by Year[390]

Year	2015	2016	2017	2018	2019	2020	2021	2022
Total Idaho resident abortions	1,272	1,749	1,730	1,742	1,892	2,007	1,985	1,207
Total Idaho chemical abortions	561	762	784	771	825	1,102	1,178	654
-under 9 weeks	497	645	678	677	721	946	997	540
-9-10 weeks	63	113	101	89	99	145	163	88

[390] This data is reported in the annual reports in charts labeled "Induced Abortions Occurring In Idaho Primary Termination Procedure by Length of Gestation." *See* Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics-Induced Abortion 2022* at 12 (Dec. 2023), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=28264&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2021* at 13 (Sept. 2022), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=23522&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2020* at 12 (Jan. 2022), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=22665&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2019* at 12 (Jan. 2021), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=22664&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2018* at 12 (Jan. 2020), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=7260&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2017* at 12 (Nov. 2018), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=7259&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2016* at 12 (Dec. 2017), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=7258&dbid=0&repo=PUBLIC-DOCUMENTS; Idaho Dep't of Health & Welfare, Division of Public Health, Bureau of Vital Records and Health Statistics, *Idaho Vital Statistics - Induced Abortion 2015* at 12 (March 2017), https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=7257&dbid=0&repo=PUBLIC-DOCUMENTS. Data is not available for year 2023 or onwards.

3. Kansas's state abortion data

429. The Kansas Department of Health and Environment collects data on Kansas abortions.[391]

430. The Kansas Department of Health and Environment's annual reports list abortions performed on Kansas residents (in Kansas and out-of-state) and out-of-state residents in Kansas. [392]

---

[391] Kansas Dep't of Health & Environment, Public Health Statistics, Public Health Reports and Statistics, https://www.kdhe.ks.gov/1089/Public-Health-Reports-Statistics (collecting reports from 2016 to 2022); Kansas Dep't of Health & Environment, Annual Summary Archives, https://www.kdhe.ks.gov/1399/Annual-Summary-Archives (collecting reports from 2016 and earlier). Data is not yet available for 2023.

[392] Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2022, Table D4 & D8 at 116, 122, https://www.kdhe.ks.gov/DocumentCenter/View/31759/2022-Annual-Summary-Full-Report-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2021, Table D4 & D8 at 116, 122, https://www.kdhe.ks.gov/DocumentCenter/View/25772/2021-Annual-Summary-Full-Report-?bidId=; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2020, Table D4 & D8 at 114, 120, https://www.kdhe.ks.gov/DocumentCenter/View/15354/2020-Annual-Summary-Full-Report-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2019, Table D4 & D8 at 106, 112, https://www.kdhe.ks.gov/DocumentCenter/View/12590/2019-Annual-Summary-Full-Report-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2018, Table D4 & D8 at 106, 112, https://www.kdhe.ks.gov/DocumentCenter/View/12588/2018-Annual-Summary-Full-Report-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2017, Table D4 & D8 at 96, 102, https://www.kdhe.ks.gov/DocumentCenter/View/12586/2017-Annual-Summary-Full-Report-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2016, Table D4 & D8 at 92, 100, https://www.kdhe.ks.gov/DocumentCenter/View/10042/Kansas-Annual-Summary-of-Vital-Statistics-2016-PDF; Kansas Dep't of Health & Environment, Kansas Annual Summary of Vital Statistics, 2015, Table D4 & D8 at 94, 98, https://www.kdhe.ks.gov/DocumentCenter/View/12578/2015-Annual-Summary-Full-Report-PDF.

431. The following chart summarizes this data.

Total Reported Kansas Abortions and Chemical Abortions by Year, Residence, and Gestational Age

Year	2015	2016	2017	2018	2019	2020	2021	2022
Total Kansas abortions	6,974	6,820	6,826	7,048	6,916	7,546	7,849	12,319
--Kansans in-state	3,536	3,409	3,371	3,474	3,521	3,625	3,933	3,842
--Kansans out-of-state	43	30	79	76	22	20	4	2
--non-residents in Kansas	3,395	3,381	3,376	3,498	3,373	3,901	3,912	8,475
Total Kansas chemical abortions	3,092	3,623	3,962	4,321	4,446	5,056	5,321	7,340
-under 9 weeks	2,673	3,154	3,521	3,828	3,922	4,310	4,439	5,533
-9-12 weeks	419	468	440	487	521	740	877	1,801

432. This data shows that since each of Defendants' actions the total number of chemical abortions, the total number of abortions in Kansas on non-Kansans, and the number of 9-12 week chemical abortions have all increased—and markedly so in 2022 the year when *Dobbs* was announced.

433. In this chart, the totals for out-of-state residents receiving abortion drugs in Kansas includes women from Missouri who received abortion drugs in Kansas and who then were sent home to Missouri without in-person follow visits—leading them to seek follow-up care as needed in Missouri.

434. This governmental data reflects the known sales data of mifepristone. Between 2019 and October 2023, "GenBioPro has marketed and sold approximately 850,000 units of generic mifepristone throughout the United States." Am. Compl., ECF No. 75, *GenBioPro, Inc. v. Raynes*, No. CV 3:23-0058, at ¶¶ 1 – 2 (S.D .W.Va. Oct. 19, 2023).

435. That being said, these reports and the medical literature underestimate abortion rates and abortion complication rates: abortion providers systemically violate their duty to report abortions or complications to state governments.

436. For at least 15 years, abortion providers in Missouri violated a law requiring them to report complications to the state.

437. In sworn testimony, David Eisenberg, then an abortionist in Missouri, admitted that he and other abortionists at his St. Louis clinic refused to file these reports even though they knew about the state law requiring the reports.[393]

438. Colleen McNicholas, another person who until recently performed abortions in Missouri, likewise admitted under oath that she violated this law for years.[394]

439. There is no reason to think that this systemic failure to file lawfully required complication reports is limited to Missouri. Those who performed abortions in Missouri also perform them elsewhere.

440. Indeed, Eisenberg admitted he did not file these reports at "other healthcare facilities" where he worked.[395] And a news story describes McNicholas as an abortionist who "zig-zags across the Midwest," performing abortions in many different states.[396]

441. Since *Dobbs*, the lack of compliance with state abortion reporting requirements has increased, and the resulting undercounts in state abortion data have increased, as out-of-state suppliers have stepped into the market with the purpose of undermining state abortion laws.

---

[393] Ex. 85, ECF 48-3, Eisenberg Dep., Doc. 141-4, No. 2:16-cv-04313 (W.D. Mo. 2018).

[394] Ex. 86, ECF 48-3, Tr. Prelim. Inj. Hr'g., Doc. 115, No. 2:17-cv-04207 (W.D. Mo. 2018).

[395] Ex. 85, ECF 48-3, Eisenberg Dep., Doc. 141-4, No. 2:16-cv-04313 (W.D. Mo. 2018).

[396] Ex. 87, On the Front Lines of the Abortion Wars, Marie Claire (Oct. 12, 2021), https://www.marieclaire.com/culture/a20565/mission-critical-abortion-rights-midwest/.

C. Non-governmental data on women in Plaintiff States receiving abortion drugs due to the FDA's deregulation

442. The abortion market shifted in 2022, 2023, and 2024 to out-of-state suppliers who do not file these reports—undermining state abortion-drug reporting laws and the completeness of government data.

443. Non-government parties provide the best current estimates of the number of abortion drugs dispensed since 2022 or 2023.

444. This nongovernmental data reflects the effect of Defendants' actions from 2021 onwards, when Defendants first enabled abortion drugs to be dispensed without any in-person dispensing protection.

445. The lack of an in-person dispensing protection in 2021 enabled many existing abortion providers to provide abortion drugs by remote means within their current states or regions as an adjunct to their current business operations.

446. Most States had various in-state abortion providers. With *Roe* in effect, abortion providers did not identify the same need to ship abortion drugs remotely into states with abortion restrictions as when *Roe* was overturned.

447. At the time of *Dobbs*, and continuing today, abortion providers in states with no abortion restrictions have continued to dispense FDA-approved abortion drugs outside of Plaintiff States in-person (as with the 2016 changes) and by mail, common carrier, or interactive computer service.

448. But, in addition, after *Dobbs*, when in-state abortion providers exited states with abortion restrictions, the lack of an in-person dispensing protection caused other abortion providers to provide FDA-approved abortion drugs to women in Plaintiff States. They did so by telehealth (websites, video chat, email, phone, or text) and through the mail or by a common carrier.

449. Unlike prior abortion providers who used telehealth, mail, or common carrier in response to Defendants' 2021 actions as an adjunct to current in-person

business operations, beginning in 2023 these new abortion providers' business operations were exclusively by mail or common carrier.

450. These mail-only abortion providers began to avail themselves of the FDA's 2021 and 2023 changes only in mid-2023. Part of the reason for this delay of one year from *Dobbs* was to create the infrastructure necessary and another part of the reason for this delay was to lobby states to enact shield laws.

451. By these abortion providers' own telling, by mid-2023 they had begun their remote abortion drug shipments in earnest. The number of FDA-approved abortion drugs shipped across state lines has increased ever since.

452. The Society of Family Planning's WeCount project aims to measure monthly abortion utilization, nationally and by state, following Dobbs, based on data from many abortion providers—including data from shield law providers.[397]

453. Telehealth is driving an increase in the national abortion totals, as the total abortions nationally was higher in 2024 than it was in 2023 or 2022.[398] For purposes of this data, a telehealth abortion is when FDA-approved abortion drugs are "offered by a clinician through a remote consultation with the patient (via video, phone, or messaging)" that results in the drugs being "dispensed via mail."[399]

454. Both in-person and telehealth abortions are increasing in Kansas. TheWeCount reports, "Comparing the first quarter of 2024 with the first quarter of 2023, the states with the largest increases in the average number of abortions per

---

[397] Ex. 88, Society of Family Planning, #WeCount Report April 2022 to March 2024 (August 7, 2024), https://societyfp.org/wp-content/uploads/2024/07/WeCount-Report-7-Mar-2024-data.pdf (hereinafter #WeCount Report).

[398] *Id.* at 2–3.

[399] *Id.*

month include New York (1,357), California (957), Virginia (597), Kansas (503), and Pennsylvania (430).

455. Among these five states, when comparing the first quarter of 2024 with the first quarter of 2023, the average number of in-person abortions per month increased by 29% in Kansas, 18% in New York, 13% in Virginia, and 4% in California, and decreased by 7% in Pennsylvania. The average number of virtual-only telehealth abortions was up by 59% in Kansas and 53% in Virginia."[400]

456. At the same time, the proportion of telehealth abortions rose "from 4% of all abortions in April 2022 to 20% in March 2024."[401] "Telehealth represented 21% of all abortions in January 2024, 19% in February, and 20% in March."[402]

457. This increase reflected not only the proliferation of shield-law providers, but an increase in brick-and-mortar abortion clinics providing telehealth (like WWH).[403] "In January-March 2024, there was a national average of nearly 1,900 brick-and-mortar telehealth abortions per month," "a 33% increase from the October-December 2023 average of over 1,400."[404] "In January-March 2024, there was an average of over 6,700 monthly telehealth abortions provided under shield laws to people in states with total abortion bans or 6-week bans, and nearly 2,500 monthly telehealth abortions provided under shield laws to people in states with restrictions on telehealth abortion."[405] "In January-March 2024, there was an average of nearly

---

[400] *Id.* at 5.

[401] *Id.* at 6.

[402] *Id.*

[403] *Id.*

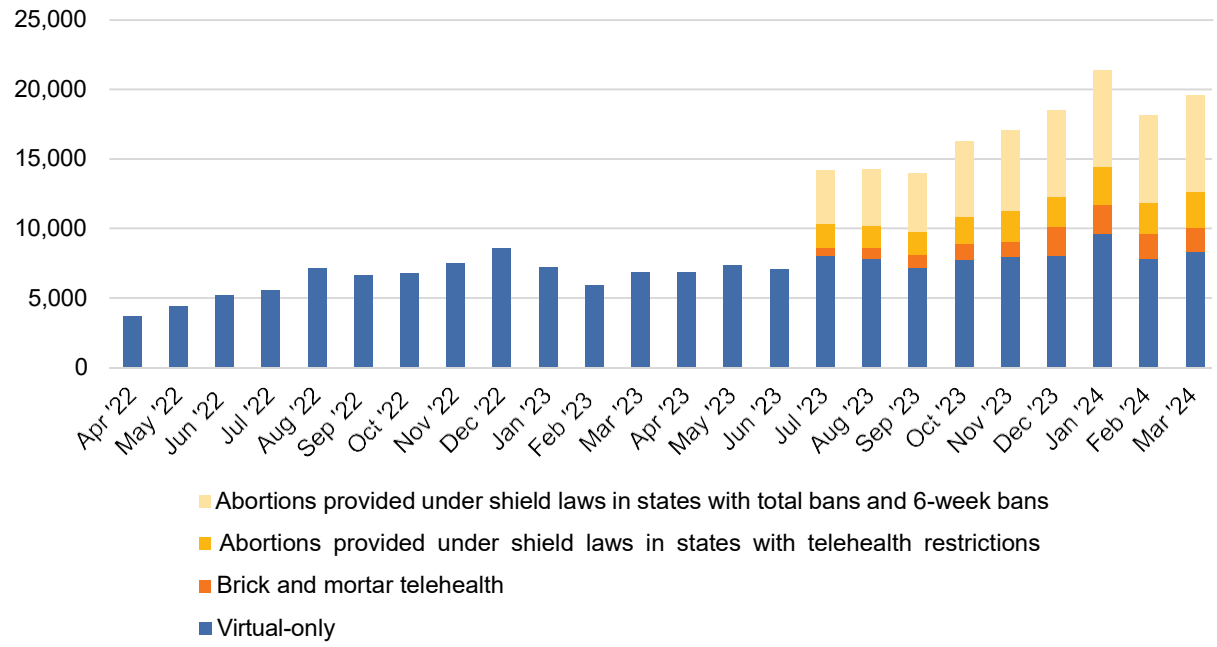
[404] *Id.*

[405] *Id.*

19,700 telehealth abortions (all types) per month, representing a 14% increase from October-December 2023.[406]

458. This data is summarized in the following graph.[407]

Figure 6. Telehealth abortions in the US from April 2022 to March 2024 (includes abortions provided under shield laws, July 2023 to March 2024)



Note: Prior to July 2023, brick and mortar telehealth abortions were categorized as in-person.

459. This graph also shows that the "average monthly number of all telehealth abortions provided under shield laws in January-March 2024 of over 9,200 represents a 16% increase from the October-December 2023 average."[408]

460. The following chart enumerates the 2023 increase of remote dispensing of abortion drugs into states that regulate abortion, as compared to the total abortions in America, by month beginning in January 2023.[409]

---

[406] *Id.* at 7.

[407] *Id.* at 8.

[408] *Id.* at 7.

[409] *Id.* at 17.

Table 1-2023. Estimated number of abortions by state and month, January 2023 to December 2023

	Jan '23	Feb '23	Mar '23	Apr '23	May '23	Jun '23	Jul '23	Aug '23	Sep '23	Oct '23	Nov '23	Dec '23
All US state totals	**86,640**	**80,740**	**93,520**	**84,200**	**87,930**	**88,020**	**88,340**	**92,640**	**85,560**	**88,210**	**86,420**	**91,470**
Abortions provided under shield laws in states with telehealth restrictions	…	…	…	…	…	…	1,720	1,640	1,650	2,000	2,180	2,220
Abortions provided under shield laws in states with total bans and 6-week bans	…	…	…	…	…	…	3,900	4,040	4,220	5,420	5,820	6,200

461. The following chart enumerates the 2024 increase of remote dispensing of abortion drugs into states that regulate abortion, as compared to the total abortions in America, by month beginning in January 2024.[410]

Table 1-2024. Estimated number of abortions by state and month, January 2024 to March 2024

	Jan '24	Feb '24	Mar '24	Apr '24	May '24	Jun '24	Jul '24	Aug '24	Sep '24	Oct '24	Nov '24	Dec '24
All US state totals	**102,350**	**94,670**	**99,950**	…	…	…	…	…	…	…	…	…
Abortions provided under shield laws in states with telehealth restrictions	2,700	2,220	2,540	…	…	…	…	…	…	…	…	…
Abortions provided under shield laws in states with total bans and 6-week bans	6,930	6,310	6,960	…	…	…	…	…	…	…	…	…

462. The following chart enumerates the 2023 increase of remote dispensing of abortion drugs into states that regulate abortion, as compared to the total amount of remote dispensing nationwide, by month beginning in January 2023.[411]

Table 3-2023. Estimated number of virtual-only abortions by state and month, January 2023 to December 2023

	Jan '23	Feb '23	Mar '23	Apr '23	May '23	Jun '23	Jul '23	Aug '23	Sep '23	Oct '23	Nov '23	Dec '23
All US state totals	**7,250**	**5,940**	**6,870**	**6,860**	**7,350**	**7,060**	**13,680**	**13,520**	**13,010**	**15,190**	**15,970**	**16,450**
Abortions provided under shield laws in states with telehealth restrictions	…	…	…	…	…	…	1,720	1,640	1,650	2,000	2,180	2,220
Abortions provided under shield laws in states with total bans and 6-week bans	…	…	…	…	…	…	3,900	4,040	4,220	5,420	5,820	6,200

[410] *Id.* at 19.

[411] *Id.* at 24.

463. The following chart enumerates the 2023 increase of remote dispensing of abortion drugs into states that regulate abortion, as compared to the total amount of remote dispensing nationwide, by month beginning in January 2023.[412]

Table 3-2024. Estimated number of virtual-only abortions by state and month, January 2024 to March 2024

	Jan '24	Feb '24	Mar '24	Apr '24	May '24	Jun '24	Jul '24	Aug '24	Sep '24	Oct '24	Nov '24	Dec '24
All US state totals	**19,210**	**16,350**	**17,790**	…	…	…	…	…	…	…	…	…
Abortions provided under shield laws in states with telehealth restrictions	2,700	2,220	2,540	…	…	…	…	…	…	…	…	…
Abortions provided under shield laws in states with total bans and 6-week bans	6,930	6,310	6,960	…	…	…	…	…	…	…	…	…

464. State-by-state data for telehealth abortions for states like Kansas (where abortion is not restricted) is broken down by virtual and brick-and-mortar providers.[413]

465. But WeCount aggregates data for telehealth abortions for states like Missouri and Idaho (where abortion is restricted or regulated), so no state-by-state data is available for these states.

466. The WeCount report does not include black-market, non-FDA-approved abortion drugs—a category of abortion drugs that are not at issue in this case.

467. WeCount concurs with the widespread reporting that remote dispensing of FDA-approved abortion drugs "under shield laws started in June 2023, which triggered their inclusion in #WeCount in July 2023."[414]

468. Some abortion providers were mailing black-market abortion drugs "to residents of states with abortion bans, states with 6-week bans, and states with

---

[412] Ex. 88, #WeCount Report, *supra* note 397, at 26.

[413] Ex. 89, Society of Family Planning, #WeCount, Tables https://societyfp.org/research/wecount/ (click download the latest data for excel chart).

[414] Ex. 88, #WeCount Report, *supra* note 397, at 11.

restrictions on telehealth prior to June 2023, but these occurred outside the formal healthcare system and were not measured by #WeCount."[415]

469. WeCount explained that the "[i]ncreased numbers of abortions in states that permit abortion likely represent a combination of two main factors: people traveling from states where they cannot access care, and increased abortions among residents of states where abortion remains legal."[416] "Such volume increases are likely influenced by reductions of barriers to abortion care, including reduced burden of cost and travel by use of telehealth, increased financial support for low-income abortion seekers, and improved access via care navigation from practical support groups and public health departments."[417]

470. The Guttmacher Institute also estimates the current number of FDA-approved abortion drugs dispensed by abortion providers in states that do not restrict abortion (excluding shield-law providers who send abortion drugs to states where abortion is restricted).

471. It estimates that there were "approximately 642,700 medication abortions in the United States in 2023, accounting for 63% of all abortions in the formal health care system."[418] "This is an increase from 2020, when medication abortions accounted for 53% of all abortions."[419]

---

[415] *Id*. at 11.

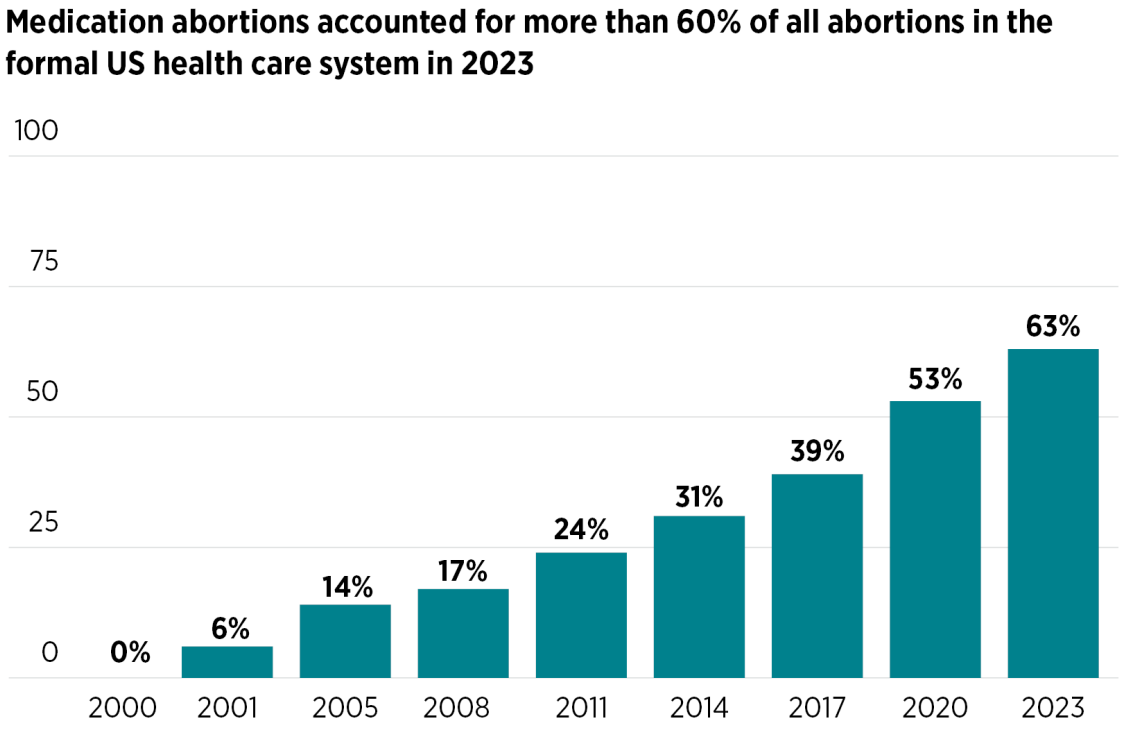
[416] *Id*. at 11.

[417] *Id*. at 11.

[418] Ex. 90, Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020,* Guttmacher Institute (March 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.

[419] *Id*.

472. This rate is shown in the following chart.[420]



473. If the Guttmacher Institute included data from shield law providers, this rate would be even higher.

474. The Guttmacher Institute collects data showing where women travel to receive abortions, including women from Plaintiff States. Although this data may be an undercount due to reporting inadequacies, this data shows that women from Missouri traveled to Kansas and Illinois; women from Idaho traveled to Oregon, Utah, and Washington; and women from Kansas largely obtained abortions in

[420] *Id.*

Colorado and Kansas.[421] It estimates that the percentage of abortions provided in Kansas to out-of-state residents has increased from 52% in 2020 to 67% in 2023.[422]

475. The Guttmacher Institute also estimates that the number of abortion providers offering abortion drugs by video, phone call, text or online platform—and mail "increased from 7% of all providers" in 2020 "to 31% in 2022."[423] "Online-only clinics, after first appearing as a new type of abortion provider in 2021, accounted for 8% of all abortions provided within the formal health care system in the first six months of 2023."[424]

XX. State laws prohibit and regulate abortion drugs.

476. Plaintiff States have the sovereign power to enact and enforce abortion laws.

477. State abortion laws serve the important state interests in "respect for and preservation of prenatal life at all stages of development, the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 301, (2022).

478. "[F]rom time immemorial," the States have maintained primary responsibility for regulating the medical field through their constitutionally reserved

---

[421] Ex. 91, Guttmacher Institute, State Abortion Travel 2023, https://osf.io/k4x7t/ (providing excel charts).

[422] Ex. 92, Guttmacher Institute, Monthly Abortion Provision Study, https://www.guttmacher.org/monthly-abortion-provision-study#interstate-travel (search Kansas).

[423] *Id.*

[424] *Id.*

powers to protect their citizens' health and welfare. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).

479. Each State "has a significant role to play in regulating the medical profession," *Gonzales v. Carhart*, 550 U.S. 124, 157 (2007), as well as "an interest in protecting the integrity and ethics of the medical profession," *Washington v. Glucksberg*, 521 U.S. 702, 731 (1997). This includes "maintaining high standards of professional conduct" in the practice of medicine. *Barsky v. Bd. of Regents of Univ. of N.Y.*, 347 U.S. 442, 451 (1954).

480. The State also "has an interest in protecting vulnerable groups … from abuse, neglect, and mistakes," *Glucksberg*, 521 U.S. at 731, and in "the elimination of particularly gruesome or barbaric medical procedures," *Dobbs*, 597 U.S. at 301. It is also "evident beyond the need for elaboration that a State's interest in 'safeguarding the physical and psychological well-being of a minor' is 'compelling.'" *New York v. Ferber*, 458 U.S. 747, 756–57 (1982) (quoting *Globe Newspaper Co. v. Superior Court*, 457 U.S. 596, 607 (1982)).

481. To serve these compelling sovereign interests, Plaintiff States have enacted statutes regulating and, in certain instances, prohibiting, abortion drugs.

482. These laws ensure the proper regulation of the practice of medicine and the medical profession but Defendants' actions undermine all these laws—including state abortion restrictions and state abortion-drug reporting laws.

483. The laws that the FDA likely considers preempted include the following.

1. Missouri's abortion laws

484. The FDA's unlawful actions threaten several laws, including (1) Missouri's prohibition on abortions "except in cases of medical emergency," Mo. Rev. Stat. § 188.017.2; (2) Missouri's prohibition on providers administering chemical abortion drugs without first submitting a sufficient plan to address complications

from chemical abortions, *id*. § 188.021.2; (3) Missouri's regulations passed under § 188.021.2 requiring physicians who perform abortions to prearrange for backup physicians to address complications if needed, 19 C.S.R. 10-15.050; (4) Missouri's requirement that chemical abortion drugs be dispensed in-person, not through the mail, Mo. Rev. Stat. § 188.021.1; (5) Missouri's requirement that no person shall perform an abortion except a physician, Mo. Rev. Stat. § 188.020; and (6) Missouri's requirement that no person shall perform or induce an abortion (except in a medical emergency) unless a physician or qualified professional has explained the general and specific risks to the woman receiving the abortion, Mo. Rev. State. § 188.039.

485. Missouri law prohibits any abortion "except in cases of medical emergency." Mo. Rev. Stat. § 188.017.2.

486. 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.

487. 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. Missouri statutes and regulations require physicians to plan for and provide care for abortion complications so that persons receiving abortions are

not forced to go to emergency rooms. *See* Mo. Rev. Stat. § 188.021.1–.2; 19 C.S.R. 10-15-050.

488. But the FDA's challenged actions cause doctors who live and work in Plaintiff States to treat more women and girls who have suffered complications from chemical abortion drugs because physicians are not providing follow-up care when individuals experience complications. ECF 176, ¶¶ 363–68.

489. Missouri law includes an in-person dispensing protection 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.

490. The in-person dispensing protection ensures that physicians "shall make all reasonable efforts" to ensure patient follow-up, decreasing the chance that a woman will find herself in an emergency room with a doctor who has no idea what happened. Mo. Rev. Stat. § 188.021.1.

491. Other states have similar protections. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 467 F. Supp. 3d 282, 286–87 (D. Md. 2020) (collecting laws from nine states, including Missouri).

492. Missouri requires the physician to make all reasonable efforts to ensure the patient returns for a follow-up visit after the administration or use of mifepristone or any drug or chemical for the purpose of inducing an abortion. Mo. Rev. Stat. § 188.021.

493. Missouri limits who may induce an abortion. State law restricts any person other than a physician with clinical privileges at a hospital from performing, inducing, or attempting to perform or induce an abortion on another, restricts any physician who does not have clinical privileges at a hospital which offers obstetrical

or gynecological care located within thirty miles of the location the abortion is to be performed to perform, induce, or attempt to perform or induce an abortion, and restricts any person, except a physician, from performing or inducing an abortion. Mo. Rev. Stat. § 188.080. No person shall perform or induce an abortion except a physician. Mo. Rev. Stat. § 188.020

494. Missouri requires informed consent and a 72-hour waiting period. Mo. Rev. Stat. § 188.027. Under this state law, a woman must give her voluntary and informed consent, freely and without coercion, at least 72 hours before an abortion is performed. For consent to be voluntary and informed, a physician must orally inform the woman of the following in person and writing:

- the name of the physician performing the abortion;
- medically accurate and relevant materials to the decision of whether to undergo the abortion;
- a description of the proposed abortion method;
- the immediate and long-term medical and psychological risks associated with the abortion and medication administered;
- the unborn child's gestational age and anatomical and physiological characteristics of the unborn child;
- alternative options to abortion;
- the opportunity for the patient to ask questions of the provider regarding the procedure; and
- the location of the nearest hospital and where the woman can receive follow-up care by the physician if complications arise.

495. Missouri's 72-hour waiting period also provides that, except in the case of medical emergency, no person shall perform or induce an abortion unless at least seventy-two hours beforehand the physician who is to perform or induce the abortion, a qualified professional, or the referring physician has conferred with the patient and discussed with her the indicators and contraindicators, and risk factors including any physical, psychological, or situational factors for the proposed procedure and the use of medications, including but not limited to mifepristone, in light of her medical history and medical condition. For an abortion performed or an abortion induced by a drug or drugs, such conference shall take place at least seventy-two hours prior to the writing or communication of the first prescription for such drug or drugs in connection with inducing an abortion. Only one such conference shall be required for each abortion. Mo. Ann. Stat. § 188.039.

496. Missouri requires parental notification and consent for a minor's abortion. Mo. Rev. Stat. § 188.028(1)(1) requires the attending physician to secure informed written consent of the minor and one parent or guardian, and the consenting parent or guardian of the minor has notified any other custodial parent in writing prior to securing the informed written consent of the minor and one parent or guardian.

497. Missouri also has an ultrasound requirement. Mo. Rev. Stat. § 188.027(4). Under this law, the performing physician must provide the woman with an opportunity to view an active and free ultrasound and hear the heartbeat of the unborn child at least 72 hours before the abortion.

498. Missouri requires abortion facilities to maintain written protocols for medical emergencies and transfer of patients, and grants the department of health to adopt rules, regulations, or standards that apply to ambulatory surgical centers and abortion facilities. Missouri requires all ambulatory and abortion facilities to obtain

a license to operate. Mo. Rev. Stat. § 188.015, Mo. Rev. Stat. § 188.215, Mo. Rev. Stat. § 197.225, Mo. Rev. Stat. § 197.205.

499. Missouri requires malpractice insurance: it restricts hospitals or abortion facilities from employing or engaging the services of a person that would perform an abortion using any drug or chemical or combination thereof, which may cause birth defects, disability, or other injury to a child who survives the abortion if the person does not have insurance. Mo. Rev. Stat. § 188.044

500. Missouri requires an individual abortion report for each abortion performed or induced upon a woman to be completed by the physician who performed or induced the abortion. This abortion report shall be made part of the medical record of the patient of the abortion facility or hospital where the abortion was performed. Mo. Rev. Stat. § 188.052.

2. Idaho's abortion laws

501. Idaho abortion laws prohibit abortion except in certain circumstances, prohibit anyone other than a physician from performing an abortion, requires in-person exams before any abortion, requires plan for local follow-up care, and requires abortions to occur in regulated medical facilities, among other restrictions that the FDA likely considers preempted by the REMS.

502. Idaho law regulates abortion-inducing drugs like mifepristone. See Idaho Code §§ 18-602 (recognizing "[t]hat children have a special place in society that the law should reflect"), 18-604(1) ("Abortion" means the use of any means to intentionally terminate the clinically diagnosable pregnancy of a woman with knowledge that the termination by those means will, with reasonable likelihood, cause the death of the unborn child"), 18-617 (defining "Abortifacient" to mean "mifepristone, misoprostol and/or other chemical or drug dispensed with the intent of causing an abortion as defined in section 18-604(1)"), and 18-622 ("Every person who

performs or attempts to perform an abortion as defined in this chapter commits the crime of criminal abortion.").

503. Idaho limits abortion unless necessary to prevent the death of the pregnant woman. Idaho Code § 18-622.

504. Idaho authorizes only a physician to perform an abortion. Idaho Code § 18-608A. It is unlawful for any person other than a physician to cause or perform an abortion.

505. As to abortion drugs, Idaho requires a physician, before dispensing or prescribing abortion-inducing drugs, to: assess the duration of the pregnancy, determine that the unborn child is within the uterus, be qualified to provide surgical intervention or have an agreement with other local physicians to provide surgical intervention, provide informed consent, and make reasonable efforts to ensure that the patient returns for a follow-up visit. Idaho Code § 18-617.

506. Idaho requires informed consent and imposes a 24-hour waiting period before any abortion. Under Idaho Code § 18-609(2), (4), at least 24 hours before performing the abortion, the physician must provide materials to the woman describing:

- services available to assist a woman through pregnancy and childbirth;
- the physical characteristics of a normal fetus at two-week intervals, accompanied by photographs;
- the abortion procedures at various stages of the fetus and any reasonable foreseeable complications and risks to the mother;
- a list of health care providers, facilities, and clinics that offer to perform ultrasounds free of charge;

- statement that the patient has a right to view an ultrasound image and observe the heartbeat monitoring;
- where to obtain further information about interventions for chemical abortion that may affect the effectiveness or reversal of a chemical abortion;
- resources on Down Syndrome.

507. Idaho requires printed materials to be provided with information directing the patient where to obtain assistance regarding chemical abortion, including the interventions, if any, that may affect the effectiveness or reversal of a chemical abortion. Idaho Code § 18-609(2)(f)

508. Idaho law provides that 24 hours before an abortion is to be performed, the physician must inform the woman that ultrasound imaging and heartbeat monitoring are available and that she has the right to view an ultrasound before an abortion is performed. Idaho Code § 18-609(5)–(6).

509. Idaho requires parental consent for a minor seeking abortion. Idaho Code § 18-609A(1). A physician must secure written consent from an unemancipated minor's parent or guardian unless the minor waives consent through a judicial bypass procedure. Idaho Code § 18-609A(2).

510. Idaho requires that all first trimester abortions be performed in a hospital or properly staffed and equipped office or clinic and requires second trimester abortions to be performed in a hospital. Idaho Code § 18-608(1).

511. Idaho requires reports on abortions to be filed describing probable postfertilization age, whether or not there was a medical emergency, and the method used for abortion. Idaho Code § 18-506.

3. Kansas's abortion laws

512. Kansas also regulates abortion and other medical services.

513. With some exceptions, including to save the life of the mother, Kansas law prohibits abortions after twenty-two weeks. Kan. Stat. Ann. § 65-6703(b)(2), (c)(2).

514. Kansas requires abortion providers to keep records of abortions. *Id.* § 65-6703(d).

515. Kansas requires minor girls seeking abortion to obtain parental consent prior to performing the abortion unless a waiver is granted or there is a medical emergency. Kan. Stat. Ann. § 65-6705.

516. Kansas provides that no abortion shall be performed or induced without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if at least 24 hours before the abortion the physician who is to perform the abortion or the referring physician has informed the woman in writing, which shall be provided on white paper in a printed format in black ink with 12-point Times New Roman font, of certain information. Kan. Stat. Ann. § 65-6709(a).

517. Kansas previously had a statute where "[n]o abortion shall be performed or induced by any person other than a physician." Kan. Stat. Ann. § 65-4a10 (West). In addition, this statute required mifepristone specifically be "initially be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient." *Id.* It also had an in-person follow-up protection. *Id.* All of these provisions would have a high risk for preemption. However, this statute was held unconstitutional very recently by the Kansas Supreme Court in *Hodes & Nauser, MDs, P.A. v. Stanek*, 551 P.3d 62 (Kan. 2024).

4. Other states' abortion laws

518. Many other state laws likewise address the risks of chemical abortions. Such laws recognize, for example, that "abortion-inducing drugs": "present[ ] significant medical risks to women," such as "uterine hemorrhage, viral infections, pelvic inflammatory disease, severe bacterial infection and death," Miss. Code Ann. § 41-41-103(1)(a); "are associated with an increased risk of complications relative to surgical abortion" that surge "with increasing gestational age," *id*. § 41- 41-103(1)(b); and "are contraindicated in ectopic pregnancies," *id*. § 41-41-107(2). So many states combat those risks by, among other things, requiring that only physicians may provide such drugs, that a physician may do so only after "physically examin[ing] the woman and document[ing] ... the gestational age and intrauterine location of the pregnancy," and that these drugs "must be administered in the same room and in the physical presence of the physician." *Id*. § 41-41-107(1)-(3).

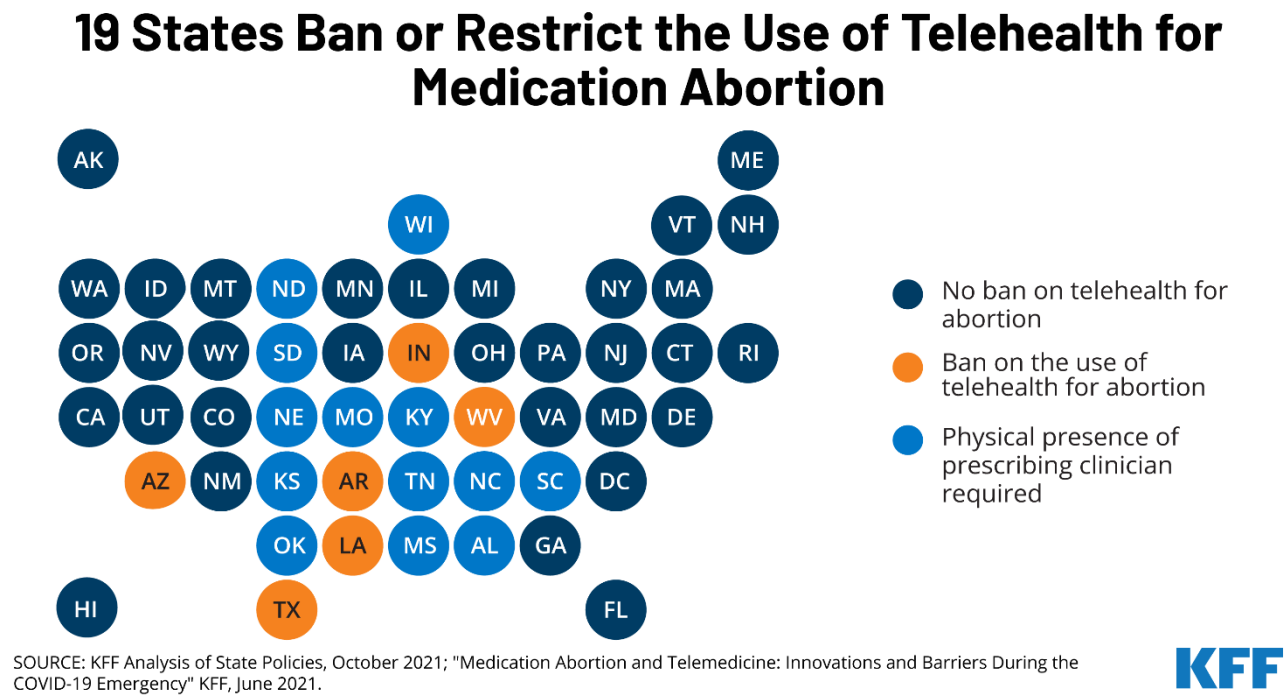
519. Many other states require in-person exams or dispensing or have other abortion statutes that the FDA likely considers preempted. *See, e.g.*, Ala. Code § 26-23E-7, 26-23A-4(a), 26-23A-4(b); Alaska Stat. Ann. §§ 08.64.364(c)(1), 08.64.364(c)(2); Ariz. Rev. Stat. Ann. §§ 36-2160(A), 36-2160(B), 36-2153(A)(1), 36-2153(A)(2); Ark. Code Ann. §§ 20-16-1504(a), 20-16-1504(b), 20-16-1504(c), 20-16-1504(f), 20-16-603(b)(1), 20-16-603(b)(2), 20-16-1505(a); Fla. Stat. Ann. §§ 390.0111(2), 390.0111(3)(a); Ga. Code Ann. §§ 43-34-110, 16-12-141(e)(2), 31-9B-2(a); Ind. Code Ann. § 16-34-2-1; Iowa Code Ann. §§ 146B.2(1), 146E.2(1); Ky. Rev. Stat. Ann. §§ 311.7733(1), 311.7733(2), 311.7734(2), 311.7734(3), 311.728; La. Rev. Stat. §§ 40:1061.11(A), 40:1061.11(D), 40:1061.10(A)(1), 40:1061.10(C), 40:962.2(B); Miss. Code Ann. §§ 41-41-107(1), 41-41-107(2), 41-41-107(3), 41-41-107(6), 41-41-109(1); Mont. Code Ann. §§ 50-20-705(1), 50-20-705(2), 50-20-705(3), 50-20-704, 37-7-106(5); Neb. Rev. Stat. Ann. §§ 28-335(1), 28-335(2); Nev. Rev. Stat. Ann. § 442.250(1); N.D. Cent. Code Ann. §§ 14-02.1-03.5(2), 14-02.1-03.5(5); Ohio Rev. Code Ann.

§§ 2919.123(A), 2919.124(B), 2317.56(1), 2919.192(A); Okla. Stat. Ann. tit. 63, §§ 1-729.1, 756.4(A), 1-756.4(C), 1-756.8(D), 1-729.1; 18 Pa. Stat. and Cons. Stat. Ann. § 3204(a); S.C. Code Ann. §§ 40-47-37(7)(c), 44-41-330(1)(a); S.D. Codified Laws §§ 36-4-47, 34-23A-56; Tenn. Code Ann. §§ 63-1-155, 63-6-1103, 63-6-1104(a), 63-6-1104(c); Tex. Health & Safety Code § 171.063; Utah Code Ann. §§ 76-7-332(2), 76-7-302(1), 76-7-302(3), 76-7-305(2)-(3); Wis. Stat. Ann. §§ 253.105(2), 253.10(3)(c)(1)(hm), 253.10(3)(c)(1), 253.10(3g); Wyo. Stat. Ann. §§ 35-6-139(a)-(b), 35-6-123.

520. And, like all elective abortions, elective chemical abortions are generally unlawful in several additional States. *E.g.*, Ark. Code Ann. § 20-16-1304 et seq.; Miss. Code Ann. § 41-41-45(2) (abortion unlawful except "where necessary for the preservation of the mother's life or where the pregnancy was caused by rape").

521. When the FDA lifted the in-person dispensing protection in 2021, 19 states prohibited or restricted dispensing abortion drugs remotely, as the following map shows.

States Protecting Against Remote Dispensing of Abortion Drugs[425]

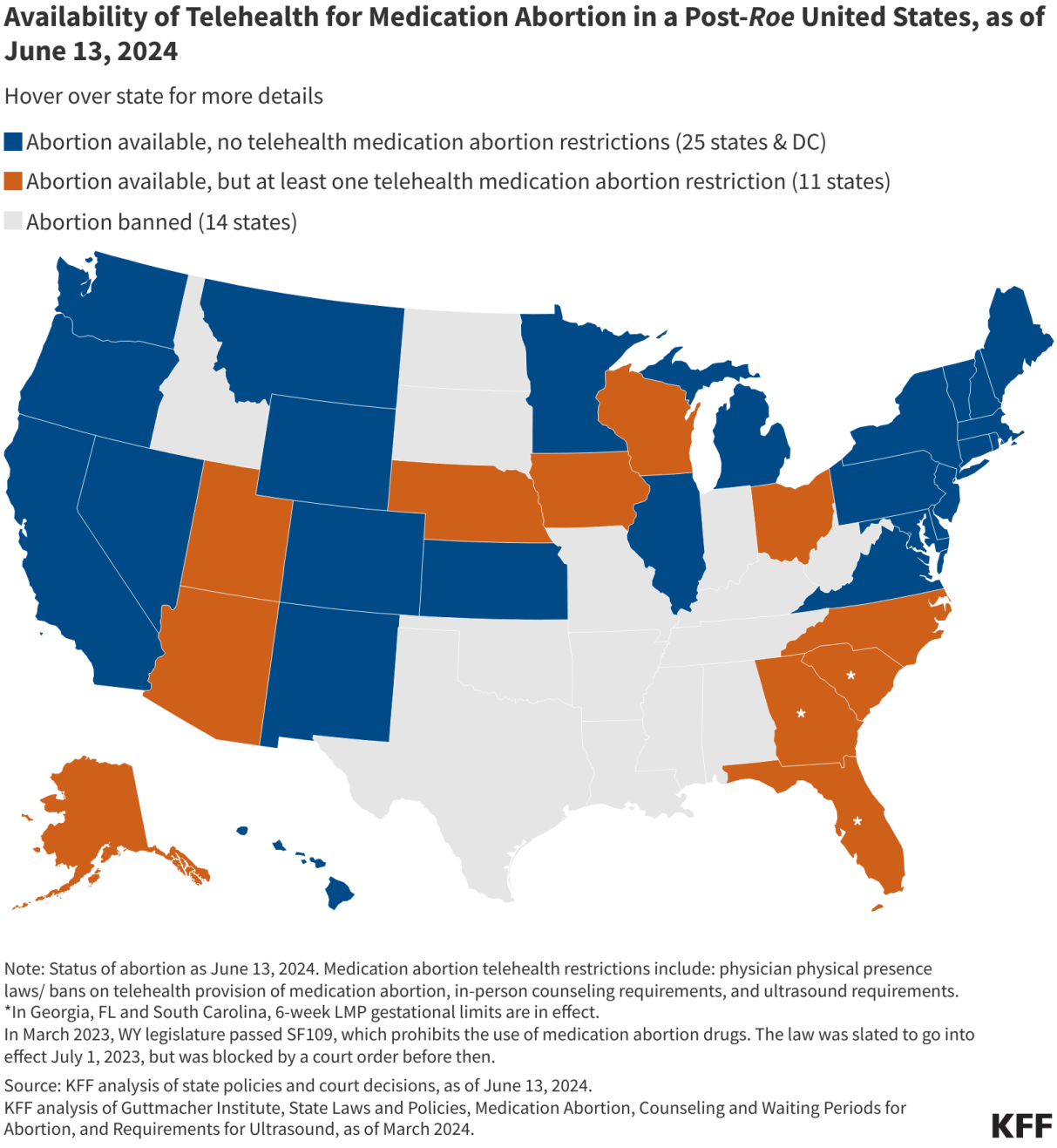


522. Today, at least 15 states have restrictions on remote dispensing of abortion drugs in effect, as the following map shows.

[425] Kaiser Family Foundation, State Restrictions on Telehealth Abortion (Dec. 2, 2021), https://www.kff.org/womens-health-policy/slide/state-restrictions-on-telehealth-abortion/; *see also* Ex. 93, Guttmacher Institute, Medication Abortion, State Laws and Policies (Oct. 31, 2023), https://www.guttmacher.org/state-policy/explore/medication-abortion

Availability of Telehealth for Medication Abortion in a Post-Roe United States, as of June 13, 2024[426]

Figure 1



[426] Kaiser Family Foundation, The Availability and Use of Medication Abortion (Mar. 20, 2024), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/ (last updated June 13, 2024).

523. Kansas provides that no abortion shall be performed or induced without the voluntary and informed consent of the woman upon whom the abortion is to be performed or induced. Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if at least 24 hours before the abortion the physician who is to perform the abortion or the referring physician has informed the woman in writing, which shall be provided on white paper in a printed format in black ink with 12-point Times New Roman font, of certain information. Kan. Stat. Ann. § 65-6709(a).

524. Kansas previously had a statute where "[n]o abortion shall be performed or induced by any person other than a physician." Kan. Stat. Ann. § 65-4a10 (West). In addition, this statute required mifepristone specifically be "initially be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient." *Id*. It also had an in-person follow-up protection. *Id*. All of these provisions would have a high risk for preemption. However, this statute was held unconstitutional very recently by the Kansas Supreme Court in *Hodes & Nauser, MDs, P.A. v. Stanek*, 551 P.3d 62 (Kan. 2024).

XXI. Sovereign Injuries to Plaintiffs' Interests in the Creation and Enforcement of State laws

525. 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)).

526. "Pursuant to that interest, states may have standing based on (1) federal assertions of authority to regulate matters they believe they control, (2) federal preemption of state law, and (3) federal interference with the enforcement of state law, at least where 'the state statute at issue regulates behavior or provides

for the administration of a state program' and does not 'simply purport to immunize state citizens from federal law.'" *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015), as revised (Nov. 25, 2015) (citation omitted) (collecting cases).

527. As a result of Defendants' actions, Plaintiffs have suffered injury to their sovereign interests in enacting and enforcing their laws. Defendants (1) intentionally facilitated widespread violations by third parties of state abortion laws by enabling an out-of-state abortion drug distribution network out of the reach of the enforcement of State laws, (2) unlawfully removed the backstop of federal law and federal law enforcement, upon which the States were entitled to rely, (3) purport to preempt state abortion laws, and (4) seek to displace and nullify the States' state-law parental rights of notice and consent for abortions for teen girls in foster care.

528. These harms are distinct (and in addition to) the harms suffered by the citizens of Plaintiffs as a result of Defendant's challenged actions.

529. The harms to Plaintiffs' sovereign interests in enacting and 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[.]").

530. "The threatened injury to a State's enforcement of its safety laws is within the zone of interests of the Administrative Procedure Act[.]" *State of Ohio ex rel. Celebrezze v. U.S. Dep't of Transp.*, 766 F.2d 228, 233 (6th Cir. 1985).

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

A. Injury to Plaintiffs' sovereign interests in the creation and enforcement of their abortion regulations through Defendants' facilitation of third parties' state-law violations.

532. Plaintiff States are injured as sovereigns by Defendants' intentional enablement of third parties to undermine state law enforcement and to violate state abortion-drug laws.

533. Plaintiff States have a sovereign interest in ensuring the enforcement of their duly passed laws. *See Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *cf. Abbott v. Perez*, 585 U.S. 579, 602 n. 17 (2018) ("[T]he inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State[.]").

534. The FDA's decision has interfered with the enforcement of state laws that prohibit abortion in certain circumstances and that require in-person administration of any abortion drugs.

535. Defendants have intentionally undermined state laws by enabling widespread state-law criminal and civil violations by third parties, which constitutes an injury to Plaintiff States' sovereign interest in creating and enforcing a legal code.

536. Defendants' actions have created a practical impediment to on-the-ground compliance with and enforcement of state laws.

537. The FDA's deregulatory actions have each increased Plaintiff States' sovereign harms.

538. By lowering the barriers to obtain mifepristone, including removing the safeguard that the drug be administered in-person by a licensed physician, Defendants have removed the restrictions that prevented or limited the ability of third parties to unlawfully provide mifepristone in Plaintiff States.

539. The 2016 Changes removed the safeguards ensuring follow-up care, enabling providers to supply women with these drugs without the ability to diagnose and treat life-threatening complications.

540. This change enabled out-of-state abortion-drug suppliers to provide abortion drugs to women from Plaintiff States by allowing women to receive drugs out of state and then immediately return home to take the drugs.

541. In 2021, the FDA began declining to enforce the in-person dispensing protection of the REMS for mifepristone.

542. Under the FDA's new regime, manufacturers may sell abortion drugs to suppliers, who then prescribe and mail the drugs to women in Plaintiff states without an in-person examination—which enables the providers to evade and violate State laws prohibiting or regulating the provision of abortion drugs.

543. This unlawful act had the direct and intended effect of enabling and encouraging third parties to provide, through the mail, mifepristone to citizens of Plaintiff States for the purpose of inducing high-risk abortions that are expressly contrary to the policies expressed in many state statutes.

544. Since 2021, abortion providers have been mailing FDA-regulated doses of mifepristone into Plaintiff States for the purpose of providing abortions to people in states that have laws prohibiting chemical abortions.

545. 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 protection and the required in-person follow-up visit.

546. This out-of-state market then exploded when the FDA allowed abortion drugs to be dispensed by mail, common carrier, and interactive computer service.

547. This market continued and increased after the FDA formalized the removal of the in-person dispensing protection in January 2023.

548. All of this makes it difficult for state law enforcement to detect and deter state law violations and to give effect to state abortion laws.

549. The FDA's actions force States to divert resources to investigate and address the harms that this lawbreaking will inflict on women, children, and the public interest.

550. The FDA's actions thus "intrude on state governmental functions[,]" *Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991), and hobble States' efforts to protect health and safety.

551. The FDA's actions moreover depart from the central tenet of our Constitution: that power—particularly over important, hard, controversial issues—resides with and must be accountable to the people.

552. Few issues are as important, difficult, and controversial as abortion. The Constitution thus leaves the task of regulating and restricting abortion to "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. Yet the FDA's actions by design and in practice rob from the people in the Plaintiff States important decisions on this vital issue.

553. State abortion laws embody the considered judgments of "the people and their elected representatives." *Dobbs*, 142 S. Ct. at 2284. Defendants' actions eviscerating these laws injures the States.

B. Injury to Plaintiffs' sovereign interests in enforcing state abortion regulations through Defendants' non-enforcement or removal of the backstop of federal law.

554. Plaintiff States are injured as sovereigns by Defendants' unlawful non-enforcement of federal statutes that result in restrictions on the dispensing of abortion drugs and by their unlawful removal of the backstop of federal law.

555. The FDA's decisions have 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.

556. 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).

557. Plaintiff States have relied on the actual or potential backdrop of federal laws and federal law enforcement so the States can implement their own policies about in-person administration, protection of human life, and other policies.

558. Before Defendants' changes to the REMS, the federal government ensured that abortion drugs were only dispensed in person, that abortion drugs were not dispensed by mail, common carrier, or interactive computer service, that abortion drugs were provided through three in-person doctor visits, and that abortion drugs were provided by doctors only.

559. Defendants actively enforced and administered this federal regulatory structure, which reflected the requirements of various federal laws. Plaintiff States relied on these various federal laws and Defendants' actual or potential enforcement of these laws.

560. During this time, no relevant federal statute changed. Instead, Defendants changed their regulatory actions and their resulting enforcement—seeking to create a change in federal law through deregulatory action.

561. But because these deregulatory actions failed to comply with federal statutes like the FDCA, PREA, and APA, these regulatory actions did not result in a valid change to federal law. Instead, they amounted to an unlawful removal of a prior federal regulatory structure that provided a backdrop to state regulations providing similar or greater restrictions on abortion.

562. In particular, Defendants' prior federal regulatory structure in practice reinforced federal and state statutes against dispensing abortion drugs remotely or by mail, common carrier, or interactive computer service.

563. Each of Defendants' challenged actions successively removed Defendants' assistance in enforcing federal and state restrictions on abortion drugs, such that abortion drugs now need not be dispensed in person, that abortion drugs may be dispensed by mail, common carrier, or interactive computer service, that abortion drugs may be provided without any in-person doctor visits, and that abortion drugs may be provided by non-doctors.

564. Plaintiff States are injured by each unlawful withdrawal of Defendants' past and future enforcement of these federal laws, including by their changes to the REMS that resulted in the REMS no longer reflecting the requirements of these federal laws.

565. Plaintiff States' sovereign interest in the enforcement of federal law and state law has now been impaired. The challenged FDA actions "impaired that interest, because [federal] officials withdrew resources and manpower that further the enforcement of federal and state] law." *United States v. Missouri*, No. 23-1457, 2024 WL 3932470, at *2 (8th Cir. Aug. 26, 2024).

566. Defendants' withdrawal of this federal assistance transfers the burden of law enforcement solely to the States and it at once makes it harder for the States to enforce these laws, by shifting abortion drugs into the widespread, anonymous stream of commerce taking place through the mail, common carriers, and interactive computer services.

567. Interference with the state government's interest in enforcing federal and state law is sufficient to establish that Defendants' action injured Plaintiff States. *Missouri*, No. 23-1457, 2024 WL 3932470, at *2.

568. "An increased regulatory burden typically satisfies the injury in fact requirement." *Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 266 (5th Cir. 2015).

C. Injury to Plaintiffs' sovereign interests in enforcing state abortion regulations through Defendants' purported preemption of state abortion regulations.

569. Plaintiffs have a sovereign interest in their laws not being displaced, preempted, or nullified by the federal government. *Texas Office of Public Utility Counsel v. F.C.C.*, 183 F.3d 393, 449 (5th Cir. 1999) (quoting *Alfred L. Snapp,* 458 U.S. at 601).

570. Thus, "irreparable harm exists when a federal regulation prevents a state from enforcing its duly enacted laws." *Texas v. Becerra*, 577 F. Supp. 3d 527, 557 (N.D. Tex. 2021) (collecting cases); *see also, e.g., Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J.: "[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury[.]").

571. Through announcements from HHS and DOJ, Defendants seek "to preempt" each States' laws, and this attempt at preemption of state law is itself an injury. *Deanda v. Becerra*, 96 F.4th 750, 760 (5th Cir. 2024) ("Deanda has shown an Article III injury because the Secretary seeks to preempt his state-conferred right to consent to his children's obtaining contraceptives").

572. Defendants purport to preempt state laws regulating the dispensing of abortion drugs, including treatment plans, state approval, physician dispensing, requirements for back-up physicians, and in-person dispensing.

573. In addition, more than one federal court has determined that state abortion drug regulations are preempted by the FDA's REMS.

574. In one case, a federal court held that the 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.* Although the plaintiff later voluntarily dismissed its (successful) preemption claim, it appears the plaintiff did so because it needed to drop the one count that was not dismissed so that the district court's ruling dismissing all other counts would become a final judgment that could be appealed. *See GenBioPro*, ECF 78 (filing a notice of appeal three days after dropping its successful preemption argument).

575. In another case, a federal court enjoined the enforcement of several North Carolina state abortion drug regulations on a similar theory. *Bryant v. Stein*, No. 1:23-CV-77, 2024 WL 3107568, at *1 (M.D.N.C. June 3, 2024). That court enjoined state laws that "prohibit any healthcare provider other than a licensed physician from providing mifepristone," *id.* (citing N.C. Gen. Stat § 90-21.83A, § 90-21.83B, § 90-21.93), that "require that mifepristone be provided in person," *id.* (citing N.C. Gen. Stat. § 14-44.1, § 90-21.83A, § 90-21.83B), state laws that "require scheduling an in-person follow-up visit after providing mifepristone or efforts to ensure such a follow-up appointment," *id.* (citing N.C. Gen. Stat. § 90-21.83A, § 90-21.83B, § 90-21.93), and state laws that require the reporting of non-fatal adverse events related to mifepristone to the FDA," *id.* (citing N.C. Gen. Stat. § 90-21.93).

576. The court held that these abortion drug regulations "stand as obstacles" to the FDA REMS. *Bryant v. Stein*, No. 1:23-CV-77, 2024 WL 1886907, at *15 (M.D.N.C. Apr. 30, 2024), appeal filed, Nos. 24-1576, 1600, 1617 (4th Cir. 2024). "When a state imposes a restriction on the sale or distribution of an FDA-approved drug that is designed to reduce the risks associated with the drug even though the FDA explicitly considered and rejected that restriction as unnecessary for safe use under the statutory regime imposed and required by Congress, then that state law is preempted." *Id.* "North Carolina cannot second-guess the FDA's explicit judgment on

how to manage risks from and safely prescribe, dispense, and administer REMS drugs, including mifepristone." *Id.* at *17.

577. If sued, Plaintiff States will vigorously dispute that their laws are preempted by FDA's REMS, but HHS and DOJ's announcements and the *GenBioPro* decision each make clear that the FDA's unlawful REMS creates a substantial risk of injury to Plaintiff States in the form of interference with Plaintiff States' ability to create and enforce a legal code.

D. Injury to Plaintiffs' sovereign interests in exercising state-law parental rights of notice and consent for abortions for teen girls in foster care.

578. Plaintiff States are also injured because Defendants have sought to interfere with and nullify the States' exercise of state-law parental rights for children in state custody, such as teen girls in the foster care system.

579. By seeking to enable teen girls to obtain abortion drugs online by mail all on their own, Defendants seek "to undermine [the States'] state right to consent to [their custodial] children's medical care[.]" *Deanda*, 96 F.4th at 755. "That invasion of [Plaintiff States'] state-created right alone creates Article III injury." *Id.* at 753.

580. The FDA's decisions to increase access to (and demand for) chemical abortions inflict substantial economic injury on Plaintiff States because it risks harm to girls in state custody, both girls in state foster care systems or other state facilities.

581. Each Plaintiff State is the legal parent or guardian of many minor girls of reproductive age.

582. Each Plaintiff State has well-established state foster care systems and other state facilities for minor girls. State foster care systems can include girls in state facilities or placed with licensed foster care families. Each State has detailed laws and procedures to protect these girls' health and welfare while in state custody or control.

583. Plaintiff States are the legal parent, guardian, or custodian of many minor girls in state foster care systems or other state facilities.

584. Plaintiff States actively enforce and administer their rights to decide whether these children obtain medical care.

585. Plaintiff States may assert parental rights that would otherwise belong to the parents of minor girls in the foster care system or other state facilities, so long as the minor's prior parents' rights have been terminated and the State has become the minor's legal parent. This standing is similar to the rights of parents to seek relief on behalf of their children as next friend.

586. Minor girls in the foster care system or other state facilities are susceptible to pregnancy and to seeking abortions.

587. These girls are protected by state laws providing for State control of their medical care and by state laws restricting or prohibiting abortion.

588. Before the FDA's deregulatory actions, the States (as legal parent or guardian) were entitled to know or consent to abortions for minor girls in the foster care system or other state facilities.

589. The FDA's deregulatory actions impede and undermine the States' state-law rights to prior notice and consent to abortions for minor girls in state foster care systems and girls in state facilities.

590. The FDA's deregulatory actions impede and undermine the States' state-law rights to restrict and prohibit abortions for minor girls in state foster care systems and girls in state facilities.

591. The interference with and attempted nullification of these state-law rights is itself an injury.

592. In addition, Defendants' actions injure Plaintiff States in a further way: by increasing the risk that children under State custody or control will obtain abortion drugs by mail, common carrier, or interactive computer service.

XXII. Economic Injuries to Plaintiffs' Medical Systems

593. In addition to the incalculable toll from the loss of human life, the FDA's decisions to increase access to abortion drugs irrespective of state law inflicts substantial economic injury on Plaintiff States as the payers or insurers of residents' medical expenses. The FDA's deregulatory actions have both caused an increase in the number of pregnant women seeking treatment for abortion drug complications paid for by the States and caused a resulting diversion of the States resources from their general budgets.

594. In addition to the immeasurable pain and suffering that their citizens suffer from the FDA's actions, the States are injured by the FDA's under-regulation of chemical abortion drugs because it causes the States to pay increased medical expenses for women seeking treatment for abortion complications.

595. For example, in 2022, Idaho Medicaid alone expended at least $12,658.05 in total funds ($3,797.42 state funds and $8,860.64 federal funds) for complications from abortion drugs.[427] This provided coverage for a woman presenting with bleeding following a failed medication abortion: Idaho Medicaid paid for her medically necessary dilation & curettage procedure.[428]

596. The actual numbers are higher. Given that miscarriage symptoms can greatly resemble symptoms from complications created by abortion drugs, and given that some patients will not disclose the cause of their complications, many procedures paid for through state Medicaid programs are not logged as expenses related to abortion complications.

---

[427] Ex. 94, Charron Affidavit ¶ 12.

[428] *Id.* ¶ 14.

597. Likewise, in 2019, Idaho Medicaid paid at least $10,086.47 in total funds ($3,025.94 state funds and $7,060.53 federal funds) for treatment and follow-up care for abortion medical complications.[429]

598. Since mid-2022, Idaho prohibits abortions except to save the life of the mother, and so it is highly unlikely that any of these drugs were dispensed by prescribers in-person in Idaho.

599. This "effect on the states' fiscs" is an economic injury for Plaintiff States. *Texas v. United States*, 809 F.3d 134, 152–53 (5th Cir. 2015), as revised (Nov. 25, 2015); *see also, e.g.*, *Biden v. Nebraska*, 143 S. Ct. at 2366 ("financial harm is an injury in fact"); *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. The most obvious are traditional tangible harms, such as physical harms and monetary harms.").

600. Indeed, "[f]or standing purposes, a loss of even a small amount of money is ordinarily an 'injury,'" *Czyzewski v. Jevic Holding Corp.*, 580 U.S. 451, 464 (2017), and here Defendants' dangerous actions have resulted in the States paying far more than mere pennies in costs for medical care.

601. This satisfies Article III. *See California v. Azar*, 911 F.3d 558, 571–73 (9th Cir. 2018) (finding state had standing based on an injury to its economic interests where the state was responsible for reimbursing women who seek contraception through state-run programs).

602. Indeed, suits like this where one entity "challenges the under-regulation of another" are well-established." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2465 (2024) (Kavanaugh, J., concurring). "One example is the Court's landmark decision in *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, (1983)." *Id.*

---

[429] *Id.* ¶ 11.

"That case arose when several insurance companies challenged a federal agency's rescission of safety standards for new motor vehicles." *Id*.

603. Decisions like *State Farm* show that third-party insurers or payers like State Medicaid programs have standing to seek redress from deregulatory actions that injure them economically by resulting in more expenses to be paid through insurance claims. "At no point in that landmark opinion on the judicial review of agency actions did the Court state (or need to state) the obvious: Because the agency did not regulate the insurers themselves, the insurers could obtain relief from the downstream effects of the agency's rescission of the safety standards only if the insurers could obtain vacatur of that rescission." *Id*.

A. The FDA's deregulatory actions predictably lead more and more patients in Plaintiff States to need medical care for complications from chemical abortion drugs.

604. Abortion suppliers are providing abortion drugs to women from Plaintiff States who travel out of state to obtain abortion drugs and then return home to complete the process.

605. Defendants' removal of three in-person doctor visits results in Plaintiff States providing emergency and follow-up care for women who receive abortion drugs in other states.

606. For example, although abortion is illegal in Missouri (except for medical emergencies), some Missourians obtain abortion drugs by traveling out of State, only to return to Missouri where they experience the chemical abortion. These women would then seek follow-up care or emergency services in Missouri.

607. In 2022, at least 2,883 Missourians obtained abortions in Kansas. A clear majority, 59.6%, of abortions performed in Kansas were chemical abortions.[430]

608. Unlike with surgical abortions, complications from chemical abortions typically occur when a woman has returned home. The FDA has warned prescribers about this since its approval of abortion drugs in 2000. As the FDA made clear in its 2000 Approval, "[i]t is important for patients to be fully informed about ... the need for follow up, especially on Day 14 to confirm expulsion."[431]

609. In fact, the FDA's original label emphasized that the Day 14 visit "is necessary" and "very important to confirm by clinical examination or ultrasonographic scan that a complete termination of pregnancy has occurred."[432]

610. The FDA's Prescriber Agreement also advises that the Day 14 follow-up visit "is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications."[433] This, "[p]atient adherence to directions for use and visits is critical to the drug's effectiveness and safety."[434]

611. But Missouri citizens are thus told "to complete the chemical abortion regimen at home," and the FDA has thus "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).

---

[430] *Abortion in Kansas, 2022 Preliminary Report*, Kan. Dep't of Health and Env't (2023), https://www.kdhe.ks.gov/DocumentCenter/View/29328/KS-Abortions-2022-PDF.

[431] Ex. 18, 2000 FDA Approval Memo at 4.

[432] Ex. 24, 2000 Mifeprex Label at 8, 15, https://perma.cc/3V7C-SU6Q.

[433] Ex. 43, Mifeprex Prescriber Agreement at 1.

[434] Ex. 18, 2000 FDA Approval Memo at 4.

612. 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, seek emergency care at facilities in Missouri.

613. Because of the FDA's actions removing all in-person dispensing protection, many women in Plaintiff States like Missouri have also obtained chemical abortion drugs through the mail, common carrier, or interactive computer service.

614. The abortion suppliers dispensing drugs to Plaintiff States through the mail, common carrier, or interactive computer service are described above, *supra* Sec. XVIII.D.

615. Women then take these drugs and suffer complications in Plaintiff States, with no need to travel out-of-state.

B. The FDA's deregulatory actions lead to increased harm and increased medical care for complications from chemical abortion drugs.

616. 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.

617. 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.

618. The FDA does "not dispute that a significant percentage of women who take mifepristone experience adverse effects." *All. for Hippocratic Med. v. Food & Drug Admin.*, 78 F.4th 210, 229 (5th Cir. 2023), *rev'd*, 602 U.S. 367 (2024). "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*.

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

620. "[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.

621. 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.*, 2023 WL 2913725, at *8.

622. Because the FDA does not require it, many abortion providers 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.

623. Given their lack of admitting privileges and treatment capabilities, abortion providers usually instruct women to go to the emergency department of the closest hospital for treatment of any severe adverse events.

624. This practice is consistent with the FDA's current Medication Guide for mifepristone. The FDA directs women to "go to the nearest emergency room" if they cannot reach their provider.[435] And because remote providers hundreds of miles away cannot perform any follow-up care, women are left with one option: the emergency room.

625. The FDA's current Patient Agreement also warns women that a range of listed "symptoms" could "require emergency care."[436]

---

[435] Ex. 5, 2023 Mifeprex Label at 16.

[436] Ex. 44, Mifepristone Patient Agreement.

626. Of those women who end up in the emergency room after taking abortion drugs, many suffer particularly severe or critical injuries. Data for emergency department visits for Medicaid-eligible women following various pregnancy outcomes shows that "an [emergency department] visit following a chemical abortion was significantly more likely to have a severe or critical acuity rating than a visit following surgical abortion, live birth, or an ED visit at any time by a woman who was never pregnant."[437]

627. The study also found that ED visits coded severe or critical for women who underwent a chemical abortion increased by 4,041.1% between 2004 and 2015, compared to a 450.6% increase for surgical abortion subjects and 20.9% for live birth subjects.[438]

628. Dispensing drugs remotely with no in-person care has higher risks than in-person care.

629. Dispensing drugs remotely increases these complication rates and number of complications.

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

631. Because of and since Defendants' actions, 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.

---

[437] James Studnicki et al., *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004-2015*, Int'l J. Epidemiology & Pub. Health Rsch. 1 (2024), https://aditum.org/images/article/1724220097International_Journal_of_Epidemiology_and_Public_Health_Research_Galley_Proof.pdf.

[438] *Id.* at 2.

632. The FDA's decision to expand the gestational age for approved mifepristone use to 70 days (10 weeks) harms women and girls and increases the number of chemical abortions and resulting complications.

633. The FDA acknowledges that abortion "failure rate" and thus the need for surgical intervention steadily "increase[ ] with ... gestational age."[439]

634. The FDA, ACOG, and others have confirmed that the "failure rate" climbs from roughly 2 to 7 percent when moving from seven to ten weeks' gestation.[440] The FDA thus recognizes that up to 7 percent of "women taking Mifeprex will need a surgical procedure" to end the pregnancy, remove retained fetal parts or tissue, or "stop bleeding."[441]

635. 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 protections.

636. For example, without an initial in-person visit, women may underestimate gestational age and take the drugs past the approved ten-week limit.[442] Women beyond ten weeks have higher "chances of complications due to the increased amount of tissue, leading to hemorrhage, infection[,] and/or the need for surgeries or other emergency care."[443] The FDA recently acknowledged that "in-person dispensing avoids the possibility of delay" in taking mifepristone and the

---

[439] Ex. 34, 2021 FDA Response at 9; Ex. 25, Mifeprex 2023 Label at 13.

[440] Ex. 5, Mifeprex 2023 Label at 13; Ex. 27, ACOG Gestation Bulletin, *supra* note 54; Ex. 2, 2016 Summary Review at 29–31.

[441] Ex. 5, Mifeprex 2023 Label at 17; *see also* 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, 931–32 (2011).

[442] Ex. 82, Skop Decl. ¶ 28; Ex. 83, Jester Decl. ¶ 13 *et seq*.

[443] Ex. 82, Skop Decl. ¶ 28.

increased "risks of serious complications" caused by such delay. Appl. for Stay, *Food & Drug Admin. v. Am. Coll. of Obstetricians and Gynecologists*, No. 20A34 at 6 (U.S. Aug. 26, 2020) (2020 FDA Stay Appl.).

637. In addition, routine follow-up examination can uncover complications—such as retained pregnancy tissue—before they become more serious.[444] Removing the requirement for those visits naturally results in more women reporting to the emergency room or seeking state-provided care.

638. The FDA's elimination of in-person drug administration, physician supervision, and patient follow-up, and its removal of the in-person dispensing protection exposes women and girls to increased risk of suffering complications from chemical abortion and requiring further medical attention following the drug regimen.

639. 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, life-threatening infections, or severe pain and must rush to the emergency department of the nearest hospital.

640. The FDA's decision not to require abortion providers 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.

[444] Ex. 83, Jester Decl. ¶ 25.

641. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain undercounted and therefore are unknown.

642. 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.

643. This prevents women and girls who are citizens of Plaintiffs from giving informed consent to these providers. This results too in an increased use of abortion drugs and resulting complications.

644. Abortion providers 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.

645. 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.

646. Women and girls often suffer distress and regret after undergoing chemical abortion, sometimes seeking to reverse the effects of mifepristone.[445]

647. A woman or girl can experience these emotions and feelings upon viewing the body of her lifeless baby after taking chemical abortion drugs.[446]

---

[445] Ex. 13, 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 (2020), DOI: 10.1080/10410236.2020.1770507.

[446] *Id.*

648. 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.[447]

649. For the years 2019 to 2022, the Idaho Department of Health & Welfare received at least 115 abortion complication reports, 75 of which (about 65.2%) were submitted following chemical abortions.[448] Thanks to a 2018 reporting law, data was collected as to the type of complication in detail.

650. For the years 2016 to 2018, the Idaho Department of Health & Welfare collected limited general data of complications from chemical abortions.[449]

651. This combined data is summarized in the following chart.

---

[447] Ex. 95, Missouri Department of Health and Senior Services Affidavit, at 2.

[448] *Induced Termination*, Idaho Dep't of Health & Welfare, https://publicdocuments.dhw.idaho.gov/WebLink/browse.aspx?id=5657&dbid=0&repo=PUBLIC-DOCUMENTS (collecting annual complication reports from 2019 to 2022).

[449] Idaho Dep't of Health & Welfare, https://publicdocuments.dhw.idaho.gov/WebLink/browse.aspx?id=5657&dbid=0&repo=PUBLIC-DOCUMENTS (collecting annual complication reports from 2019 to 2022); *see*, Idaho Dep't of Health & Welfare, Div. of Pub. Health, Bureau of Vital Recs. and Health Stats., *Idaho Vital Statistics - Induced Abortion 2018* (Jan. 2020); Idaho Dep't of Health & Welfare, Div. of Public Health, Bureau of Vital Recs. and Health Stats., *Idaho Vital Statistics - Induced Abortion 2017* (Nov. 2018); Idaho Dep't of Health & Welfare, Div. of Public Health, Bureau of Vital Recs. and Health Stats., *Idaho Vital Statistics - Induced Abortion 2016* (Dec. 2017). Data is not available for 2023 onwards.

Total Reported Idaho Chemical Abortions Complications by Year

Year	2016	2017	2018	2019	2020	2021	2022	Total
Total Reported Abortion Complications	9	9	14	21	39	39	16	115
Total Abortion Complications Requiring Follow-Up Care, Surgery, Or Aspiration Procedure Because Of Incomplete Abortion Or Retained Tissue	N/A	N/A	N/A	15	35	35	13	98
Percentage Of Abortion Complications Requiring Follow-Up Care, Surgery, Or Aspiration Procedure Because Of Incomplete Abortion Or Retained Tissue	N/A	N/A	N/A	71%	90%	90%	81%	85%
Total Reported Chemical Abortion Complications	5	6	9	10	26	30	9	75
Percentage Of Total Abortion Complications From Chemical Abortions	55%	66%	64%	48%	67%	77%	56%	65%
Total Chemical Abortions Resulting In Failure To Actually Terminate The Pregnancy	N/A	N/A	N/A	1	3	14	6	24
Total Chemical Abortions Resulting In Incomplete Abortion Or Retained Tissue	3	4	6	9	22	16	3	50
Total Chemical Abortions Resulting In Hemorrhage	0	0	0	0	2	1	0	3

N/A indicates that the data is not available for these years.

652. Women and girls who are citizens of Plaintiffs will continue to suffer complications from chemical abortion drugs.

653. Although abortion suppliers have responded to *Dobbs* by no longer submitting the required state abortion reports, other data from non-governmental sources shows that Defendants' 2021 and 2023 actions removing any in-person dispensing protections have harmed Plaintiff States.

654. In Plaintiff States Missouri and Idaho, the baseline for abortions via abortion drugs should be low or near zero beginning in mid-2022, when each states' abortion laws were allowed to take effect.

655. As described above, these states allow for abortions only in certain circumstances, and these circumstances (such as the need to save the life of the mother) do not occur in high numbers.

656. The non-governmental data nevertheless shows that the number of abortions via abortion drugs for Missouri and Idaho residents with no in-person follow-up care is not low and is much higher than zero.

657. These abortions, and the resulting harmful complications, are traceable to Defendants' 2021 and 2023 removal of in-person dispensing protections. Defendants' removal of in-person dispensing protections allowed these drugs to be dispensed in other states without in-person follow-up visits and, significantly, by mail, common carrier, or interactive computer service.

658. This lack of in-person dispensing not only results in the use of abortion drugs by state residents, it resulted in an increase in the use of these drugs, and it resulted in increased harm to women that leads them to receive follow-up care and emergency services in Plaintiff States.

659. Plaintiff States operate Medicaid and other programs to pay medical expenses for reproductive-age women.

660. Missouri, through its state-level agencies and political subdivisions, oversees and operates Missouri Medicaid programs.

661. As of May 2024, a total of 1,180,637 Missourians are enrolled in Medicaid.[450]

662. Missouri Medicaid spending is historically 37.5% percent of the state's total budget (for comparison, total state spending on elementary and secondary education is 21.3% of the total state budget and total state spending on higher education is 4.3% of the total state budget).[451]

663. Missouri historically spends about $13.44 billion on Medicaid each year with the help of $10.563 billion in annual federal funding.[452]

664. Idaho, through its state-level agencies and political subdivisions, oversees and operates Idaho Medicaid programs.

665. As of May 2024, a total of 307,199 Idahoans are enrolled in Medicaid.[453]

666. Idaho Medicaid spending is historically 24.1% percent of the state's total budget (for comparison, total state spending on elementary and secondary education

---

[450] *May 2024 Medicaid & CHIP Enrollment Data Highlights*, Medicaid.gov (Aug. 2024), https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html.

[451] *Exhibit 5: Medicaid as a Share of States' Total Budgets and State-Funded Budgets, SFY 2021*, Medicaid and CHIP Payment and Access Commission (MACPAC) (2023), https://www.macpac.gov/wp-content/uploads/2023/12/EXHIBIT-5.-Medicaid-as-a-Share-of-States-Total-Budgets-and-State-Funded-Budgets-SFY-2021.pdf (hereinafter MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets). The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan federal legislative branch agency that provides data analysis on Medicaid to Congress, HHS, and the States. *See* 42 U.S.C. § 1396(b)(3).

[452] Spending by State, Category, and Source of Funds, FY 2022 (millions) (Dec. 2023), https://www.macpac.gov/wp-content/uploads/2023/12/EXHIBIT-16.-Medicaid-Spending-by-State-Category-and-Source-of-Funds-FY-2022.pdf (herein after MACPAC Exhibit 16 Medicaid Spending by State).

[453] CMS May 2024 Medicaid & CHIP Enrollment Data Highlights, *supra* note 450.

is 23.7% of the total state budget and total state spending on higher education is 8.7% of the total state budget).[454]

667. Idaho historically spends about $3.33 billion on Medicaid each year with the help of $2.638 billion in annual federal funding.[455]

668. Kansas, through its state-level agencies and political subdivisions, oversees and operates Kansas Medicaid programs.

669. As of May 2024, a total of 347,473 Kansans are enrolled in Medicaid.[456]

670. Kansas Medicaid spending is historically 18.6% percent of the state's total budget (for comparison, total state spending on elementary and secondary education is 26.1% of the total state budget and total state spending on higher education is 14.2% of the total state budget).[457]

671. Kansas historically spends about $4.551 billion on Medicaid each year with the help of $3.122 billion in annual federal funding.[458]

672. Various data sources show that large numbers of reproductive-age women are on state Medicaid.

673. 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.[459]

---

[454] MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets, *supra* note 451.

[455] MACPAC Exhibit 16 Medicaid Spending by State, *supra* note 452.

[456] CMS May 2024 Medicaid & CHIP Enrollment Data Highlights, *supra* note 450.

[457] MACPAC Exhibit 5 Medicaid as a Share of States' Total Budgets, *supra* note 451.

[458] MACPAC Exhibit 16 Medicaid Spending by State, *supra* note 452.

[459] Ex. 96, Brown Affidavit ¶¶ 5–6.

674. 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.[460]

675. The American Community Survey is the Census Bureau's source for information about America's changing population. It provides estimates on Medicaid coverage by State by year and by sex and age.[461]

676. This data estimates the number of women covered by Medicaid in each state for the years 2022, 2021, 2019, 2018, and 2017 and for women age 18–44 for the year 2016 by state.

677. The following table shows in year 2022 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

2022 State Population and Medicaid Estimates for Reproductive-Age Women[462]

	Idaho	Kansas	Missouri
19 to 25 years:	90,623	140,806	277,361
With Medicaid/means-tested public coverage	16,272	18,354	42,864
26 to 34 years:	110,489	162,871	362,638
With Medicaid/means-	24,883	19,839	58,023

[460] Ex. 94, Charron Affidavit ¶ 16–17.

[461] U.S. Census Bureau, Table ID B27007, Medicaid/Means-Tested Public Coverage by Sex by Age, https://data.census.gov/table/ACSDT1Y2022.B27007?q=B27007 (click the plus sign to "View all 12 products" for tables for each year). No data is available for 2020.

[462] All figures are rounded to the nearest one-hundredth.

tested public coverage			
35 to 44 years:	123,221	184,554	394,217
With Medicaid/means-tested public coverage	22,078	18,486	49,902
Total percentage on Medicaid	19.5%	11.6%	14.6%

678. The following table shows in year 2021 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

2021 State Population and Medicaid Estimates for Reproductive-Age Women[463]

	Idaho	Kansas	Missouri
19 to 25 years:	80,413	136,935	267,312
With Medicaid/means-tested public coverage	15,061	17,774	30,268
26 to 34 years:	108,066	161,509	362,703
With Medicaid/means-tested public coverage	23,568	19,476	49,105
35 to 44 years:	125,343	182,903	394,069
With Medicaid/means-tested public coverage	23,803	17,682	44,586
Total percentage on Medicaid	19.9%	11.4%	12.1%

[463] All figures are rounded to the nearest one-hundredth.

679. This data shows in year 2019 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

2019 State Population and Medicaid Estimates for Reproductive-Age Women[464]

	Idaho	Kansas	Missouri
19 to 25 years:	76,691	135,444	271,087
With Medicaid/means-tested public coverage	7,964	13,358	25,579
26 to 34 years:	104,846	168,661	369,531
With Medicaid/means-tested public coverage	12,006	16,511	45,174
35 to 44 years:	110,404	177,461	376,496
With Medicaid/means-tested public coverage	8,797	15,758	39,837
Total percentage on Medicaid	9.9%	9.5%	10.9%

680. The following table shows in year 2018 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

[464] All figures are rounded to the nearest one-hundredth.

2018 State Population and Medicaid Estimates for Reproductive-Age Women[465]

	Idaho	Kansas	Missouri
19 to 25 years:	75,957	138,105	275,564
With Medicaid/means-tested public coverage	7,323	15,095	31,319
26 to 34 years:	100,693	164,706	363,982
With Medicaid/means-tested public coverage	11,631	18,642	49,054
35 to 44 years:	109,566	175,725	367,880
With Medicaid/means-tested public coverage	10,865	15,704	38,837
Total percentage on Medicaid	10.4%	10.3%	11.8%

681. The following table shows in year 2017 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

2017 State Population and Medicaid Estimates for Reproductive-Age Women[466]

	Idaho	Kansas	Missouri
19 to 25 years:	73,770	137,577	270,317
With Medicaid/means-tested public coverage	10,647	14,955	33,496

[465] All figures are rounded to the nearest one-hundredth.

[466] All figures are rounded to the nearest one-hundredth.

26 to 34 years:	96,334	165,429	368,575
With Medicaid/means-tested public coverage	13,950	17,504	51,199
35 to 44 years:	106,152	175,975	364,271
With Medicaid/means-tested public coverage	10,492	14,721	39,780
Total percentage on Medicaid	12.7%	9.9%	12.4%

682. The following table shows in year 2016 the total population of women of reproductive age, the total number of women of reproductive age on Medicaid, and the fraction that the Medicaid population represents by state.

2016 State Population and Medicaid Estimates for Reproductive-Age Women[467]

	Idaho	Kansas	Missouri
18 to 24 years:	76,622	140,415	277,813
With Medicaid/means-tested public coverage	10,807	16,749	36,273
25 to 34 years:	107,986	185,928	397,612
With Medicaid/means-tested public coverage	15,736	18,248	47,745
35 to 44 years:	102,560	172,249	370,413
With Medicaid/means-	10,255	15,103	34,213

[467] All figures are rounded to the nearest one-hundredth.

tested public coverage			
Total percentage on Medicaid	12.8%	10.0%	11.3%

683. The Guttmacher Institute has also published tables with their estimates of the number of women on Medicaid per state, reflecting slightly different age groups.

684. The Guttmacher Institute estimates that in 2019, 11.4% of reproductive-age women were on Medicaid in Idaho.[468]

685. The Guttmacher Institute estimates that in 2019, 11.9% of reproductive-age women were on Medicaid in Kansas.[469]

686. The Guttmacher Institute estimates that in 2019, 12.6% of reproductive-age women were on Medicaid in Missouri.[470]

687. The Guttmacher Institute estimates that in 2016, 14% of reproductive-age women were on Medicaid in Idaho.[471]

688. The Guttmacher Institute estimates that in 2016, 11% of reproductive-age women were on Medicaid in Kansas.[472]

---

[468] Ex. 97, Adam Sonfield, *Uninsured Rate for People of Reproductive Age Ticked Up Between 2016 and 2019,* Guttmacher Institute (April 2021), https://www.guttmacher.org/article/2021/04/uninsured-rate-people-reproductive-age-ticked-between-2016-and-2019 (see background tables, Table 2 Women).

[469] *Id.*

[470] *Id.*

[471] Ex. 98, *Dramatic Gains in Insurance Coverage for Women of Reproductive Age Are Now in Jeopardy, Policy Analysis*, Guttmacher Institute (January 2018), https://www.guttmacher.org/article/2018/01/dramatic-gains-insurance-coverage-women-reproductive-age-are-now-jeopardy.

[472] *Id.*

689. The Guttmacher Institute estimates that in 2016, 13% of reproductive-age women were on Medicaid in Missouri.[473]

C. The States operate Medicaid programs to pay medical expenses for reproductive-age women.

690. Plaintiff States' residents in Medicaid and other programs suffer chemical abortions in the absence of FDA safeguards.

691. Combining the above data from the Census Bureau about the percentage of women on Medicaid with state health department abortion totals, it is possible to estimate the total number of chemical abortions on state Medicaid enrollees.

692. It is further possible to approximate the number of Medicaid enrollees in each state who will seek emergency care after suffering complications from abortion drugs.

693. The FDA label for abortion drugs says that an estimated 2.9 to 4.6 percent of women will visit the emergency room after taking mifepristone.[474] Applying this rate to the estimated number of Medicaid enrollees taking abortion drugs yields the following estimates of the number of abortion complications paid for by each states' Medicaid program.

694. The following table shows the estimated chemical abortions and complications from abortion drugs for Missouri Medicaid enrollees per year.

---

[473] *Id.*

[474] Ex. 5, 2023 Mifeprex Label at 8.

Estimated chemical abortions for and complications from abortion drugs for Missouri Medicaid enrollees by year[475]

Year	2016	2017	2018	2019	2020	2021	2022
Total estimated Missouri chemical abortions	2,931	2,893	2,529	2,189	2,298	2,503	1,792
Percentage of reproductive-age women on Medicaid	11.3%	12.4%	11.8%	10.9%	12.1%[476]	12.1%	14.6%
Estimated chemical abortions performed on Medicaid enrollees	331	358	298	238	278	302	261
Low estimate of abortion-drug ER visits for Medicaid enrollees (2.9% complication rate)	9.60	10.38	8.64	6.90	8.06	8.76	7.57
High estimate of abortion-drug ER visits for Medicaid enrollees (4.6% complication rate)	15.23	16.47	13.71	10.95	12.79	13.89	12.00

695. The following table shows the estimated chemical abortions and complications from abortion drugs for Idaho Medicaid enrollees per year.

[475] All figures are rounded to the nearest one-hundredth.

[476] Because there is no 2020 data from the U.S. Census Bureau, 2021 data is used.

Estimated chemical abortions for and complications from abortion drugs for Idaho Medicaid enrollees by Year[477]

Year	2016	2017	2018	2019	2020	2021	2022
Total Idaho chemical abortions	762	784	771	825	1,102	1,178	654
Percentage of reproductive-age women on Medicaid	12.8%	12.7%	10.4%	9.9%	19.9%[478]	19.9%	19.5%
Estimated chemical abortions performed on Medicaid enrollees	97	99	80	82	219	234	127
Low estimate of abortion-drug ER visits for Medicaid enrollees (2.9% complication rate)	2.81	2.87	2.32	2.38	6.35	6.79	3.68
High estimate of abortion-drug ER visits for Medicaid enrollees (4.6% complication rate)	4.46	4.55	3.68	3.77	10.07	10.76	5.84

696. It is also possible to identify another minimum estimate of the number of abortion complications paid for by Idaho Medicaid by applying Idaho's Medicaid coverage rate for its population of reproductive-age women to Idaho's data about known complications from abortion drugs. (Again, this data is also likely an undercount due to reporting inadequacies). It is also possible to estimate the number of Idaho women enrolled in Medicaid who needed a D&C in particular for an incomplete abortion or retained tissue.

697. The following table summarizes this data.

[477] All figures are rounded to the nearest one-hundredth.

[478] Because there is no 2020 data from the U.S. Census Bureau, 2021 data is used.

Total Reported Idaho Chemical Abortions Complications by Year

Year	2016	2017	2018	2019	2020	2021	2022	Total
Total Reported Chemical Abortion Complications	5	6	9	10	26	30	9	75
Percentage of reproductive-age women on Medicaid	12.8%	12.7	10.4%	9.9%	19.9% [479]	19.9%	19.5%	N/A
Estimated Abortion Drug Complications Covered by Medicaid	.6	.76	.93	.99	5.17	5.97	1.75	16.17
Total Chemical Abortions Resulting In Incomplete Abortion Or Retained Tissue	3	4	6	9	22	16	3	50
Estimated D&C's Covered by Medicaid for Abortions Resulting In Incomplete Abortion Or Retained Tissue	.38	.51	.62	.89	4.38	3.18	.58	10.54

D. The FDA's actions result in Plaintiff States' public insurance paying for medical expenses for the increasing number of patients suffering abortion-drug complications.

698. Abortion has many victims. That is why even though many States like Missouri and Idaho do not pay for abortions, they do pay for many medical expenses for women who need treatment after suffering chemical abortions.

[479] Because there is no 2020 data from the U.S. Census Bureau, 2021 data is used.

699. Plaintiff States pay for medical bills related to abortion-drug 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.

700. Sometimes these costs are individually identifiable. But often they are not because it is often not clear to a physician if a woman is presenting because of a natural miscarriage or a drug-induced abortion. But it is a statistical certainty that women harmed by these drugs obtain emergency services that are paid for by Medicaid.

701. Even in States that have greatly restricted abortions, women suffer severe complications after taking abortion drugs and must seek emergency medical services.

702. 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.

703. "Medicaid … is designed to advance cooperative federalism." *Wisconsin Dep't of Health and Fam. Services v. Blumer*, 534 U.S. 473, 495 (2002). And yet the FDA's actions increase the number of women who must seek emergency medical care, including care paid for by Medicaid. At the same time that the States have agreed to operate a cooperative-federalism program to cover emergency medical costs, the FDA has taken action to drain state resources that go into that program.

704. HHS estimates that the average cost of a Medicaid-covered ER visit in 2017 was $420, a number only set to increase over time due to inflation and increasing

medical costs.[480] Of course, a Medicaid "covered charge" figure may be a fraction of total costs for that visit.

705. One common method of treating abortion drug complications is a D&C (dilation and curettage) to evacuate the contents of the uterus. The costs of a D&C to Medicaid may vary by State, by practice setting, and by level of care.

706. According to the state reimbursement schedule, Missouri Medicaid reimburses $2,544.80 for a D&C at an outpatient hospital.[481] Missouri Medicaid reimburses $227.86 for a D&C in general surgical settings.[482] Missouri Medicaid reimburses $316.25 to $1388.51 for a D&C at other service settings.[483] At an outpatient hospital, Missouri Medicaid reimburses $360.52 for an ER visit requiring a moderate amount of medical decision making and $522.83 for an ER visit requiring a high amount of medical decision making.[484]

707. According to the state reimbursement schedule, Idaho Medicaid reimburses as a general allowed amount $248.12 for a D&C, and Idaho Medicaid

---

[480] Ex. 99, Brian J. Moore and Lan Liang, HHS, Agency for Healthcare Research and Quality, *Costs of Emergency Department Visits in the United States, 2017*, (Dec. 8, 2020), https://hcup-us.ahrq.gov/reports/statbriefs/sb268-ED-Costs-2017.jsp.

[481] Ex. 100, Mo. Dep't of Social Servs., Outpatient Hospital Fee Schedule, https://apps.dss.mo.gov/fmsFeeSchedules/DLFiles.aspx (Diagnostic Code 58120).

[482] Ex. 101, Mo. Dep't of Social Servs., Surgery and Epidurals Fee Schedule, https://apps.dss.mo.gov/fmsFeeSchedules/DLFiles.aspx (Diagnostic Code 58120).

[483] Ex. 102, Mo. Dep't of Social Servs., Other Medical Fee Schedule, https://apps.dss.mo.gov/fmsFeeSchedules/DLFiles.aspx (Diagnostic Code 58120).

[484] Ex. 100, Mo. Dep't of Social Servs., Outpatient Hospital Fee Schedule, https://apps.dss.mo.gov/fmsFeeSchedules/DLFiles.aspx (Diagnostic Code 99284 and 99285).

reimburses at $1,250.54 for a D&C at an ambulatory surgical center.[485] Idaho Medicaid reimburses $102.71 for an ER visit requiring a moderate amount of medical decision making and $149.13 for an ER visit requiring a high amount of medical decision making .[486] Idaho Medicaid may reimburse $52.45 for an established patient office or other outpatient visit of 10–19 minutes.[487]

708. According to the state reimbursement schedule, Kansas Medicaid reimburses $402 for a D&C.[488] reimburses $143.48 for an ER visit requiring a moderate amount of medical decision making and $208.08 for an ER visit requiring a high amount of medical decision making.[489]

709. State reimbursement schedules also provide historical data for similar charges for a D&C in past years.

---

[485] Ex. 103, Idaho Dep't of Health & Welfare, April to June 2024 fee Schedule, https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=29550&dbid=0&repo=PUBLIC-DOCUMENTS (search diagnostic code 58120 for D&C).

[486] Ex. 103, Idaho Dep't of Health & Welfare, April to June 2024 fee Schedule, https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=29550&dbid=0&repo=PUBLIC-DOCUMENTS (search diagnostic code 99284 and 99285).

[487] Ex. 103, Idaho Dep't of Health & Welfare, April to June 2024 fee Schedule, https://publicdocuments.dhw.idaho.gov/WebLink/DocView.aspx?id=29550&dbid=0&repo=PUBLIC-DOCUMENTS (search diagnostic code 99212).

[488] Ex. 104, Kansas Medical Assistance Program (KMAP), Search By Procedure (HCPCS Codes), https://portal.kmap-state-ks.us/PublicPage/ProviderPricing/HCPCSSearch?searchBy=HCPCS (search Diagnostic Code/HCPCS 58120 for D&C, Date of Service Sept. 25, 2024, Benefit Plan TXIX- Title XIX (Medicaid), Provider Type 02 Ambulatory Surgical Center (ASC), Provider Specialty 020 Ambulatory Surgical Center).

[489] Ex. 105, Kansas Medical Assistance Program (KMAP), Search By Procedure (HCPCS Codes), https://portal.kmap-state-ks.us/PublicPage/ProviderPricing/HCPCSSearch?searchBy=HCPCS (search Diagnostic Codes/HCPCS 99284 and 99285, Date of Service Sept. 25, 2024, Benefit Plan TXIX- Title XIX (Medicaid), Provider Type 01 Hospital, Provider Specialty 010 Acute Care).

710. These figures do not include the standard per diem rate for hospital stays, if needed.

711. Much care for abortion-drug complications and other maternity care is billed for in bundled payments. "A bundled payment is a single, fixed payment for a group of services provided to treat a condition during a defined episode of care."[490] As a result, some Medicaid data often may not break down the true costs of care with this level of specificity and may simply describe care as maternity services.

712. Each year Plaintiff States expend funds covering expenses associated with medical complications from abortions.

713. "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 & curettage."[491]

714. Beginning in 2022, Idaho prohibited abortions except to save the life of the mother, and so it is unlikely that any of these drugs were dispensed by in-person prescribers in Idaho.

715. "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."[492]

---

[490] MACPAC, Medicaid Payment Initiatives to Improve Maternal and Birth Outcomes at 3 (April 2019), https://www.macpac.gov/wp-content/uploads/2019/04/Medicaid-Payment-Initiatives-to-Improve-Maternal-and-Birth-Outcomes.pdf.

[491] Ex. 94, Charron Affidavit ¶ 14.

[492] *Id.* ¶ 12.

716. 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."[493]

717. These numbers likely understate the true cost because chemical abortions routinely are miscoded as miscarriages. Chemical abortions among Medicaid recipients have historically often been misclassified by ER staff as natural miscarriages.

718. Abortion activists and providers encourage women to mislead ER doctors by saying they are having a miscarriage.[494] It is also possible to estimate how much Idaho has paid for complications from abortion drugs by applying Idaho's current reimbursement rates to the estimated number of abortion drug complications and estimated number of Medicaid-covered D&C's for abortion drug complications (even though these abortion complication reports likely are an undercount).

Estimated Medicaid Costs Based on Total Reported Idaho Chemical Abortions Complications by Year

Year	2016	2017	2018	2019	2020	2021	2022	Total
Total Reported Chemical Abortion Complications	5	6	9	10	26	30	9	75
Estimated Abortion Drug Complications Covered by Medicaid	.6	.76	.93	.99	*5.17*	5.97	1.75	16.17
Estimated Minimum Payments for	0 to $52.45	0 to $52.45	0 to $52.45	0 to $52.45	$262.25 to $314.70	$209.80 to $262.25	$52.45 to $104.9	$839.20 to $891.65

[493] *Id.* ¶ 11.

[494] *See, e.g.*, Ex. 11, *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; Ex. 12, *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 Aug. 28, 2024).

Abortion Drug Complications Covered by Medicaid (at current rate of $52.45 for a minimal outpatient visit)								
Estimated Higher Medicaid Payments for Abortion Drug Complications for D&C's (at current general setting rate of $248.12)	0 to $248.12	0 to $248.12	0 to $248.12	0 to $248.12	$1240.60 to $1488.72	$1240.60 to $1488.72	$248.12 to $496.24	$3,969.92 to $4,218.04
Total Chemical Abortions Resulting In Incomplete Abortion Or Retained Tissue	3	4	6	9	22	16	3	50
Estimated D&C's Covered by Medicaid for Abortions Resulting In Incomplete Abortion Or Retained Tissue	.38	.51	.62	.891	4.38	3.18	.58	10.54
High Estimate for Medicaid Payments for D&C's for Abortions Resulting In Incomplete Abortion Or Retained Tissue (at current general setting rate of $248.12)	0 to $248.12	0 to $248.12	0 to $248.12	0 to $248.12	$992.48 to $1240.60	$744.36 to $992.48	0 to $248.12	$2,481.20 to $2,729.32
Low Estimate for Medicaid Payments for D&C's for Abortions Resulting In Incomplete Abortion Or Retained Tissue (at current ASC rate of $1,250.54)	0 to $1,250.54	0 to $1,250.54	0 to $1,250.54	0 to $1,250.54	$5002.16 to $6252.70	$3751.62 to $5002.16	0 to $1,250. 54	$12,505.40 to $13,755.94

719. Using the data above showing the estimated numbers of complications from abortion drugs requiring ER visits for Medicaid enrollees, it is possible to estimate the States' payments for this treatment in Missouri and Idaho.

720. The following table shows the estimated Medicaid payments for ER visits for Medicaid enrollees in Missouri at current reimbursement rates.

Estimated payments for ER visits for complications from abortion drugs for Missouri Medicaid enrollees by year[495]

Year	2016	2017	2018	2019	2020	2021	2022
Low estimate of abortion-drug ER visits for Medicaid enrollees (2.9% complication rate)	9.60	10.38	8.64	6.90	8.06	8.76	7.60
Low estimate of Medicaid payments for abortion-drug ER visits (2.9% complication rate) at $360.52 per moderate ER visit	$3244.68 to $3605.20	$3605.20 to $3965.72	$2884.16 to $3244.68	$2163.12 to $2523.64	$2884.16 to $3244.68	$2884.16 to $3244.68	$2523.64 to $2884.16
Low estimate of Medicaid payments for abortion-drug ER visits (2.9% complication rate) at $522.83 for a high-severity ER visit	$4705.47 to $5228.30	$5228.30 to $5751.13	$4182.64 to $4705.47	$3136.98 to $3659.81	$4182.64 to $4705.47	$4182.64 to $4705.47	$3659.81 to $4182.64
High estimate of abortion-drug ER visits for Medicaid enrollees (4.6% complication rate)	15.23	16.47	13.71	10.95	12.79	13.89	12.00
High estimate of Medicaid payments for abortion-drug	$5407.80 to $5768.32	$5768.32 to $6128.84	$4686.76 to $5047.28	$3605.2 to $3965.72	$4326.24 to $4688.76	$4686.76 to $5047.28	$4326.24 to $4686.76

[495] All figures are rounded to the nearest one-hundredth.

ER visits (4.6% complication rate) at $360.52 per moderate ER visit							
High estimate of Medicaid payments for abortion-drug ER visits (4.6% complication rate) at $522.83 for a high-severity ER visit	$7842.45 to $8365.28	$8365.28 to $8888.11	$6796.79 to $7319.62	$5228.3 to $5751.13	$6273.96 to $6796.79	$6796.79 to $7319.62	$6273.96

721. The following table shows the estimated Medicaid payments for ER visits for Medicaid enrollees in Idaho at current reimbursement rates.

Estimated payments for ER visits for complications from abortion drugs for Idaho Medicaid enrollees by Year[496]

Year	2016	2017	2018	2019	2020	2021	2022
Low estimate of abortion-drug ER visits for Medicaid enrollees (2.9% complication rate)	2.81	2.87	2.32	2.38	6.35	6.79	3.68
Low estimate of Medicaid payments for abortion-drug ER visits (2.9% complication rate) at $102.71 per moderate ER visit	$205.42 to $308.13	$205.42 to $308.13	$205.42 to $308.13	$205.42 to $308.13	$616.26 to $718.97	$616.26 to $718.97	$308.13 to $410.84
Low estimate of Medicaid payments for abortion-drug ER visits (2.9% complication rate) at $149.13 for a high-severity ER visit	$298.26 to $447.39	$298.26 to $447.39	$298.26 to $447.39	$298.26 to $447.39	$894.78 to $1043.91	$894.78 to $1043.91	$447.39 to $596.52
High estimate of abortion-drug ER visits for Medicaid enrollees (4.6% complication rate)	4.46	4.55	3.68	3.77	10.07	10.76	5.84
High estimate of Medicaid payments for abortion-drug ER visits (4.6% complication rate) at $102.71 per moderate ER visit	$410.84 to $513.55	$410.84 to $513.55	$308.13 to $410.84	$308.13 to $410.84	$1027.10 to $1129.81	$1027.10 to $1129.81	$513.55 to $616.26
High estimate of Medicaid payments for abortion-drug ER visits (4.6% complication rate) at $149.13 for a high-severity ER visit	$596.52 to $745.65	$596.52 to $745.65	$447.39 to $596.52	$447.39 to $596.52	$1491.30 to $1640.43	$1491.30 to $1640.43	$745.65 to $894.78

[496] All figures are rounded to the nearest one-hundredth.

722. Of course, these estimates may be an undercount if actual charges are higher or there is a higher number of patients presenting for treatment.

723. 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.[497]

724. Similarly, government employees can receive payments from government health insurance programs for government employees out of state.

725. Plaintiff States routinely spend money through public insurance treating medical complications related to abortion drugs, even in states where such abortions are unlawful in most circumstances.

E. States pay costs of public hospitals for medical expenses for the increasing number of patients in Plaintiff States suffering complications from chemical abortion drugs.

726. Another way that Plaintiff States subsidize healthcare for reproductive-age women is through public medical facilities.

727. Each Plaintiff State has public and private medical facilities that provide care for complications from chemical abortion drugs even if the facilities do not provide elective abortions.

728. Plaintiff States operate various public hospitals that serve women who obtain chemical abortions. The public hospitals act as an arm of the State.

729. In Missouri, public hospitals are ultimately controlled by the State of Missouri and receive state funds.

730. MO HealthNet (Missouri Medicaid) pays a determined rate to public hospitals, which in some circumstances may be lower than the hospital's costs.

---

[497] https://mydss.mo.gov/media/pdf/out-state-non-bordering-services

731. 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.

732. 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.

733. 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.

734. 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.[498]

735. Under the Emergency Medical Treatment and Active Labor Act (EMTALA), public hospitals are required to evaluate patients and provide stabilizing treatment in emergency situations, regardless of a patient's ability to pay. *See Moyle v. United States*, 144 S. Ct. 2015, 2016 (2024) (Kavanaugh, J., concurring in dismissal). So, public hospitals cannot choose not to treat women who arrive needing emergency treatment after they experience complications from a chemical abortion.

F. The FDA's actions result in the States paying the costs to public insurance for mental health care for the increasing number of women suffering negative effects from chemical abortion drugs

736. As with medical complications, Plaintiff States also provide public coverage of certain mental health expenses such as psychiatry, psychology, and

[498] Ex. 95, Missouri Department of Health and Senior Services Affidavit, at 2.

counseling, including through Medicaid and public insurance programs for government employees.

737. Post-abortion regret and mental health effects are common, as evidenced by the proliferation of counseling programs for suffering women in churches and pregnancy resource centers.

738. Some women retrospectively report that they underwent abortions without adequate time to consider their actions or without true informed consent.[499] And a recent U.S. study on abortion and coercion found that "[o]ver 60 percent of women who had abortions report high levels of pressure to abort from one or more sources, and those same women report higher levels of subsequent mental health and quality of life issues."[500]

739. Chemical abortions in particular have devastating mental health effects for women who experience physical trauma at home and without a doctor or other support persons present, who often view the unborn child as he or she is aborted, or by directly participating in the procedure that ends their child's life.

740. Seeing the unborn child as it is aborted is associated with more intrusive events such as nightmares, flashbacks, and unwanted thoughts related to the experience.

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

---

[499] Ex. 13, 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 (2020), DOI: 10.1080/10410236.2020.1770507.

[500] Ex. 106, David C. Reardon & Tessa Longbons, *Whose Choice? Pressure to Abort Linked to Worsening of Subsequent Mental Health*, Charlotte Lozier Inst. (Feb. 7, 2023), https://lozierinstitute.org/whose-choice-pressure-to-abort-linked-to-worsening-of-subsequent-mental-health/.

choose chemical abortion report feeling that they have actively participated in their child's death.

742. 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.

743. 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.

744. And mifepristone itself releases inflammatory cytokines, which have been identified as contributing to depression. In one rat model, the group of pregnant rats given mifepristone had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety.[501]

745. 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.

XXIII. Sovereign Injuries to Plaintiffs' Population Interests

746. Plaintiff States also suffer injuries from the loss of fetal life and potential births, leading to a resulting reduction in the actual or potential population of each state.

---

[501] Ex. 107, Christina Camilleri et al., *Biological, Behavioral and Physiological Consequences of Drug-Induced Pregnancy Termination at First-Trimester Human Equivalent in an Animal Model*, 13 Frontiers in Neurosci. 544 (2019).

747. Defendants' actions are causing a loss in potential population or potential population increase. Each abortion represents at least one lost potential or actual birth.

748. The Supreme Court has recognized "the legitimacy of the States' interest in protecting fetal life." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 262 (2022). States' "legitimate interests include respect for and preservation of prenatal life at all stages of development." *Id.* at 301.

749. Defendants' efforts enabling the remote dispensing of abortion drugs has caused abortions for women in Plaintiff States and decreased births in Plaintiff States. This is a sovereign injury to the State in itself.

750. One study highlighted that the removal of in-person follow-up visits has an effect on birth rates. In Missouri, state laws result "in an average increase in driving distance of 2.2 miles" for an in-person out-of-state dispensing of abortion drugs, "compared to a 453-mile increase in Texas, illustrating that states with the greatest increases in driving distance also tend to have the greatest estimated increases in births.[502] That is because it is relatively easy for a Missouri woman to drive to Illinois or Kansas than for a Texas woman to drive to New Mexico or Colorado. Reflecting the ease of driving to another state to receive abortion drugs, it is estimated that just 2.4 percent of abortion-minded women were prevented from getting abortions" in Missouri after *Dobbs*.[503] This data thus reflects the FDA's removal of a requirement for three in-person doctor visits.

751. These estimates also show the effect of the FDA's decision to remove all in-person dispensing protections. When data is examined in a way that reflects

---

[502] Daniel Dench et al., The Effects of the Dobbs Decision on Fertility, Inst. of Labor Economics, IZA DP No. 16608 at 12 (Nov. 2023), https://docs.iza.org/dp16608.pdf.

[503] *Id.*

sensitivity to expected birth rates, these estimates strikingly "do not show evidence of an increase in births to teenagers aged 15-19," even in states with long driving distances despite the fact that "women aged 15-19 … are more responsive to driving distances to abortion facilities than older women."[504] The study thus concludes that "one explanation may be that younger women are more likely to navigate online abortion finders or websites ordering mail-order medication to self-manage abortions.[505] This study thus suggests that remote dispensing of abortion drugs by mail, common carrier, and interactive computer service is depressing expected birth rates for teenaged mothers in Plaintiff States, even if other overall birth rates may have been lower than otherwise was projected.

752. A loss of potential population causes further injuries as well: the States subsequent "diminishment of political representation" and "loss of federal funds," such as potentially "losing a seat in Congress or qualifying for less federal funding if their populations are" reduced or their increase diminished. *Dep't of Com. v. New York*, 588 U.S. 752, 766–67, (2019).

XXIV. Injury from 2019 approval of generic mifepristone

753. The same is true of the 2019 Generic Approval. By approving a generic version of the drug, the FDA increased supply and availability, lowering cost and thus increasing use of chemical abortions.[506]

754. 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,"

---

[504] *Id.*

[505] *Id.*

[506] Ex. 108, Solanky Affidavit.

increasing the use of chemical abortion compared to surgical abortion. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019).

755. The number of women obtaining chemical abortions has increased as a result of the 2019 generic approval,[507] 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).

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

FIRST CLAIM

The Challenged 2016 Major Changes

***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

757. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 756 of this complaint.

758. The FDA lacked legal authority when issuing the challenged 2016 Major Changes.

759. The FDA's illegal and unreasonable rationales for the challenged 2016 Major Changes—in light of the political context of the agency's actions—indicate that the stated reasons are pretext. Therefore, they are 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).

---

[507] *Id.*

760. The challenged 2016 Major Changes were unlawful because the FDA acknowledged that they were "interrelated," but failed to explain why the agency did not consider the cumulative impact of removing them all at once or why the agency could extrapolate safety conclusions for its omnibus changes from studies that did not evaluate those changes as a whole.

761. The FDA's actions seek to enable the violation of state laws restricting abortion, as described above. But a federal agency cannot disregard applicable state law or seek to enable and encourage what state law expressly prohibits, so the FDA lacked legal authority and acted arbitrarily and capriciously when issuing the challenged 2016 Major Changes.

762. Therefore, the challenged 2016 Major Changes, and, by necessity, the 2019 Mifepristone REMS Program and the 2021/2023 Removal of the In-Person Dispensing Protection must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA and the Court's inherent equitable power to enjoin *ultra vires* actions, *Larson*, 337 U.S. at 689–91.

SECOND CLAIM

2019 MIFEPRISTONE REMS PROGRAM AND 2019 ANDA APPROVAL

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

763. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 762 of this complaint.

764. The FDA lacked legal authority when issuing the 2019 Mifepristone Shared REMS Program and 2019 ANDA Approval.

765. The FDA's illegal and unreasonable rationales for the 2019 Mifepristone Shared REMS Program and 2019 ANDA Approval—in light of the political context of the agency's actions—indicate that the stated reasons are pretext. Therefore, they are 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).

766. The FDA's actions seek to enable the violation of state laws restricting abortion, as described above. But a federal agency cannot disregard applicable state law or seek to enable and encourage what state law expressly prohibits, so the FDA lacked legal authority and acted arbitrarily and capriciously when issuing the 2019 Mifepristone Shared REMS Program and 2019 ANDA Approval.

767. Therefore, the 2019 Mifepristone Shared REMS Program and 2019 ANDA Approval must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA and the Court's inherent equitable power to enjoin ultra vires actions, *Larson*, 337 U.S. at 689–91.

THIRD CLAIM

2021/2023 REMOVAL OF THE IN-PERSON DISPENSING PROTECTION, INCLUDING THE PHARMACY AUTHORIZATION

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

768. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 767 of this complaint.

769. The FDA lacked legal authority when issuing the 2021/2023 Removal of the In-Person Dispensing Protection (consisting of the 2021 Non-Enforcement

Decision, the 2023 Removal of In-Person Dispensing Requirement, and the Pharmacy Authorization).

770. The FDA's 2021/2023 Removal of the In-Person Dispensing Protection violates the federal laws that expressly prohibit the mailing or delivery by any letter carrier, express company, or other common carrier, or by interactive computer service, of any substance or drug intended for producing abortion. 18 U.S.C. §§ 1461–62.

771. The FDA's 2021/2023 Removal of the In-Person Dispensing Protection violated these federal laws because they impermissibly removed the in-person dispensing requirement for abortion drugs and, accordingly, authorized the downstream distribution of abortion drugs by mail, express company, other common carriers, and interactive computer service.

772. Because a federal agency cannot permit what federal law expressly prohibits, the FDA lacked legal authority when issuing the 2021/2023 Removal of the In-Person Dispensing Protection.

773. The FDA's illegal and unreasonable rationales for the 2021/2023 Removal of the In-Person Dispensing Protection —in light of the political context of the agency's actions—indicate that the stated reasons are pretext. Therefore, they are 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).

774. The 2021/2023 Removal of the In-Person Dispensing Protection are also unlawful because they were based on adverse event data that the FDA elsewhere recognizes as unreliable and studies that it considered "not adequate" on their own to establish the safety of dispensing mifepristone by mail.

775. The FDA's actions seek to enable the violation of state laws restricting abortion, as described above. But a federal agency cannot disregard applicable state law or seek to enable and encourage what state law expressly prohibits, so the FDA

lacked legal authority and acted arbitrarily and capriciously when issuing the 2021/2023 Removal of the In-Person Dispensing Protection.

776. Therefore, the 2021/2023 Removal of the In-Person Dispensing Protection must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA and the Court's inherent equitable power to enjoin ultra vires actions, *Larson*, 337 U.S. at 689–91.

FOURTH CLAIM

The Challenged 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, of Otherwise Not in Accordance with Law

777. Plaintiffs re-allege and incorporate, as though fully set forth, all paragraphs 1 to 776 of this complaint.

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

779. The FDA lacked legal authority under PREA to make the challenged 2016 Major Changes, and the challenged 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.

780. Defendants lacked legal authority under PREA to make the challenged 2016 Major Changes and the challenged 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.

781. For the reasons stated above, the challenged 2016 Major Changes must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined.

782. Because the challenged 2016 Major Changes were unlawful, the FDA's 2019 action to create a single, shared REMS—the Mifepristone REMS Program—for both Mifeprex and generic mifepristone must also be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined.

FIFTH CLAIM

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

783. Plaintiffs re-allege and incorporate, as though fully set forth, all paragraphs 1 to 782 of this complaint.

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

785. Because the FDA relied on the unlawful 2016 Major Changes labeling as a means to approve GenBioPro's generic drug, Mifepristone Tablets, 200 mg, the 2019 ANDA Approval was unlawfully approved.

786. Unable to rely on an unlawful approval, the FDA's 2019 ANDA Approval violated the FDCA 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).

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

788. GenBioPro may submit an application with proposed labeling consistent with the pre-2016 Major Changes labeling, but, unlike Danco, GenBioPro cannot simply revert to a previously approved label.

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 or a stay of the effective dates that

1. reinstates the REMS that were in place before 2016 insofar as they restore the Day 3 and Day 14 follow-up visits, restore the gestational age to 7 weeks from 10 weeks, restore the requirement that prescribers be physicians, and restore the requirement that prescribers must report all serious non-fatal adverse events to the agency;

2. rescinds the 2019 generic approval; and

3. restores the in-person dispensing requirement.

B. Issues a permanent injunction ordering Defendants to withdraw Defendants' actions to deregulate these abortion drugs.

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

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

E. Holds unlawful, sets aside, and vacates the 2021/2023 Removal of the In-Person Dispensing Protection, including the Pharmacy Authorization.

F. Holds unlawful the provision of drugs to adolescent populations because the FDA lacked authority under § 355c(a)(2)(B)(i) to extrapolate pediatric effectiveness.

G. Declares that the Federal Food, Drug, and Cosmetic Act prohibits the FDA from relying exclusively on studies that fail to evaluate the safety of interrelated changes in the proposed labeling thereof when reviewing and approving a supplemental new drug application without explaining why it was permissible to do so.

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

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

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

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

Respectfully submitted this 11th day of October, 2024.

ANDREW BAILEY
Missouri Attorney General

/s/ Joshua M. Divine
*Joshua Divine, #69875MO
Solicitor General
Maria Lanahan, #65956MO
*Samuel C. Freedlund, #73707MO
Deputy Solicitors General

Office of the Missouri Attorney General
207 W. High Street
P.O. Box 899
Jefferson City, Missouri 65102
Telephone: (573) 751-8870
Facsimile: (573) 751-0774
Josh.Divine@ago.mo.gov
Maria.Lanahan@ago.mo.gov
Samuel.Freedlund@ago.mo.gov

Counsel for Intervenor Plaintiff State of Missouri

KRIS W. KOBACH
Attorney General of Kansas

/s/ *Erin B. Gaide*
*Abhishek S. Kambli, #29788KS
Deputy Attorney General
*Erin B. Gaide, #29691KS
Assistant Attorney General

Office of the Attorney General
120 SW 10th Ave., 2nd Floor
Topeka, Kansas 66612
Telephone: (785) 296-7109
Facsimile: (785) 296-3131
Erin.Gaide@ag.ks.gov

Counsel for Plaintiff State of Kansas

RAÚL R. LABRADOR
Idaho Attorney General

/s/ *Alan Hurst*
**Alan Hurst, #12425ID
Solicitor General
**Michael Zarian, #12418ID
Deputy Solicitor General

Office of the Idaho Attorney General
P.O. Box 83720
Boise, Idaho 83720
Telephone: (208) 334-2400
Facsimile: (208) 854-8071
alan.hurst@ag.idaho.gov
michael.zarian@ag.idaho.gov

Counsel for Plaintiff State of Idaho

*Admitted pro hac vice
**Pro hac vice application forthcoming