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

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

PROPOSED COMPLAINT IN INTERVENTION OF THE STATES OF FLORIDA AND TEXAS

1. The United States Food and Drug Administration (FDA) is responsible for "protect[ing] the public health by ensuring that . . . drugs are safe and effective." 21 U.S.C.A. § 393(b)(2)(B).

2. Yet the FDA's approval and deregulation of abortion drugs has placed women and girls in harm's way.

3. The chemical abortion regimen includes two drugs: mifepristone and misoprostol. The former starves the child to death by blocking progesterone receptors in the uterus. The latter induces contractions to expel the child from the womb.

4. These abortions also endanger the mother. Common complications

include severe bleeding, undetected rupture of the fallopian tube, and sepsis.

5. Studies estimate that as many as 20% of women who take mifepristone suffer a serious adverse event, and the FDA's own label estimates that one in every 25 users will need to visit the emergency room.

6. The risks do not end with hospitalization. FDA data shows that, on average, abortion drugs claim the life of at least one woman each year in the United States.

7. These are the tragic but predictable consequences of prioritizing politics over public health.

8. The FDA's regulation of mifepristone was political from the start. As a presidential candidate, Bill Clinton promised to bring mifepristone to market in the United States. The drug, then known as RU-486, was available only in Europe. On his second day in office, President Clinton directed the Department of Health and Human Services to "promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins." *Infra* n. 13.

9. Correspondence from President Clinton's first term reveals that HHS viewed the approval of mifepristone as a "political issue." For instance, a memorandum composed by the agency's chief of staff in 1994 reminded the White House that mifepristone was of "great significance to the pro-choice and women's groups" who expected the Clinton administration to "do everything possible to get RU 486 introduced in this country." *Infra* n. 19. Failure to do so, the memo warned, "weakens our political base and may subject the President to criticism that he is not sticking to his

original position." *Id.* At the same time, the President's advisors cautioned that approving mifepristone before the 1996 presidential election would "provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision *and on its aftermath*." *Id.*

10. President Clinton devised a clever solution to this political problem. First, he coerced the European company holding the American patent to mifepristone to transfer the patent to the Population Council, an allied abortion advocacy organization, in 1994. The Population Council then waited until 1996 to file its new drug application with the FDA.

11. But that did not leave much time. The FDA therefore used Subpart H, an expedited review process reserved for products treating "serious or life-threatening illnesses" and offering "meaningful therapeutic benefit over existing treatments." 21 U.S.C. § 355c(a)(5)(A), (B). Mifepristone does neither, as the FDA was warned by the Population Council. Over this objection, the FDA approved brand name mifepristone under the name "Mifeprex" in 2000 (the "2000 Approval").

12. Aware of the risk it was posing to the public, the FDA conditioned the approval on a risk evaluation and mitigation strategy (REMS) that included, among other things:

- A restriction to pregnancies through 49 days' gestation.
- A requirement that abortion drugs be dispensed and administered in-person by a physician capable of accurately assessing gestational age, diagnosing ectopic pregnancies, and providing surgical intervention.
- A minimum of three office visits: (1) the Day 1 in-person dispensing and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 return to the doctor's

office to confirm no fetal parts or tissue remain.

- A requirement to report any hospitalization, transfusion, or other serious events.

The FDA deemed these safeguards "necessary to ensure the benefits of the drug outweigh the risks of serious complications." *Infra* n. 54.

13. But in 2007, a new campaign promise was made. Then-Senator Barack Obama, speaking to the Planned Parenthood Action Fund, declared that the upcoming presidential election was about "more than just about standing our ground. It must be about more than protecting the gains of the past. We're at a crossroads right now in America, and we have to move this country forward. This election is not just about playing defense, it's also about playing offense." *Infra* n. 58.

14. President Obama made good on his promise in 2016, when the FDA adopted "major changes" to the mifepristone REMS. These changes extended the maximum gestational age from 49 to 70 days, eliminated the requirement that administration of misoprostol occur in-clinic, removed the requirement for an in-person follow-up examination, allowed non-physicians to dispense and administer abortion drugs, and relieved physicians of their obligation to report non-fatal complications (the "2016 Major Changes").

15. These changes were made without a *single study* evaluating the safety and effectiveness of mifepristone and misoprostol under the new conditions and without the safety assessment for pediatric populations required by law.

16. Based on the prior approval of Mifeprex, the FDA approved a generic version of mifepristone in 2019 (the "2019 Generic Approval").

17. There was another presidential primary in 2020, and more promises to Planned Parenthood. At the organization's Candidates Forum in June 2019, then-Vice President Joe Biden declared that he would "vastly expand" access to abortion "across the spectrum," going so far as to say that "there should be no restrictions at all on the ability to get those drugs." *Infra* n. 91.

18. After Biden's inauguration as President, the FDA gutted what was left of the mifepristone REMS from 2021 to 2023, authorizing abortion drugs to be sent by mail and dispensed at pharmacies (the "2021/2023 Dispensing Changes").

19. In addition to being untethered to any medical research evaluating the safety and effectiveness of mail-order abortion drugs, these changes openly defy federal law criminalizing the use of the mails to convey "any article or thing designed, adapted, or intended for producing abortion." 18 U.S.C. §§ 1461–62.

20. Each of these actions—the 2000 Approval, the 2016 Major Changes, the 2019 Generic Approval, and the 2021/2023 Dispensing Changes (collectively, the "Challenged Actions")—were arbitrary, capricious, an abuse of discretion, not in accordance with law, and therefore invalid under the Administrative Procedure Act.

21. To protect their residents and vindicate their economic and sovereign interests, the States of Florida and Texas ("Plaintiffs") petition this Court to declare the actions unlawful and set them aside.

JURISDICTION AND VENUE

22. 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 Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*.

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

24. 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.

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

26. This lawsuit seeks declaratory, injunctive, vacatur, 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. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

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

28. Defendants are United States officers or agencies sued in their official capacities. 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" the States of Florida and Texas and their medical providers and health plans. *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 881 (2011).

29. Venue properly lies in this Court because a substantial part of the facts,

events, or omissions giving rise to the claims occurred in this district. 28 U.S.C. § 1391(b)(2), (e)(1). Plaintiffs brought this intervention action in the same district and division in which an action involving the same subject matter is already pending.

30. Moreover, venue lies in this Court pursuant to 28 U.S.C. § 1391(e)(1) because Defendants are agencies, officers, and employees of the United States sued in their official capacities; no real property is involved in the action; and the State of Texas resides in this judicial district. *Texas v. United States Dep't of Homeland Sec.*, 661 F. Supp. 3d 683, 689 (S.D. Tex. 2023) ("[T]he Court finds . . . Texas resides at every point within the boundaries of this State").

PARTIES

Plaintiffs

31. Plaintiff the State of Florida is a sovereign State of the United States of America. Florida sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens.

32. James Uthmeier, the Attorney General of Florida, is authorized to "appear in and attend to, in behalf of the state [of Florida], all suits or prosecutions, civil or criminal or in equity, in which the state may be a party, or in anywise interested . . . in any courts . . . of the United States." § 16.01(4-5), Fla. Stat.

33. Plaintiff the State of Texas is a sovereign State of the United States of America. Texas sues to vindicate its sovereign, quasi-sovereign, and proprietary interests, including its interests in protecting its citizens.

34. Ken Paxton, the Attorney General of Texas, is authorized to "prosecute

and defend all actions in which the state [of Texas] is interested." Tex. Gov. Code § 402.021.

Defendants

35. Defendant United States Food and Drug Administration is an agency of the federal government within the Department of Health and Human Services (HHS). The HHS Secretary has delegated to the FDA Commissioner the authority to administer the provisions of the FDCA for approving new drug applications and authorizing a Risk Evaluation and Mitigation Strategy (REMS) for high-risk drugs. FDA's headquarters is located at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

36. Defendant Martin A. Makary, M.D., M.P.H., named in his official capacity, is the Commissioner of Food and Drugs at FDA. Dr. Makary supervises the activities of FDA, including the approval of new drug applications, supplemental new drug applications, and the issuance, modification, waiver, suspension, or removal of a REMS. Dr. Makary's official address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

37. Defendant Jacqueline Corrigan-Curay, M.D., J.D., named in her official capacity, is the Acting Director of FDA's Center for Drug Evaluation and Research. Dr. Corrigan-Curay is tasked with regulating drugs throughout their lifecycle, evaluating and approving new and existing drugs, monitoring post-marketing drug safety, and taking enforcement actions necessary to protect the public from harmful drugs. Dr. Corrigan-Curay's official address is 10903 New Hampshire Avenue, Silver

Springs, Maryland 20993.

38. Defendant HHS is a federal agency. Its address is 200 Independence Avenue SW, Washington, D.C. 20201.

39. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS and is named in his official capacity. Defendant Kennedy is responsible for the overall operations of HHS, including the operations of FDA. His official address is 200 Independence Avenue SW, Washington, D.C. 20201.

40. 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). Plaintiffs' claims against Defendants include all employees, agents, or successors in office of Defendants.

FACTUAL ALLEGATIONS

41. The following discussion describes (I) federal law governing the FDA's approval and regulation of drugs; (II) President Clinton's approval of brand name mifepristone in 2000; (III) major changes to the mifepristone REMS made by President Obama in 2016; (IV) the approval of a generic version of mifepristone in 2019, (V) President Biden's 2023 REMS, which facilitated mail-ordered mifepristone as a response to *Dobbs* and as a means of circumventing pro-life States' abortion bans; (VI) the FDA's denial of citizen petitions; (VII) the physical and mental harm inflicted on women by abortion drugs; (VIII) the economic injuries suffered by Plaintiffs; and (IX) the sovereign injuries suffered by Plaintiffs.

I. The FDA's Authority to Review, Approve, and Deny New Drug Applications

42. The FDA's approval and modification of drugs must comply with the

Food, Drug, and Cosmetic Act, the Pediatric Research Equity Act, the agency's regulations, and federal law governing distribution of drugs.[1]

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

43. Under the Food, Drug, and Cosmetic Act (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).

44. 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.

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

46. 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).

47. 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).

48. 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

[1] 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.

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).

49. "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).

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

51. "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).

52. 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).

53. A generic drug manufacturer may submit an abbreviated new drug application (aNDA) to sell and distribute a generic version of an approved drug. 21 U.S.C. § 355(j).

54. 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 must also be identical to the approved drug. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94.

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

55. On December 11, 1992, the FDA published a final rule entitled "New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval."[2]

56. The rule established procedures "under which FDA will accelerate approval of certain new drugs and biological products for *serious or life-threatening illnesses*, with provision for required continued study of the drugs' clinical benefits after approval or for restrictions on distribution or use, where those are necessary for safe use of the drugs."[3]

57. The FDA intended these procedures "to provide expedited marketing of drugs for patients suffering from *such illnesses* when the drugs provide a *meaningful*

[2] Ex. 7, HHS, *New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval*, 57 Fed. Reg. 58,942 (Dec. 11, 1992).
[3] *Id.* (emphasis added).

therapeutic advantage over existing treatment."[4]

58. The FDA codified the rule in Title 21, Part 314, Subpart H of the Code of Federal Regulations. Subpart H makes clear that its expedited process is limited to:

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

21 C.F.R. § 314.500 (emphasis added).

59. If the FDA's review under Subpart H concludes that a drug is effective but can be safely used only if distribution or use is restricted, the agency must "require such postmarketing restrictions as are needed to assure safe use of the drug product." 21 C.F.R. § 314.520(a). Such restrictions may include distribution (1) "restricted to certain facilities or physicians with special training or experience" or (2) "conditioned on the performance of specified medical procedures." 21 C.F.R. § 314.520(a)(1), (2). The limitations must "be commensurate with the specific safety concerns presented by the drug product." 21 C.F.R. § 314.520(b).

60. Under 21 C.F.R. § 314.530, the FDA may withdraw approval of drugs approved under Subpart H if:

> (1) A postmarketing clinical study fails to verify clinical benefit;
>
> (2) The applicant fails to perform a required postmarketing study with due diligence;
>
> (3) Use after marketing demonstrates that postmarketing restrictions

[4] *Id.* (emphasis added)

> are inadequate to assure safe use of the drug product;
>
> (4) The applicant fails to adhere to the postmarketing restrictions agreed upon;
>
> (5) The promotional materials are false or misleading; or
>
> (6) Other evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use.

61. The FDA's preamble to the Subpart H rulemaking stated that "[t]he burden is on the applicant to ensure that the conditions of use under which the applicant's product was approved are being followed."[5]

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

63. In 2007, Congress adopted Subpart H into statute. 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).

64. 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,

[5] *Id.* at 58,952.

if the FDA previously attached postmarketing restrictions on a drug approved under Subpart H, the FDAAA converted those restrictions into a REMS.

65. 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 drug "is associated with a serious adverse drug experience." 21 U.S.C. § 355-1(f)(1).

66. These "Elements to Assure Safe Use" 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).

67. 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).

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

69. An applicant "may propose the addition, modification, or removal of [the REMS] . . . and shall include an adequate rationale to support such proposed addition,

modification, or removal." 21 U.S.C. § 355-1(g)(4)(A).

C. PREA's Required Assessments on Pediatric Populations

70. The Pediatric Research Equity Act (PREA) was enacted in 2003 to require studies on the safety and effectiveness of drugs intended for pediatric populations, unless certain exceptions apply. 21 U.S.C. § 355c. The legislation codified the FDA's "Pediatric Rule," promulgated in 1998.[6]

71. 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).

72. 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).

73. But to support this extrapolation, the FDA must include "brief documentation of the scientific data supporting the conclusion" that the course of the "disease"

[6] Ex. 8, HHS, *Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients*, 63 Fed. Reg. 66,632 (Dec. 2, 1998).

and the effects of the drug are sufficiently similar in adults and pediatric patients. 21 U.S.C. § 355c(a)(2)(B)(iii).

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

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

D. The Comstock Act's Restriction on the Distribution of Abortion Drugs

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

77. *First*, 18 U.S.C. § 1461 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."

78. *Second*, 18 U.S.C. § 1462 broadly prohibits the use of "any express company or other common carrier" or "interactive computer service" to transport "any

drug, medicine, article, or thing designed, adapted, or intended for producing abortion" in interstate or foreign commerce.

II. The 2000 Approval of Mifeprex

79. A chemical abortion requires two drugs: mifepristone and misoprostol.

80. 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 uterine environment, prevents the baby from receiving nutrition, and ultimately starves the baby to death in the womb.[7] There is no FDA-approved use of mifepristone other than to end the life of a preborn child.

81. The second drug, misoprostol, induces cramping and contractions to expel the baby from the mother's womb.[8] Misoprostol was approved by the FDA in 1988 for use unrelated to chemical abortion.[9]

82. The French pharmaceutical company Roussel Uclaf S.A. developed and tested mifepristone under the name RU-486. By April 1990, the drug was available in France.[10]

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[7] *See* Ex. 4, Harrison Decl. at ¶ 21; Ex. 82, Skop Decl. at ¶ 10; Ex. 47, *The FDA and RU-486: Lowering the Standard for Women's Health:* Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform, 109th Cong. 4 (2006).

[8] *Id.*

[9] *See* FDA Center for Drug Evaluation and Research, *Summary Review of NDA Application Number: 020687Orig1s020* Misoprostol (Cytotec) at 3, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020OtherR.pdf.

[10] Ex. 15, Citizen Petition of AAPLOG to FDA at 7–8 (Aug. 8, 2002) ("2002 Citizen Petition"); *see also* Ex. 19, Citizen Petitioners' Response to Opposition Comments filed

83. Roussel Uclaf's German parent company, Hoechst AG, prohibited the drug manufacturer from attempting to enter the U.S. market or filing a new drug application with the FDA. This decision was motivated by Hoechst's corporate history and complicity in mass genocide. "Hoechst traces its corporate history to I.G. Farben, the manufacturer of Zyklon-B, which was used in the gas chambers of Auschwitz," and therefore "did not want to be credited with doing to fetuses what the Nazis had done to the Jews."[11]

84. However, during the 1992 presidential campaign, Arkansas Governor Bill Clinton earned the support of pro-abortion groups by promising to bring RU-486 to the United States.[12]

85. In January 1993, on his second full day in office, President Bill Clinton directed then-HHS Secretary Donna Shalala to assess initiatives to promptly "promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins."[13]

86. According to a Roussel Uclaf official, President Clinton also wrote to Hoechst asking the company to file a new drug application with the FDA, which Hoechst refused to do.[14]

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by The Population Council, Inc. and Danco Laboratories, LLC to Comments (Oct. 10, 2003).

[11] Julie A. Hogan, THE LIFE OF THE ABORTION PILL IN THE UNITED STATES, at 23-24 (2000), http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852153.

[12] Carrie N. Baker, ABORTION PILLS: U.S. HISTORY AND POLITICS 38 (2024); Feminist Majority Foundation, *A Brief Chronology in the Fight to Make RU 486 Available in the US*, https://feminist.org/our-work/mifepristone/timeline/.

[13] Letter from William Clinton to Donna Shalala (Jan. 22, 1993); Baker, *supra* n. 12 at 39; Ex. 15, 2002 Citizen Petition at 8.

[14] Ex. 15, 2002 Citizen Petition at 8.

87. In early 1993, as HHS later reported, Secretary Shalala and then-FDA Commissioner David Kessler likewise "communicated with senior Roussel Uclaf officials to begin efforts to pave the way for bringing RU-486 into the American marketplace."[15]

88. According to HHS, "[i]n April 1993, representatives of FDA, Roussel Uclaf and the Population Council . . . met to discuss U.S. clinical trials and licensing of RU-486."[16] "The Population Council is a nonprofit founded in 1952 by John D. Rockefeller III to address supposed world overpopulation."[17] Between April 1993 and May 1994, the parties continued their negotiations.

89. Correspondence during this time reveals that HSS viewed the approval of mifepristone as a "political issue."[18] For instance, a memorandum composed by HHS Chief of Staff Kevin Thurm in 1994 reminded the White House that mifepristone was of "great significance to the pro-choice and women's groups" who expected the Clinton administration to "do everything possible to get RU 486 introduced in this country."[19] Thurm warned that failing to deliver on this "promise" would "weaken[] our political base and may subject the President to criticism that he is not sticking to

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[15] *Id.* (quoting HHS Fact Sheet: Mifepristone (RU-486): Brief Overview (May 16, 1994), available in 144 Congressional Record 150 (Tuesday, October 20, 1998), https://www.govinfo.gov/content/pkg/CREC-1998-10-20/html/CREC-1998-10-20-pt1-PgS12688-3.htm).
[16] HHS Fact Sheet: Mifepristone, *supra* n. 15.
[17] Influence Watch, *Population Council*, https://www.influencewatch.org/non-profit/population-council/.
[18] Ex. 48, Memorandum on RU-486 from HHS Chief of Staff Kevin Thurm to White House Director of Domestic Policy Carol Rasco, Tab 4 Political Issue Discussion (May 11, 1994).
[19] *Id.*

his original position."[20]

90. Other officials publicly admitted that the administration's purpose in approving mifepristone was to undermine state abortion laws. Ruth B. Merkatz, PhD, RN, FAAN served as the director of HHS's Office of Women's Health from 1994 to 1996. In her oral history of the approval of mifepristone, she explained that the FDA approved mifepristone with the intent to facilitate evasion of those 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."[21]

91. However, President Clinton's advisors cautioned that approving mifepristone before the 1996 presidential election would "provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision and on its aftermath."[22] "In the worst case, it could put the abortion issue centerstage, with the Clinton Administration as a high-profile player right up through the kick-off of the 1996 re-election campaign."[23]

92. President Clinton navigated these political straits by coercing Hoechst to transfer its patent rights to the Population Council, which would wait until 1996 to file a new drug application.

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[20] *Id.*
[21] FDA, Oral History Interview with Ruth B. Merkatz at 39 (Oct. 16, 2019), https://www.fda.gov/media/165295/download?attachment.
[22] Ex. 48, Memorandum from Kevin Thurm to Carol Rasco, Tab 4 Political Issue Discussion.
[23] *Id.* at Tab 5 Press Issues Discussion.

93. The transfer was secured by threatening to use laws allowing "the United States government to take a patent for an essential drug that was being withheld from the US market." [24] The Clinton Administration, working closely with then-Representative Ron Wyden of Oregon, raised this possibility through a series of congressional hearings. "Those hearings were very important because Roussel Uclaf could use them in his bargaining with Hoechst AG. In other words, 'you guys are going to lose this patent because the United States isn't going to take this.' They thought that the Congress was going to act. That was important."[25]

94. To further coerce Hoechst, the FDA granted the Population Council permission to test "cloned" RU-486 pills. As the Population Council explained, "Our purpose is to pressure Roussel Uclaf. We are trying to get them into immediate and decisive action."[26]

95. These actions culminated in what HHS called a "donation" of Roussel Uclaf's patent rights to the Population Council in May 1994.[27]

96. The following year, the Population Council granted Danco Laboratories, LLC ("Danco"), newly incorporated in the Cayman Islands, an exclusive license to manufacture, market, and distribute Mifeprex in the United States.

97. The Population Council filed an NDA for "mifepristone 200 mg tablets" in 1996.[28]

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[24] Baker, *supra* n. 12 at 33.
[25] *Id.*
[26] *Id.* at 36.
[27] Ex. 15, 2002 Citizen Petition at 8-9 (quoting HHS, Press Release: Roussel Uclaf Donates U.S. Patent Rights for RU-486 to Population Council (May 16, 1994)).
[28] *Id.* at 10.

98. The clock was ticking for the term-limited President Clinton. So, on May 7, 1996, the FDA's Center for Drug Evaluation and Research notified the Population Council that mifepristone would receive priority review.[29]

99. On September 18, 1996, the FDA issued a letter stating that the application was "approvable" and requested more information from the Population Council.[30]

100. On February 18, 2000, the FDA issued a second "approvable" letter, setting forth the remaining prerequisites for approval. This letter announced that the FDA had "considered this application under the restricted distribution regulations contained in 21 C.F.R. § 314.500 (Subpart H) and [had] concluded that restrictions as per [21] CFR § 314.520 on the distribution and use of mifepristone are needed to assure safe use of this product."[31]

101. The FDA told the Population Council that the agency would proceed under Subpart H because "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."[32]

102. The FDA needed to approve the Population Council's application under Subpart H not only because it facilitated accelerated review, but also because it provided the FDA with the only means to restrict the drugs' distribution and apply post-marketing restrictions use "to assure safe use." 21 C.F.R. 314.520.

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[29] *Id.*
[30] *Id.* at 10–11.
[31] Ex. 16, Letter re NDA 20-687 from FDA to Population Council at 5 (Feb. 18, 2000).
[32] *Id.*

103. The Population Council objected, explaining that its application for mifepristone did not fall within the scope of Subpart H.[33]

104. Just three weeks before the final approval of mifepristone, the Population Council wrote a letter to the FDA arguing that "it is clear that the imposition of Subpart H is unlawful, unnecessary, and undesirable. We ask FDA to reconsider."[34]

105. The letter stated that "[n]either pregnancy nor unwanted pregnancy is an illness, and Subpart H is therefore inapplicable for that reason alone. Neither is pregnancy nor unwanted pregnancy a 'serious' or 'life-threatening' situation as that term is defined in Subpart H."[35]

106. And after quoting the preamble to the FDA's Subpart H Final Rule, the Population Council stated that "[t]he plain meaning of these terms does not comprehend normal, everyday occurrences such as pregnancy and unwanted pregnancy."[36]

107. The letter added that unlike HIV infection, pulmonary tuberculosis, cancer, and other illnesses, "pregnancy and unwanted pregnancy do not affect survival or day-to-day functioning as those terms are used in Subpart H." It explained that "although a pregnancy 'progresses,'" the development of a pregnancy "is hardly the same as the worsening of a disease that physicians call progression."[37]

108. Nevertheless, on September 28, 2000, the FDA approved mifepristone under Subpart H "for the medical termination of intrauterine pregnancies through

[33] Ex. 15, 2002 Citizen Petition at 20.
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.*

49 days' pregnancy."[38]

109. To defend its use of Subpart H, the FDA agency declared that "the termination of an unwanted pregnancy is a serious condition within the scope of Subpart H" and asserted that "[t]he meaningful therapeutic benefit over existing surgical abortion is the avoidance of a surgical procedure."[39]

110. 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."[40]

111. The FDA required the drugs' label to include a "black box warning for special problems, particularly those that may lead to death or serious injury."[41]

112. The FDA also mandated measures to assure safe use, including requiring at least three office visits: (1) the Day 1 in-person dispensing and administration of mifepristone; (2) the Day 3 in-person dispensing and administration of misoprostol; and (3) the Day 14 return to the doctor's office to confirm no fetal parts or tissue remain.[42]

113. 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

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[38] Ex. 18, Memorandum from FDA to Population Council re NDA 20-687 Mifeprex (mifepristone) at 6 (Sept. 28, 2000) ("2000 Approval Memo").
[39] *Id.*
[40] *Id.* at 2.
[41] *Id.*
[42] *Id.* at 2–3.

"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."[43]

114. The FDA's Subpart H restrictions included the following requirements for abortionists: the ability to assess the duration of pregnancy accurately and to diagnose ectopic pregnancies (chemical abortion drugs cannot end an ectopic pregnancy, but the symptoms of these drugs resemble hemorrhaging from a life-threatening ectopic pregnancy); the requirement to report any hospitalization, transfusion, or other serious events; and the ability to provide surgical intervention or to ensure that the patient has access to other qualified physicians or medical facilities.[44]

115. The FDA did not require abortionists to perform an ultrasound to accurately date the gestational age of the preborn child or rule out ectopic pregnancy, nor did the FDA require a blood test to detect Rh-negative blood type.

116. 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.[45]

117. The FDA did not include prohibitions on the upstream distribution of the chemical abortion drugs—from the manufacturer or importer to the abortionist—

[43] *Id.* at 3.
[44] *Id.* at 6.
[45] *Id.*

by mail, express company, or common carrier as proscribed by federal laws, nor did the FDA acknowledge and address these laws.[46]

118. The FDA also required two post-approval study commitments. The Population Council was to conduct "a monitoring study to ensure providers who did not have surgical-intervention skills and referred patients for surgery had similar patient outcomes as those patients under the care of physicians who possessed surgical skills (such as those in the clinical trial)." The Population Council also agreed "to study ongoing pregnancies and their outcomes through a surveillance, reporting, and tracking system."[47]

119. The FDA informed the Population Council that the agency was "waiving the pediatric study requirement for this action on this application."[48] Without explanation of the effects of chemical abortion drugs on puberty or substantiation of its decision, the FDA asserted that "there is no biological reason to expect menstruating females under age 18 to have a different physiological outcome with the regimen."[49]

120. The FDA nonetheless highlighted the findings of one limited study that included 51 subjects under 20 years of age. The agency explained that the approved labeling states that the safety and efficacy for girls under 18 years of age "have not been studied" because the raw data from this limited study had not been submitted for review, the pediatric population was not part of the NDA indication, the data on

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[46] *Id.*
[47] *Id.* at 7.
[48] Ex. 17, Letter from FDA to Population Council re NDA 20-687 Mifeprex (mifepristone) at 3 (Sept. 28, 2000) ("2000 Approval Letter").
[49] Ex. 18, 2000 Approval Memo. at 7.

safety and effectiveness were only reviewed for the indication's age group (18–35 years of age), and the clinical trials excluded patients younger than 18 years old.[50]

121. The FDA believed it would eventually overcome this data deficiency because the Population Council would "collect outcomes in their [post-approval] studies of women of all ages to further study this issue"[51]—even though those studies were not designed to evaluate the safety and effectiveness of mifepristone on girls under the age of 18 years.

122. But the FDA released the Population Council from its obligation to conduct these studies in 2008.[52]

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

124. In a Federal Register notice dated March 27, 2008, the FDA identified mifepristone as one of "those drugs that FDA has determined will be deemed to have in effect an approved REMS"[53] pursuant to section 909(b)(1) of the FDAAA.

125. In 2011, the FDA approved a REMS for mifepristone. The agency "determined that a REMS is necessary for MIFEPREX (mifepristone) to ensure the

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[50] *Id.*
[51] *Id.*
[52] Ex. 22, Letter from FDA to AAPLOG, Christian Medical & Dental Associations, and Concerned Women for America, Docket No. FDA-2002-P-0364, at 31 (Mar. 29, 2016) ("2016 Petition Denial").
[53] Ex. 56, HHS, *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).

benefits of the drug outweigh the risks of serious complications."[54]

126. The REMS incorporated the previous Subpart H restrictions, including a "black box warning for special problems, particularly those that may lead to death or serious injury."[55]

127. 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.[56]

128. 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."[57]

III. The 2016 Major Changes to the Mifeprex REMS

129. To obtain his party's presidential nomination, Barack Obama promised to wield the machinery of the federal government to the abortion industry's benefit.

130. At a Planned Parenthood Action Fund event in 2007, he declared that the upcoming presidential election was about "more than just about standing our ground. It must be about more than protecting the gains of the past. We're at a crossroads right now in America, and we have to move this country forward. This election is not just about playing defense, it's also about playing offense . . . . On this

[54] Ex. 20, Supplemental Approval Letter from FDA to Danco Laboratories, LLC at 1 (June 6, 2011) ("2011 Approval Letter").
[55] Ex. 17, 2000 Approval Letter at 2.
[56] Ex. 20, 2011 Approval Letter at 1.
[57] *Id.*; Ex. 21, REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011) ("2011 REMS").

fundamental issue, I will not yield."[58]

131. On May 28, 2015, Danco submitted an sNDA to the FDA.[59]

132. In February 2016, 30 pro-abortion organizations wrote to the FDA urging it to eliminate mifepristone's Elements to Assure Safe Use given "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."[60]

133. On March 29, 2016, the FDA approved several "major changes" to the mifepristone regimen recommended by Danco.[61] The 2016 Major Changes included:

- extending the maximum gestational age at which a woman or a girl can abort her baby from 49 days to 70 days;
- removing the requirement for any in-person follow-up examination after an abortion (including follow-up examinations on Days 3 and 14);
- allowing "healthcare providers" other than physicians to dispense and administer the abortion drugs; and
- eliminating the instruction that administration of misoprostol must be done in-clinic, to allow for administration at home or other

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[58] Planned Parenthood, *What Are the 2008 Presidential Candidates Saying About Women's Health Issues?* (Jan. 24, 2013) (excerpting speech to Planned Parenthood Public Affairs Retreat and Roundtable on July 17, 2007), https://www.plannedparenthoodaction.org/pressroom/what-are-2008-presidential-candidates-saying-about-womens-he.

[59] Ex. 23, Letter re NDA 020687 from FDA to Danco Laboratories (Mar. 29, 2016).

[60] 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; and Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin. 2, 5 (Feb. 4, 2016) (emphasis added).

[61] Ex. 2, FDA Center for Drug Evaluation and Research, *Summary Review of sNDA Application Number: 020687Orig1s020* at 6 (Mar. 29, 2016) ("2016 Summary Review").

location convenient for the woman.[62]

134. The FDA acknowledged that "these major changes are interrelated," demonstrating the agency's awareness that each change impacted the others.[63]

135. Despite these 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."[64]

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

A. Lack of Evidence Demonstrating Safety and Effectiveness

137. Despite acknowledging that the 2016 Major 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 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.

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[62] *Id.* at 6–10.
[63] *Id.* at 6.
[64] *Id.* at 27.

138. 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.

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

140. For example, the FDA relied on three studies that "closely mirrored" the 2016 changes,[65] 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."[66] 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.

141. Additionally, increasing the maximum gestational age by three full weeks indisputably increases rates of abortion failures, surgical interventions, and complications.[67] Simultaneously removing the two in-person follow-up visits that afford the opportunity to diagnose and treat complications before they result in an emergency only compounds these risks. But the FDA did not assess the impacts of doing both in *any* study.

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[65] *See* Brief for the Federal Petitioners at 38-39, *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024) (No. 23-235).
[66] Ex. 24, 2000 Mifeprex Label at 15, https://perma.cc/3V7C-SU6Q.
[67] 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.

142. 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.[68] 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."[69]

B. Lack of Research on Pediatric Populations

143. The 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.

144. 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.[70]

145. 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

[68] *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 246 (5th Cir.), *rev'd and remanded sub nom. Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 144 S. Ct. 1540, 219 L. Ed. 2d 121 (2024).
[69] *Id.*
[70] Ex. 2, 2016 Summary Review at 18–20.

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

146. 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).

147. Pregnancy is not a disease.[71] The FDA therefore lacked authority under § 355c(a)(2)(B)(i) to extrapolate pediatric effectiveness.

148. 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.[72] None of them satisfied the PREA requirement for a specific assessment of safety for pediatric populations.

149. 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.

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[71] *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.").

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

150. The primary study on which the FDA relied, *Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days* by Mary Gatter and Deborah Nucatola of Planned Parenthood of Los Angeles and Kelly Cleland of Princeton University's Office of Population Research, evaluated the proposed dosing regimen followed by home administration of misoprostol through 63 days' gestation. The study also included postmenarcheal girls in the study population, from which the FDA extrapolated its conclusion.[73]

151. 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.[74] For the adolescent cohort who had chemical abortions, the study found that 12.8% experienced hemorrhaging, 7% had incomplete abortions, and 11% needed surgical evacuation of "retained products of conception."[75] 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.[76]

152. 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. The authors of this study cautioned that a larger study was needed to make any

[73] *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)).
[74] Ex. 2, 2016 Summary Review at 19-20 (citing 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 5 (Apr. 20, 2011)).
[75] Ex. 6, Niinimaki, *Comparison of rates of adverse events* at 3–4.
[76] Ex. 2, 2016 Summary Review at 20.

generalizable conclusions for pediatric populations.[77]

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

154. Given the limitations with the three cited studies, the 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."

IV. The 2019 Approval of a Generic Version of Mifepristone

155. On April 11, 2019, the FDA approved GenBioPro, Inc.'s generic version of Mifeprex, "Mifepristone Tablets, 200 mg" because they were "bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Mifeprex Tablets, 200 mg, of Danco Laboratories, LLC."[78] GenBioPro's generic version of mifepristone has the same labeling and REMS as Danco's Mifeprex.[79]

156. 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 marketing. The FDA did not make any substantive modifications to the REMS approved in 2016.[80]

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[77] *Id.* at 19–20.
[78] Ex. 30, ANDA Approval Letter from FDA to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.
[79] *Id.*
[80] Ex. 58, Supplemental Approval Letter from FDA to Danco Laboratories, LLC

V. The 2021/2023 Dispensing Changes to the Mifepristone REMS

A. *Am. Coll. of Obstetricians & Gynecologists v. FDA*

157. On April 20, 2020, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) sent a joint letter to the FDA (the "ACOG-SMFM letter") asking the agency to allow dispensing by mail or mail-order pharmacy and remove the in-person dispensing protection for mifepristone during the COVID-19 pandemic.[81]

158. One month later, ACOG and others filed suit to enjoin the FDA's in-person dispensing protection for mifepristone during the pandemic.[82]

159. The district court granted a nationwide preliminary injunction and lifted the in-person dispensing protection for the pandemic.[83] The Fourth Circuit denied a stay.[84]

160. The FDA then filed for an emergency stay of the injunction with the U.S. Supreme Court.[85] 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 take abortion drugs.[86] The FDA also explained

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(Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020687Orig1s022ltr.pdf.

[81] Ex. 31, Letter from ACOG and SMFM to FDA (Apr. 20, 2020).

[82] *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020).

[83] *Id.* at 233, *order clarified*, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

[84] Ct. Order Denying Mot. for Stay Pending App., *Am. Coll. of Obstetricians & Gynecologists v. FDA*, No. 20-1824 (4th Cir. Aug. 13, 2020), ECF No. 30.

[85] Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 (U.S. Aug. 26, 2020).

[86] *Id.* at 4, 13.

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."[87] The U.S. Supreme Court granted the requested stay.[88]

B. 2021 Non-Enforcement Decision

161. The FDA reversed course, however, after President Biden took office in January 2021.

162. During the 2020 Democratic presidential primary, then-Vice President Biden promised to "vastly expand" access to abortion "across the spectrum."[89] With respect to chemical abortion, Biden said: "there should be no restrictions at all on the ability to get those drugs."[90]

163. Early in his administration, Vice-President Kamala Harris promised that she and President Biden would "fight to protect access" to abortion and "use every lever of our Administration to defend the right to safe and legal abortion—and to strengthen that right."[91]

164. The President tasked HHS and the Department of Justice (DOJ) to explore steps to "ensure access to safe and legal abortion."[92] Officials were to "use every

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[87] *Id.* at 4, 7, 21.
[88] *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).
[89] C-SPAN, Planned Parenthood Candidates Forum, Part 2 at 8:35, 15:45 (June 22, 2019), https://www.c-span.org/program/campaign-2020/planned-parenthood-candidates-forum-part-2/528774.
[90] *Id.* at 17:00.
[91] White House, Statement by Vice President Kamala Harris on Supreme Court Ruling on Texas Law SB8 (Sept. 2, 2021), https://perma.cc/7VDJ-MKZB.
[92] White House, Readout of White House Roundtable Meeting with Women's Rights and Reproductive Health Leaders (Sept. 3, 2021), https://perma.cc/CN85-AZM2.

lever at their disposal to ensure . . . access" for "every woman . . . across the country."[93]

165. HHS would be a key part of this "whole-of-government approach."[94] 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.[95]

166. On April 12, 2021, just three months after the Supreme Court granted FDA's request for a stay, the FDA replied to the ACOG-SMFM letter expressing its "inten[t] to exercise enforcement discretion" of the in-person dispensing protection during the COVID pandemic (the "2021 Non-Enforcement Decision").[96]

167. Specifically, 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."[97] The FDA's April 2021 action expressly allowed "dispensing [] mifepristone through the mail . . . or through a mail-order pharmacy" during the applicable time period.[98]

168. The FDA admitted that the studies cited in support of its decision were "not adequate on their own to establish the safety of the model of dispensing

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[93] White House, Press Briefing by Press Secretary Jen Psaki and Deputy National Security Advisor for Cyber and Emerging Technologies Anne Neuberger (Sept. 2, 2021), https://perma.cc/6CVF-3MMQ.
[94] White House, Press Gaggle by Principal Deputy Press Secretary Karine Jean-Pierre (Sept. 3, 2021), https://perma.cc/4AWK-DQQW.
[95] White House, Press Briefing by Press Secretary Jen Psaki, Secretary of Agriculture Tom Vilsack, and National Economic Council Director Brian Deese (Sept. 8, 2021), https://perma.cc/HJ77-7KFR.
[96] Ex. 32, Letter from FDA to ACOG and SMFM at 2 (Apr. 12, 2021).
[97] *All. for Hippocratic Med.*, 78 F.4th at 226.
[98] Ex. 32, Letter from FDA to ACOG and SMFM at 2.

mifepristone by mail[.]"[99]

169. The FDA's letter explained that the agency was also relying on the "small" number of adverse events voluntarily reported in the Adverse Event Reporting System (FAERS) database. But this "small number" was of the FDA's own doing, because the 2016 Major Changes abandoned the requirement that abortion providers report nonfatal adverse events.[100]

170. FDA conceded elsewhere that: (1) "FAERS data does have limitations"; (2) the "FDA does not receive reports for every adverse event"; and thus (3) "FAERS data cannot be used to calculate the incidence of an adverse event . . . in the U.S."[101]

171. Indeed, the FAERS database "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 FDA "represent a fraction of the actual adverse events occurring in American women."[102] Compounding the problem, the complicated FAERS electronic submission process itself erodes its reliability, since it takes FDA 48 pages of guidance to instruct users how to use it.[103] For all of these reasons, reporting "discrepancies render the FAERS

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[99] Ex. 34, 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 at 35 (Dec. 16, 2021) ("2021 FDA Response").

[100] *Id.* at 21.

[101] Ex. 35, FDA, Questions and Answers on FDA's Adverse Event Reporting System (FAERS), https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html#_Toc514144622 (last visited May 13, 2025).

[102] 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).

[103] Ex. 39, FDA, *Specifications for Preparing and Submitting Electronic ICSRs and*

inadequate to evaluate the safety of mifepristone abortions."[104]

172. Given the limitations of the reporting, the FDA could not—and did not—conclude that the data showed it was safe to remove the in-person dispensing protection.

173. The letter 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" and that "a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care."[105]

174. 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."[106]

175. Later that year, the FDA decided to permanently remove the in-person dispensing protection.[107]

ICSR Attachments (Apr. 2021), https://www.fda.gov/media/132096/download.

[104] 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 EFpidemiology 1 (2021).

[105] Ex. 34, 2021 FDA Response at 34.

[106] *Id.* at 2.

[107] On May 14, 2021, the FDA approved changes to the Patient Agreement Form to use "gender neutral language," replacing the pronouns "she" and "her" with "the patient." The FDA made similar revisions to the REMS document to reflect the removal of the gender-specific pronouns in the Patient Agreement Form. Despite these changes, the FDA did not require Danco to submit studies showing the safety and

176. 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."[108]

177. 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.[109]

C. 2023 REMS Change

178. *Dobbs* was decided on June 24, 2022. The decision recognized that States may regulate and prohibit abortion drugs.[110]

179. President Biden called it "an extreme decision"[111] by "not a normal Court"[112] and "committed to doing everything in his power" to "protect access" to

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effectiveness of chemical abortion on women and girls who may be taking puberty blockers, testosterone injections, or other hormones in addition to the chemical abortion drugs. Ex. 59, Supplemental Approval Letter from FDA to Danco Laboratories, LLC (May 14, 2021), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/020687Orig1s024ltr.pdf.

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

[109] *Id.*

[110] *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 259 (2022).

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

[112] White House, Remarks by President Biden on the Supreme Court's Decision on

abortion.[113]

180. 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."[114] President Biden specifically directed HHS Secretary Xavier Becerra to ensure women have "access" to abortion drugs "no matter where they live."[115]

181. 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."[116]

182. Secretary Becerra explained in a written statement: "At the Department of Health and Human Services, we stand unwavering in our commitment to ensure

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Affirmative Action (June 29, 2023), https://perma.cc/7XU8-3KL4.

[113] 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.

[114] 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.

[115] 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.

[116] HHS, Press Release: 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.

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."[117]

183. At a press conference the same day, Secretary Becerra repeated that HHS "will take steps to increase access to medication abortion" and "leave no stone unturned."[118]

184. President Biden then issued a follow-up executive order again directing HHS "to protect and expand access to abortion care, including medication abortion."[119]

185. 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."[120]

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[117] *Id.*
[118] HHS, Press Release: 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.
[119] Exec. Order No. 14,076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053, 42,053 (July 8, 2022).
[120] HHS, Press Release: HHS Takes Action to Strengthen Access to Reproductive Health Care, Including Abortion Care (Aug. 26, 2022) https://perma.cc/JH79-NBEB;

186. 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."[121]

187. 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."[122]

188. 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."[123]

189. 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 requirement and add pharmacy certification," and that the "[c]hanges are in line with the REMS Modification Notification letters sent December 16, 2021."[124]

190. The FDA's January 2023 REMS permanently "[r]emov[ed] the

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HHS, Secretary's Report: Health Care Under Attack, An Action Plan to Protect and Strengthen Reproductive Care (Aug. 2022), https://perma.cc/2SYF-G624.

[121] *All. for Hippocratic Med.*, 78 F.4th at 226.

[122] Ex. 3, FDA Center for Drug Evaluation and Research, *Summary Review of sNDA Application No: 020687Orig1s025* at 6 (Jan. 3, 2023) ("2023 Summary Review").

[123] *Id.* at 38.

[124] *Id.* at 8-9, 16.

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.[125]

191. The 2023 REMS also permanently "remove[d] the statement that the Medication Guide will be taken to an emergency room or provided to a healthcare provider who did not prescribe mifepristone so that it is known that the patient had a medical abortion with mifepristone."[126]

192. FDA formerly conditioned a mifepristone prescription on a patient's agreement to take the Medication Guide with her if she visits an emergency room or health care facility with complications "so that they will understand that [the patient is having] a medical abortion[.]"[127] Such disclosure ensures that providers explain to each "what to do if the patient experiences symptoms that may require emergency care."[128] It likewise ensures that a third-party physician will effectively diagnose and treat a woman's abortion-drug complication.[129]

193. Even so, the 2023 REMS jettisons the requirement that a woman "take the Medication Guide with [her if she] visit[s] an emergency room or [health care

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[125] Ex. 41, REMS Single Shared System for Mifepristone 200 mg (Jan. 2023), https://perma.cc/MJT5-35LF.
[126] Ex. 3, 2023 Summary Review at 11.
[127] Ex. 44, Patient Agreement for Mifepristone Tablets, 200mg (Apr. 2019), https://www.fda.gov/media/164650/download ("Mifepristone Patient Agreement").
[128] *Id.* at 12.
[129] Ex. 21, 2011 REMS at 4-5 ("When you visit an emergency room or a provider who did not give you your Mifeprex, you should give them your MEDICATION GUIDE so that they understand that you are having a medical abortion with Mifeprex.").

provider] who did not give [her] mifepristone so the emergency room or HCP will understand that the patient is having a medical abortion."[130] Despite the Guide's longstanding role in administration of mifepristone, FDA "concluded"—without citing any literature or evidence—that "patients seeking emergency medical care are not likely to carry a Medication Guide with them, the Medication Guide is readily available online, and information about medical conditions and previous treatments can be obtained at the point of care."[131]

194. FDA did not address the health risks associated with misdiagnosing an abortion-drug complication, or the common practice among abortion-drug providers of encouraging women to tell emergency staff that they are having a miscarriage when they present with complications.

195. 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 to protect access to abortion after *Dobbs*.[132] In an accompanying press release, HHS highlighted the FDA's modification of the REMS for mifepristone as one of the Department's "six core priorities" to "protect and expand access" to abortion post-*Dobbs*.[133]

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[130] *Id.* at 20.
[131] *Id.* at 12.
[132] 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).
[133] HHS, Press Release: HHS Releases Report Detailing Biden-Harris Administration

196. 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."[134]

197. 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 executive order directing HHS to "protect and expand access to abortion care, including medication abortion."[135]

198. 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.[136]

VI. The FDA's Denial of Citizen Petitions

199. The FDA has repeatedly ignored and denied citizen petitions demonstrating the dangers of the FDA's approval and progressive deregulation of abortion drugs.

200. In August 2002, physician member organizations submitted a citizen

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Efforts to Protect Reproductive Health Care Since *Dobbs* (Jan. 19, 2023), https://perma.cc/6CE3-J7DD.

[134] HHS, Press Release: 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.

[135] 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).

[136] 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.

petition with the FDA pursuant to 21 C.F.R. §§ 10.30 and 10.35; 21 C.F.R. Part 314, Subpart H (§§ 314.500–314.560); and Section 505 of the FFDCA (21 U.S.C. § 355). The petition asked the FDA to stay and ultimately reverse the 2000 Approval because of (1) the inapplicability of Subpart H, (2) the absence of an ultrasound requirement to assess gestational age and rule out ectopic pregnancy, (3) a lack of clinical research demonstrating that the restrictions would ensure safe use, (4) physicians' failure to comply with the restrictions, and (5) the fact that no sNDA was submitted for the new use of misoprostol. The petition also challenged the FDA's decision to waive the regulatory requirement to conduct a pediatric study.[137]

201. In March 2016—almost 14 years later—the FDA denied the petition.[138]

202. On March 29, 2019, physician member organizations submitted another petition urging the FDA to return to the 2000 REMS, detailing the risks posed to women and girls by the 2016 Major Changes.[139]

203. In December 2021—more than two and half years later—the FDA denied the petition and announced it would not "restore and strengthen elements of the Mifeprex regimen."[140]

VII. The Harms of Abortion Drugs

204. Abortion drugs harm women and girls.

205. The FDA's Patient Agreement warns women that a range of listed

[137] Ex. 15, 2002 Citizen Petition.
[138] Ex. 22, 2016 Petition Denial at 31 (Mar. 29, 2016).
[139] Ex. 29, Citizen Petition of AAPLOG to FDA (Mar. 29, 2019).
[140] Ex. 34, 2021 FDA Response; *see also* Ex. 40, Letter from FDA to Students for Life of Am. denying 2022 SFLA Petition, Docket No. FDA-2022-P-3209 (Jan. 3, 2023).

"symptoms" could "require emergency care."[141] Mifepristone's label states that roughly one in 25 women who take abortion drugs will end up in the emergency room.[142]

206. The FDA acknowledges that up to 7% of these women require a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding"[143] and other "miscellaneous complications."[144]

207. Recent studies demonstrate that the incidence of serious adverse events and failure is much higher. A study released earlier this year based on an all-payer insurance claims database of 865,727 mifepristone abortions found that 10.93% of women experienced sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion from 2017 to 2023.[145]

208. Others paint an even bleaker picture. A 2009 study estimated that 20% of women have an adverse event after taking chemical abortion drugs. This includes over 15% experiencing hemorrhaging and 2% having an infection during or after taking chemical abortion drugs.[146]

209. These studies confirm that 7–10% of women who take chemical abortion

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[141] Ex. 44, Mifepristone Patient Agreement.
[142] Ex. 5, FDA-Approved Label for Mifepristone (Mifeprex) (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf ("2023 Mifepristone Label").
[143] *Id.*
[144] *All. for Hippocratic Med.*, 78 F.4th at 229.
[145] Ex. 81, Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event* President, Ethics and Public Policy Center (Apr. 28, 2025).
[146] Ex. 49, Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).

drugs will need follow-up medical treatment for an incomplete or failed chemical abortion.[147]

210. Dr. Ingrid Skop is a board-certified OB/GYN with privileges in the Baptist Hospital System and a 25-year career in clinic and hospital care. She has "often treat[ed] patients who are admitted through the hospital's emergency department with complications from chemical abortions."[148]

211. Dr. Skop's patients include women below the age of 18 who have obtained abortion drugs.[149]

212. 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."[150]

213. Dr. Skop has also "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."[151]

214. Unfortunately, the effects of the abortion pill are sometimes far more devastating than a trip to the emergency room, or even surgical intervention. Since mifepristone's approval in 2000, 36 mifepristone-related deaths have been reported

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[147] Ex. 6, Niinimaki, *Comparison of rates of adverse events* at 4; Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34.
[148] Ex. 82, Skop Decl. ¶ 12.
[149] *Id.* ¶ 24.
[150] *Id.* ¶ 18.
[151] *Id.* ¶ 17.

to the FDA.[152]

215. Academic studies confirm a high incidence of morbidity and mortality.[153]

216. As between surgical and chemical abortion, the latter is far more dangerous. Chemical abortions are four times more likely than surgical abortions to result in an adverse event.[154] Chemical abortions are also much more likely to lead to complications requiring emergency medical attention.[155]

217. Studies indicate that complications following chemical abortion are not only more frequent, but are also more severe.

218. Chemical abortions are often deleterious to mental health and leave women feeling unprepared, silenced, and filled with regret.[156]

219. These effects are sometimes experienced immediately, and some women seek to reverse the effects of mifepristone.[157]

220. For others, these feelings develop upon seeing the bodies of their lifeless

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[152] FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation ("As of December 31, 2024, there were 36 reports of deaths in patients associated with mifepristone since the product was approved in September 2000.").
[153] *See* Ex. 4, Harrison Decl. ¶ 23; *see also* Ex. 36, Aultman, *supra* n. 103.
[154] Ex. 49, Maarit Niinimaki et al., *Immediate complications after medical compared with surgical termination of pregnancy*, 114 Obstetrics & Gynecology 795 (2009).
[155] *See* Ushma D Upadhyay et al., *Incidence of emergency department visits and complications after abortion*, 1 Obstet Gynecol 125, 175-183 (2015).
[156] *See* 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).
[157] *Id.*

children.[158]

221. Some abortion providers exacerbate the risk of psychological harm by failing to inform women what they may witness when they use abortion drugs. For example, one woman was surprised and devastated to see that her baby "had a head, hands, and legs" with "[d]efined fingers and toes."[159] It is common for women who see the aborted child to experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion.[160]

222. Psychological trauma is also caused both by the physical toll of the chemical abortion, as many women are "totally unprepared for the pain and bleeding they experience[] due to chemical abortion."[161]

A. Harms Caused by the 2000 Approval

223. These deaths and injuries are a direct consequence of the FDA's

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[158] *See* Ex. 82, Skop Decl. ¶ 15 (describing at least a dozen patients have expressed significant emotional distress "when they viewed the body of their unborn child in the toilet after the chemical abortion"); Pauline Slade et al., *Termination of pregnancy: Patient's perception of care*, J. OF FAMILY PLANNING & REPRODUCTIVE HEALTH CARE Vol. 27, No. 2, 72–77 (2001) ("Seeing the foetus, in general, appears to be a difficult aspect of the medical termination process which can be distressing, bring home the reality of the event and may influence later emotional adaptation.").

[159] Ex. 14, Caroline Kitchener, *Covert network provides pills for thousands of abortions in U.S. post Roe*, Wash. Post: Politics (Oct. 18, 2022), https://www.washingtonpost.com/politics/2022/10/18/illegal-abortion-pill-network/.

[160] *See* David C. Reardon et al., *Deaths Associated with Pregnancy Outcome: A Record Linkage Study of Low Income Women*, 95 S. Med. J. 834, 834–41 (2002) (women who receive abortions have a 154% higher risk of death from suicide than if they gave birth, with persistent tendencies over time and across socioeconomic boundaries, indicating "self-destructive tendencies, depression, and other unhealthy behavior aggravated by the abortion experience"); Priscilla K. Coleman, *Abortion and Mental Health: Quantitative Synthesis and Analysis of Research Published 1995–2009*, 199 British J. Psychiatry 180, 180-86 (2011).

[161] Ex. 82, Skop Decl. ¶ 13.

approval of mifepristone. But for such approval, these complications would not have occurred.

224. Each of the subsequent Challenged Actions are premised and depend on the legitimacy of the 2000 Approval.

225. While the 2000 Approval was conditioned on a lengthy list of safeguards, the drug's therapeutic benefits were still far outweighed by its risks to life and health, many of which were not accounted for by the REMS.

226. For example, abortion drugs present heightened risks based on blood type. If women with Rh-negative blood type are not administered Rhogam at the time of their chemical abortion, they may experience isoimmunization, which threatens their ability to have successful pregnancies in the future.[162] If such women are left untreated, their future children will have a 14% chance of being stillborn and a 50% chance of suffering neonatal death or a brain injury.[163]

227. Around 15% of the U.S. population has Rh-negative blood type.[164]

228. Abortion pills also pose particular danger to women with ectopic pregnancies.

229. In ectopic pregnancies, an embryo implants and grows outside the main cavity of the uterus, most often in the fallopian tube.[165] Ectopic pregnancies are not

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[162] Ex. 9, Am. Coll. of Obstetricians and Gynecologists, *Practice Bulletin No. 181: Prevention of Rh D Alloimmunization*, 130 Obstetrics & Gynecology 481 (Aug. 2017).
[163] Ingrid Skop, *The Evolution of "Self-Managed" Abortion: Does the Safety of Women Seeking Abortion Even Matter Anymore?*, Charlotte Lozier Institute (Mar. 1, 2022), https://lozierinstitute.org/the-evolution-of-self-managed-abortion/.
[164] *Id.*
[165] *See* Ex. 10, Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 193: Tubal Ectopic Pregnancy*, 131 Obstetrics & Gynecology 91, 92 (Mar. 2018),

viable and pose risks to the mother, as the fallopian tube sometimes bursts due to the growth of the embryo.

230. A ruptured fallopian tube causes life-threatening blood loss and requires immediate medical attention.

231. "[A]pproximately 2% of pregnancies are ectopic pregnancies, implanted outside of the uterine cavity. Chemical abortion drugs will not effectually end an ectopic pregnancy because they exert their effects on the uterus, which leaves women at risk of severe harm from hemorrhage due to tubal rupture, in need of emergent surgery or potentially at risk of death."[166]

232. A woman experiencing a ruptured fallopian tube may easily mistake the heavy bleeding for a side effect of the abortion pill and delay seeking medical care.[167]

233. Therefore, women should receive an ultrasound screening to confirm the absence of an ectopic pregnancy prior to being administered abortion drugs.[168]

234. An ultrasound is also the most accurate method to determine gestational age. Without one, abortionists can badly misdate the gestational age of a baby.[169]

235. One young woman reports that she did not receive an ultrasound or any

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https://perma.cc/3AA3-CNQX.

[166] Ex. 82, Skop Decl. ¶ 29.

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

[168] Ex. 10, Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 193* at 92 ("The minimum diagnostic evaluation of a suspected ectopic pregnancy is a transvaginal ultrasound evaluation and confirmation of pregnancy."); *see also* Ex. 4, Harrison Decl. ¶ 16 (recommending pre-abortion ultrasound to rule out ectopic pregnancy and confirm gestational age).

[169] Ex. 10, Am. Coll. of Obstetricians & Gynecologists, *Practice Bulletin No. 193* at 92; *see also* Ex. 4, Harrison Decl. ¶ 16.

other physical examination to determine her baby's gestational age prior to receiving chemical abortion drugs from Planned Parenthood. The abortionist misdated the baby's gestational age as six weeks, resulting in the at-home delivery of a "lifeless, fully-formed baby in the toilet," later determined to be between 30 to 36 weeks old. Because of this chemical abortion, the woman alleges that she "has endured significant stress, trauma, emotional anguish, physical pain, including laceration and an accelerated labor and delivery unaided by medication, lactation, soreness, and bleeding."[170]

236. The 2000 Approval did not require or even recommend screenings for gestational age, blood type, or ectopic pregnancy.

B. Harms Caused by the 2016 Major Changes

237. Other risks have been amplified by the FDA's steady deregulation of the mifepristone REMS.

1. Expanded gestational age

238. Take the 2016 Major Changes' extension of approved use from 49 days to 70 days.

239. The dangers of abortion drugs increase as a pregnancy progresses. The FDA acknowledges that abortion "failure rate" and thus the need for surgical intervention steadily "increase[ ] with . . . gestational age."[171]

240. The FDA, ACOG, and others have confirmed that the "failure rate"

[170] Complaint, *Doe v. Shah*, No. 501531/2021 at 9-11 (Sup. Ct. of N.Y., Cnty. of Kings Jan. 20, 2021).
[171] Ex. 34, 2021 FDA Response at 9; Ex. 5, 2023 Mifepristone Label at 13.

climbs from 2% to 7% percent when moving from seven to 10 weeks' gestation.[172] The FDA explains that these failed chemical abortions require a surgical procedure to end the pregnancy, remove retained fetal parts or tissue, or "stop bleeding."[173]

241. One study found that, after nine weeks' gestation, women who use abortion drugs are almost four times more likely to experience an incomplete abortion, nearly twice as likely to suffer an infection, and over six times more likely to require surgical intervention.[174]

242. The FDA's label notes that the rate of surgical intervention is over 10 times higher for women at 64–70 days' gestation than for women at 49 days or fewer.[175]

2. Elimination of in-person administration

243. The expansion of the permissible gestational age is especially dangerous when combined with the FDA's elimination of in-person administration of misoprostol.

244. Many abortion providers and facilitators shroud their operations in deception and encourage women to lie to emergency room staff by saying they are having a miscarriage if they suffer complications requiring urgent care.[176]

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[172] Ex. 5, 2023 Mifepristone Label at 13; Ex. Ex. 27, Am. Coll. of Obstetrics & Gynecology, *Practice Bulletin No. 225*; Ex. 2, 2016 Summary Review at 29–31.
[173] Ex. 5, 2023 Mifepristone 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).
[174] Ex. 6, Niinimaki, *Comparison of rates of adverse events* at 5.
[175] Ex. 5, 2023 Mifepristone Label.
[176] *See, e.g.,* Ex. 11, Women Help Women, *Will a doctor be able to tell if you've taken abortion pills?* (Sept. 23, 2019), https://womenhelp.org/en/page/1093/will-a-doctor-be-able-to-tell-if-you-ve-taken-abortion-pills; Ex. 12, AidAccess, *How do you know if you*

245. For example, one abortionist told *The New York Times* that she gives her patients who wish to obscure their abortions "additional 'plausible deniability'" by, for example, "send[ing] receipts with a medical code for a urinary tract infection consultation, one of the conditions the service treats, along with written information about U.T.I.s."[177] If women ask what they should do if they want or need to visit an emergency room, the abortionist "counsels that there is no medical reason for women to tell hospitals they have taken abortion pills," and that they "can allow hospitals to assume they are miscarrying[.]"[178]

246. This advice places women in significant danger, as doctors who mistake botched abortions for a miscarriages may not provide the proper care.[179]

247. Allowing the drug to be self-administered has thus created a state of affairs where emergency room doctors often do not know that their patients are experiencing complications from abortion drugs.[180]

3. Elimination of in-person follow up examination

248. Eliminating the in-person follow-up examination also compounded the risks of abortion drugs.

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have complications and what should you do?, https://aidaccess.org/en/page/459/how-do-you-know-if-you-have-complications-and-what-should-you-do.

[177] Pam Belluck, *A day with one abortion pill prescriber*, The New York Times (Jun. 9, 2025), https://www.nytimes.com/2025/06/09/health/a-day-with-one-abortion-pill-prescriber.html?smid=nytcore-ios-share (last visited Jun. 9. 2025).

[178] *Id.*

[179] Ex. 90, Declaration of Dr. Nancy Wozniak ¶¶ 21–22; Ex. 91, Declaration of Dr. Jeffrey Barrows ¶¶ 22–24; Ex. 83, Declaration of Dr. Shaun Jester ¶ 21; Ex. 88, Declaration of Dr. Tyler Johnson ¶ 15; Ex. 89, Declaration of Dr. Steven Foley ¶ 14; Ex. 86, Declaration of Dr. Regina Frost-Clark ¶¶ 16–18; Ex. 87, Declaration of Mario Dickerson ¶ 15.

[180] *Id.*

249. Unlike with surgical abortion, complications from chemical abortion 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."[181]

250. Routine follow-up examinations uncovered complications—such as retained pregnancy tissue—before they became life-threatening.[182] Removing the requirement for those visits naturally resulted in more women reporting to the emergency room to receive treatment for infections and other serious complications.

251. 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."[183]

252. The FDA's Prescriber Agreement continues to advise 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."[184] The patient's "adherence to directions for use and visits is critical to the drug's effectiveness and safety."[185]

253. Dr. Shaun Jester has seen firsthand the harm caused by the lack of follow-up care for women given abortion drugs.[186] Dr. Jester is a board-certified

[181] Ex. 18, 2000 Approval Memo at 4.
[182] Ex. 83, Jester Decl. ¶ 25.
[183] Ex. 24, 2000 Mifeprex Label at 8, 15.
[184] Ex. 43, 2023 Mifeprex Prescriber Agreement at 1.
[185] Ex. 18, 2000 Approval Memo at 4.
[186] Ex. 83, Jester Decl. ¶¶ 2, 17.

obstetrician and gynecologist and the Medical Director of Moore County Ob/Gyn.[187]

254. 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 Dr. Jester 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."[188]

255. 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 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."[189] 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."[190]

256. In his experience, "the requirement for an in-person, postabortion office

[187] *Id.* ¶ 2.
[188] *Id.* ¶ 17
[189] *Id.* ¶ 20.
[190] *Id.* ¶ 27.

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."[191] "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."[192]

4. Elimination of reporting for non-fatal adverse events

257. The FDA's decision not to require abortion providers to report all adverse events for chemical abortion drugs harms created an inaccurate and false safety profile for the use of chemical abortion drugs.

258. Due to inadequate adverse event reporting, the true rates of risks associated with chemical abortion drugs remain undercounted and therefore are unknown.

259. 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.

260. 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.

261. Abortion providers who prescribe or dispense chemical abortion drugs

[191] *Id.* ¶ 10.
[192] *Id.* ¶ 25.

to citizens of Plaintiffs are not providing women with an adequate, accurate assessment of the known risks and effects associated with chemical abortion.

262. 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.

263. These reckless actions were taken in the face of data showing that chemical abortion was already resulting in emergency room visits at a much higher rate than surgical abortion or childbirth.[193]

C. Harms Caused by the 2021/2023 Dispensing Changes

264. Dispensing drugs remotely with no in-person care creates higher risks and complication rates than in-person care.

265. Without an initial in-person visit, women may underestimate gestational age and take the drugs past the approved 10-week limit,[194] or do so intentionally. 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."[195]

266. Just before eliminating the in-person dispensing requirement, the FDA told the Supreme Court that "in-person dispensing avoids the possibility of delay" in taking mifepristone and the increased "risks of serious complications" caused by such delay.[196]

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[193] *See supra* nn. 154–55.
[194] *Id.* ¶ 28; Ex. 83, Jester Decl. ¶ 13 *et seq*.
[195] Ex. 82, Skop Decl. ¶ 28.
[196] Appl. for Stay, *Food & Drug Admin. v. Am. Coll. of Obstetricians and*

267. As witnessed first-hand by physicians like Dr. Skop, the "FDA's actions in 2016 and 2021 have increased the frequency of complications from chemical abortion."[197]

268. 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."[198]

269. "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)."[199]

270. In another example, 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

Gynecologists, No. 20A34 at 6.
[197] Ex. 82, Skop Decl. ¶¶ 20–21.
[198] *Id.* ¶ 26.
[199] *Id.* ¶ 22.

aspiration procedure to resolve her complication."[200]

271. 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.[201] 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."[202]

272. 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]."[203] These conditions cannot be guaranteed during standard shipping transit, particularly in summer or winter weather conditions. The FDA's decision to allow mail-order abortion drugs neither acknowledged nor addressed this known issue.

273. 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. Two

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[200] *Id.* ¶ 23.
[201] Chloe Murtagh et al., *Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet*, 97 Contraception 287 (2018).
[202] *Id.* at 288 (emphasis added).
[203] Ex. 5, 2023 Mifepristone Label at 13.

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."[204]

D. Harms Caused by the 2019 Generic Approval

274. Plaintiffs' sovereign injuries are aggravated and worsened by the FDA's approval of a generic version of mifepristone in 2019.

275. The introduction of the generic version of mifepristone jumpstarted competition and lowered prices for abortion drugs.[205]

276. As one abortion advocate explained, "The minute GenBioPro was in the act, all sorts of things started happening. Danco reduced its price because there was competition . . . . Danco wasn't interested at all in anything innovative because they were happily doing their thing and already had their people on board. So having competition in the market was critical."[206]

277. "FDA approval of the generic set price competition in motion: GenBioPro set their price lower than Danco, which then dropped their price. Lower prices and more options increased access to mifepristone for clinicians and patients across the country."[207]

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[204] Murtagh, *supra* n. 202 at 288.
[205] Brief Amicus Curiae by GenBioPro, Inc., *FDA v. Alliance for Hippocratic Medicine*, No. 22A901 (U.S. Apr. 14, 2023); 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.
[206] Baker, *supra* n. 12 at 92 (quoting Francine Coeytaux, interview by Carrie N. Baker (Apr. 3, 2023)).
[207] *Id.*

278. Studies confirm that the cost of chemical abortion has decreased since the 2019 Generic Approval. For example, a 2012 study showed that the median charge for a surgical abortion in the first 10 weeks ($704) was comparable to the median charge for a chemical abortion ($717).[208] By 2023, with generic mifepristone competing with Mifeprex, the median charge for chemical abortion had fallen to $607.[209]

279. Meanwhile, the cost of first-trimester surgical abortion increased from $631 in 2017 to $771 in 2021.[210]

280. Lower prices have solidified chemical abortion as the dominant means of terminating pregnancies in the United States. A study conducted in three-year intervals by the Guttmacher Institute estimates that, in 2017, 31% of abortions in the United States were chemical abortions. In 2020, after the approval of generic mifepristone, that number skyrocketed to 53%. In 2023, chemical abortion accounted "for 63% of all abortions in the formal health care system."[211] And these figures do not even include the flood of chemical abortions "obtained outside of the formal health

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[208] Jenna Jerman & Rachel K. Jones, *Secondary Measures of Access to Abortion Services in the United States, 2011 and 2012: Gestational Age Limits, Cost, and Harassment*, Womens Health Issues (Jul.-Aug. 2014).
All values are adjusted for inflation using the United States Bureau of Labor Statistics CPI Inflation Calculator available at https://www.bls.gov/data/inflation_calculator.htm.

[209] Ushma D. Upadhyay et al., *Pricing of medication abortion in the United States, 2021-2023*, Perspect. Sex. Reprod. Health (Sept. 2024).

[210] Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017-2021*, Abortion Facility Database Project by the University of California San Francisco's Advancing New Standards in Reproductive Health (2022).

[211] Ex. 92, Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—An Increase from 53% in 2020*, Monthly Abortion Provision Study by the Guttmacher Institute (Mar. 2024).

care sector or any abortions—whether self-managed or provided by out-of-state clinicians—involving medication mailed to states with total abortion bans."[212]

VIII. Economic Injuries to Plaintiffs

281. In addition to the incalculable toll of pain, suffering, and loss of human life, the FDA's actions have inflicted concrete economic injury on states as the payers and insurers of residents' medical expenses.

282. This "effect on the states' fiscs" is a concrete, economic injury. *Texas v. United States (DAPA)*, 809 F.3d 134, 152 (5th Cir. 2015); *see also, e.g., Biden v. Nebraska*, 600 U.S. 477, 490 (2023) ("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."). 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); *United States v. Texas*, 599 U.S. 670, 687-88 (2023) (acknowledging that the same principle of concrete, monetary injury applies to states challenging the federal government under the APA); *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).

A. Medicaid reimbursements

283. Plaintiffs, through their state-level agencies and political subdivisions,

[212] *Id.*

operate Medicaid programs to pay medical expenses for their residents.

284. While Plaintiffs do not pay for abortions, they do pay for medical expenses incurred to treat women suffering from post-abortion complications.

285. In 2020, Florida Medicaid paid at least $543.73 to treat complications from a chemical abortion. The patient received a dose of mifepristone and four doses of misoprostol from an abortion clinic. After taking the drugs, she experienced nausea, vomiting, and abdominal pain with a fever of 103 degrees. She reported to the hospital and was administered laboratory testing, an ultrasound, IV fluids, and antibiotics for endometritis (inflammation of the uterine lining caused by bacterial infection).[213]

286. In 2022, Florida Medicaid paid at least $433.39 to treat complications from a chemical abortion. The patient received a dose of mifepristone and two doses of misoprostol from an abortion clinic. After taking the drugs, she experienced heavy bleeding and flank pain. She reported to the emergency room and was administered laboratory tests, an ultrasound, medications, and a pelvic exam that led to the removal of tissue from her cervical os and vaginal vault. Pathology showed the tissue to be "degenerated chorionic villi in a background of purulent exudate consistent with inflamed/infected products of conception."[214]

287. On information and belief, the Texas Medicaid program has also reimbursed healthcare providers who provided emergency treatment to women suffering from chemical abortion complications during the last six years.

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[213] Ex. 73, Declaration of Julie Webster ¶ 6; Ex. 72, Declaration of Ann Dalton ¶ 12.
[214] Ex. 73, Declaration of Julie Webster ¶ 7; Ex. 72, Declaration of Ann Dalton ¶ 13.

288. These Medicaid reimbursements, which diverted resources from Plaintiffs' general budgets, are a direct and foreseeable result of the FDA's approval and deregulation of abortion drugs.

289. The FDA has consistently identified emergency rooms as the backstop for abortion drug harms.

290. 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."[215] The 2000 REMS required dispensing physicians to be capable of providing emergency care, and the FDA still requires doctors "to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary."[216] The drug was also "contraindicated" where "access to emergency services" was "[in]adequate."[217] And the FDA required prescribing physicians without the ability to perform emergency services to "direct" women "to a hospital for emergency services."[218]

291. 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 present in an emergency room setting" after taking abortion drugs. 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.[219]

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[215] Ex. 18, 2000 Approval Memo at 3 (emphasis added).
[216] *Id.* at 6; *see also* Ex. 44, Mifepristone Patient Agreement.
[217] Ex. 18, 2000 Approval Memo at 5.
[218] *Id.*
[219] Ex. 45, Letter from Danco Labs. to Emergency Room Doctors 1 (Nov. 12, 2004) https://perma.cc/734R-LLSQ.

292. 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.[220] The REMS required prescribers "to assure patient access to appropriate medical facilities" that were "equipped to provide blood transfusions and resuscitation, if necessary."[221] And the agency instructed women to take the medication guide with them "[w]hen [they] visit an emergency room."[222]

293. In its 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.[223]

294. The agency did the same in denying the 2019 citizen petition, noting prescribers were required to "ensure that mifepristone is prescribed [only] to women for whom emergency care is available."[224] 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."[225] Recognizing 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."[226]

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[220] Ex. 21, 2011 REMS at 5.
[221] *Id.* at 1, 7.
[222] *Id.* at 4.
[223] Ex. 22, 2016 Petition Denial at 21.
[224] Ex. 34, 2021 FDA Response at 39.
[225] *Id.* at 9.
[226] *Id.* at 12.

295. In evaluating mail-order dispensing, the FDA relied on five studies. In one, "7 percent of participants had clinical encounters in [emergency room (ER)]/urgent care centers."[227] 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."[228] A third study revealed that "12.5 percent had an unplanned clinical encounter."[229] 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."[230] 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."[231]

296. Finally, the FDA's current label for mifepristone also directs women to emergency rooms if one of many adverse events arises.[232] It says that an estimated 2.9 to 4.6 percent of women will visit the emergency room after taking mifepristone on the label.[233] That's roughly one in 25 women who will end up in the emergency room if they take abortion drugs as directed.

B. Investigative and Prosecutorial Costs

297. The 2021/2023 Dispensing Changes inflict economic injury in another way: the expense of investigating, prosecuting, and enforcing judgments for illegal

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[227] Ex. 34, 2021 FDA Response at 32.
[228] *Id.*
[229] *Id.* at 32–33.
[230] *Id.* at 33.
[231] *Id.* at 34.
[232] Ex. 5, 2023 Mifepristone Label at 2.
[233] *Id.* at 8.

mail-order abortions.

298. Telehealth abortion is illegal in Florida and Texas.

299. But as discussed below, the 2023/2023 Dispensing Changes created a mail-order abortion economy in all 50 states.

300. Plaintiffs have been forced to divert resources to address the explosion of abortion drugs mailed to their residents by abortionists operating under the 2021/2023 Dispensing Changes and their States' "shield laws."

301. For example, in December 2024, Texas Attorney General Ken Paxton petitioned for an injunction and civil penalties against Dr. Margaret Carpenter, a New York-based physician and abortion activist, for sending mifepristone and misoprostol to a Texas woman.[234] The woman, who did not have any physical conditions justifying the abortion under state law, suffered hemorrhaging and was taken to the hospital. On February 13, a Texas judge entered a default judgment ordering Carpenter to pay over $100,000 in penalties.[235] However, when Texas attempted to domesticate the judgment in July, the county clerk refused to docket Texas's filing in light of New York's shield law.[236] Texas is pursuing a mandamus action against the clerk, but New York Governor Kathy Hochul has publicly vowed to oppose Texas's efforts: "Texas Attorney General Ken Paxton has repeatedly tried to file a judgment

[234] Ex. 50, Pet. and App. for Temporary and Permanent Injunctive Relief, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Dec. 12, 2024).
[235] Ex. 51, Final Judgment and Order Granting Permanent Injunction, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Feb. 13, 2025).
[236] *See* Michael Hill, *New York clerk again refuses to enforce Texas judgment against doctor who provided abortion pills*, Associated Press (July 14, 2025).

against a New York doctor and our response has been clear: hell no."[237]

302. Law enforcement agencies in the State of Florida are also actively investigating out-of-state abortionists.

IX. Sovereign Injuries to Plaintiffs

303. States have the sovereign power to enact and enforce regulations on abortion.

304. State abortion laws serve the important state interests of "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).

305. "[F]rom time immemorial," States have maintained primary responsibility for regulating the medical field through their constitutionally reserved powers to protect their citizens' health and welfare. *Dent v. West Virginia*, 129 U.S. 114, 122 (1889).

306. 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.*,

[237] *See* Alejandra O'Connell-Domenech, *Texas Attorney General Paxton sues New York county clerk over abortion ruling*, The Hill (July 28, 2025).

347 U.S. 442, 451 (1954).

307. 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.

308. To serve these compelling sovereign interests, Plaintiffs have enacted statutes regulating and, in many instances, prohibiting, abortion drugs.

1. Florida Law

309. In 1868, following the Union's victory in the Civil War, Floridians amended their state constitution to recognize that "all men are by nature free and equal, and have certain inalienable rights." Fla. Const. Dec. of Rights, § 1 (1868). Delegates to the constitutional convention made clear that these rights—including the right to life—belong to each member of "humanity."

310. The same year, the Florida Legislature (which included many delegates to the constitutional convention) enacted a statute criminalizing elective abortion from conception. Laws of Fla. ch. 1637, subc. 3, § 11, subc. 8, § 9 (1868), codified at Fla. Rev. St. §§ 2387, 2618 (1892); Fla. Stat. §§ 782.10, 797.01 (1941). Florida had theretofore punished elective abortion under the common law. *See State v. Barquet*, 262 So. 2d 431, 438 (Fla. 1972).

311. Florida's statutory ban on elective abortion remained in effect for over a century, until the Florida Supreme Court declared it void for vagueness in 1972. *Id.* at 438. The Florida Legislature reacted swiftly. Within months, it enacted another statute prohibiting abortion from conception, with narrow exceptions. Laws of Fla. ch. 1972-196, § 2 (1972).

312. Less than a year later, the United States Supreme Court discovered a right to abortion in the Fourteenth Amendment's Due Process Clause. *Roe v. Wade*, 410 U.S. 113, 164 (1973).

313. Relying on *Roe*, the Florida Supreme Court discovered an analogous right to abortion in the "Privacy Clause" of the Florida Constitution in 1989. *In re T.W.*, 551 So. 2d 1186 (Fla. 1989).

314. On June 24, 2022, the United States Supreme Court overturned *Roe*, calling it "egregiously wrong from the start." *Dobbs*, 597 U.S. at 231. The United States Constitution "does not confer a right to abortion." *Id.* at 292.

315. On April 1, 2024, the Florida Supreme Court deemed *In re T.W.* "clearly erroneous" and held that the Florida Constitution does not guarantee a right to elective abortion. *Planned Parenthood of Sw. & Cent. Fla. v. State*, 384 So. 3d 67, 88 (Fla. 2024).

316. That decision triggered Florida's Heartbeat Protection Act, which prohibits abortion of any child with a gestational age of more than six weeks. Fla. Stat. § 390.0111(1). The Act includes exceptions in cases where an abortion is necessary to save the mother's life or avert serious risk of substantial and irreversible physical impairment of a major bodily function; where a fatal fetal abnormality exists prior to the third trimester; and before 15 weeks where the pregnancy is a result of rape, incest, or human trafficking. Fla. Stat. § 390.0111(1)(a-d). A person who willfully performs, or actively participates in, a termination of pregnancy in violation of these requirements commits a third-degree felony. Fla. Stat. § 390.0111(10)(a).

317. The Act prohibits physicians from using telehealth to perform an abortion. "Any medications intended for use in a medical abortion must be dispensed in person by a physician and may not be dispensed through the United States Postal Service or by any other courier or shipping service." Fla. Stat. § 390.0111(2).

318. These provisions took effect on May 1, 2024.

2. Texas Law

319. Texas law protects all "human being[s] who [are] alive, including [] unborn child[ren] at every stage of gestation from fertilization until birth." Tex. Penal Code § 1.07(26).

320. Articles 4512.1–4512.6 of the Texas Revised Civil Statutes prohibit "destroying unborn children" or administering, or furnishing the means of procuring, any drug or medicine that procures an abortion, unless the life of the mother is endangered. Violations are punishable by two to five years' imprisonment. These laws were codified in 1925 but could not be enforced between January 22, 1973 (when *Roe* held them unconstitutional) and June 24, 2022 (when *Roe* and its progeny were overturned).

321. Section 170A.002 of the Texas Health and Safety Code also makes abortion a felony criminal offense unless the abortion is performed to avert the risk of death or a serious risk of substantial impairment of a major bodily function. *See* Tex. Health & Safety Code § 170A.004. Violations of section 170A.002 are punishable by five to 99 years' imprisonment. *See* Tex. Penal Code § 12.32. Section 170A.002 was enacted in 2021 and went into effect on August 25, 2022, 30 days after judgement was issued in *Dobbs*.

322. Texas law prohibits anyone not licensed as a physician in Texas from performing an abortion. Tex. Health & Safety Code §§ 171.003; 171.063(a)(1). Texas law also requires physicians to conduct an in-person examination of a pregnant woman before providing an abortion-inducing drug. Tex. Health & Safety Code § 171.063(c)(1). It is a felony under Texas law for a manufacturer, supplier, physician, or any other person from providing to a patient any abortion-inducing drug by courier, delivery, or mail service. Tex. Health & Safety Code § 171.063(b-1).

3. Effects of the Challenged Actions on the Enforcement of Plaintiffs' Law

323. 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[.]").

324. A State may establish standing against the federal government based on its "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.'" *DAPA*, 809 F.3d at 153 (citation omitted) (collecting cases).

325. The FDA's actions interfere with Plaintiffs' "sovereign interest in 'the power to create and enforce a legal code'" by enabling state-law criminal and civil violations by third parties. *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)); *see also Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991); *Louisiana v.*

EEOC, 705 F. Supp. 3d 643, 654 (W.D. La. 2024) (if states "have unambiguously expressed their opposition to purely elective abortions by passing laws prohibiting the same," then "the principles of federalism" "clearly" give the states Article III standing to challenge a federal agency's intrusion upon that sovereign prerogative).

326. These harms are distinct (and in addition to) the harms suffered by Plaintiffs' citizens as a result of Defendant's challenged actions.

327. Harms to sovereign interests in enacting and enforcing state law are irreparable. *See, e.g., Kansas v. United States*, 249 F.3d 1213, 1227 (10th Cir. 2001).

328. "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).

329. These effects on state sovereignty were not only predictable; they were by design.[238]

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

i. *The 2000 Approval*

331. As a result of the 2000 Approval, Plaintiffs have suffered injury to their sovereign interests in enacting and enforcing their laws.

332. The 2000 Approval authorized the administration of abortion drugs through 49 days' (seven weeks') gestation.

[238] *See, e.g., supra* n. 21.

333. Plaintiffs prohibit elective abortion at an earlier point in pregnancy.

334. Allowing physicians to administer mifepristone at seven weeks' gestation frustrates Florida's ability to enforce its prohibition on elective abortion from a detectable heartbeat.

335. Allowing physicians to administer mifepristone at seven weeks' gestation frustrates Texas's ability to enforce its prohibition on elective abortion from conception.

336. Were the 2000 REMS to operate post-*Dobbs*, a woman unable to obtain an elective abortion in Florida or Texas could travel to an out-of-state abortionist and be administered mifepristone. The woman could then return home, where her child would be starved to death over the ensuing days. These abortions, while set into motion by drugs ingested outside the state, would take place and be completed in Florida or Texas.

337. Thus, the 2000 Approval frustrates Florida's ability to ensure that no elective abortions occur within Florida borders on Florida women and children after six weeks' gestation.

338. The 2000 Approval frustrates Texas's ability to ensure that no elective abortions occur within Texas borders on Texas women and children.

ii. *The 2016 Major Changes*

339. While Plaintiffs' sovereign injuries would exist under the 2000 REMS, the 2016 Major Changes exacerbate Plaintiffs' inability to regulate abortion within their borders.

340. Extending the period of authorized use from seven to 10 weeks' gestation causes more children to be illegally aborted within Florida and Texas by making more women eligible for chemical abortion.

341. Eliminating the physician requirement causes more children to be illegally aborted within Florida and Texas by expanding the class of providers authorized to offer chemical abortion.

342. Eliminating the mandatory in-person follow-up examination and the requirement that misoprostol be administered in-person causes more children to be illegally aborted within Florida and Texas by making chemical abortion a seemingly more convenient and therefore more popular option.

iii. *The 2021/2023 Dispensing Changes*

343. While Plaintiffs' sovereign injuries would exist under the 2000 or 2016 REMS, the 2021/2023 Dispensing Changes exacerbate Plaintiffs' inability to regulate abortion within their borders.

344. The 2021/2023 Dispensing Changes removed all in-person dispensing and administration protections, enabling abortion drugs to be mailed to any State regardless of federal or state law.

345. This 50-state mailing economy was not merely a side-effect of the FDA's actions—it was the agency's express purpose.

346. 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.

347. The FDA worked in tandem with pro-abortion states that responded to *Dobbs* by enacting "shield" laws designed to facilitate out-of-state mail-order abortions and prevent States like Plaintiffs from enforcing their abortion laws.[239]

348. These shield laws often explicitly name mifepristone, and the proponents of those laws openly proclaim that they seek to abrogate the sovereignty of other states.[240]

349. The actions have had their intend result: a mail-order abortion economy and widespread use of drugs up to and past 10 weeks of pregnancy "in all 50 states."[241]

Aid Access

350. Many abortion providers, like Aid Access, have explained to the press how Defendants' actions enabled them to frustrate state abortion restrictions and mail FDA-approved abortion drugs "to people in all 50 states, even those [like Plaintiffs] that have banned it."[242]

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[239] 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/; 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/.

[240] *Id.*

[241] 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; Rebecca Grant, ACCESS (2025) ("Post-*Dobbs*, activist groups have once again stepped up and put themselves on the line to resist. Building on the work of their feminist forebearers and international allies, they are charting new pathways for access in the face of unprecedented acts to subjugate and control half of America's population. Working above ground, underground, and in legal gray areas, they've . . . formed community networks to distribute pills for free to people who needed them.").

[242] Ex. 62, Grant, *supra* n. 243.

351. Before the 2021/2023 Dispensing Changes, Aid Access did not mail FDA-approved abortion drugs.

352. 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."[243]

353. But then in 2021 the "in-person dispensing requirement for mifepristone" was removed.[244] 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 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."[245]

354. 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.

355. 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.

356. This change transformed the process from "needing to wait three or four

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[243] *Id.*
[244] *Id.*
[245] *Id.*

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."[246]

357. 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 Florida and Texas. People "feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline" rather than from India.[247]

358. 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 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."[248]

359. 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."[249]

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

360. 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.[250]

361. The NBC story provided images of New York's Aid Access providers mailing GenBioPro's generic mifepristone to women in states like Florida and Texas. The images show that next to pill bottles and mailing envelopes, the abortion providers have stacks of white boxes of mifepristone with GenBioPro's distinctive purple and pink circular logo.[251]

362. 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.[252]

363. 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

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[250] 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.

[251] Ex. 63, Brooks & Burns, *supra* n. 250.

[252] 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."[253]

364. 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."[254] "People from anywhere can be freaking out because everyone is taking these pills at home alone."[255] 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."[256]

365. When women call about complications, Dr. Prine tells them "that their experiences are nothing out of the ordinary, and that they almost certainly don't need to go to the emergency room."[257]

366. 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.'"[258]

367. The Washington Post shared Dr. Prine's comments with other doctors.

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

It reported, "A woman in that situation could have hemorrhaged or become septic, according to five OB/GYNs interviewed for this article."[259]

368. 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 that situation to go to the hospital immediately. "At that point, your life is the most important thing."[260]

369. Aid Access will provide abortion drugs to a woman or girl of any age.[261]

370. 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."[262]

371. 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.[263]

372. In February 2024, the *New York Times* profiled Ms. Jacobson and her

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[259] *Id.*
[260] *Id.*
[261] Ex. 75, Plan C, Florida, https://www.plancpills.org/abortion-pill/florida#tele-health; Ex. 76, Plan C, Texas, https://www.plancpills.org/abortion-pill/texas#tele-health.
[262] Ex. 66, Kitchener, *supra* n. 256.
[263] *Id.*

Boston-based mailing operations. The *New York Times* likewise reported that these 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."[264]

373. 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."[265]

374. 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."[266]

375. The *New York Times* article profiled two Texas women who received FDA-approved abortion drugs through this service.[267] 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.[268]

376. 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

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[264] 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.
[265] *Id.*
[266] *Id.*
[267] *Id.*
[268] Ex. 66, Kitchener, *supra* n. 256.

and thousands of pills are being shipped everywhere across the United States from a handful of providers. That alone speaks to the nature of what mailed medication abortion can do."[269]

377. By mailing abortion drugs to men in Texas, Aid Access has facilitated the death of multiple preborn children in Texas. *See Davis v. Cooprider*, No. 2:25-cv-00220 (S.D. Tex. Aug. 11, 2025), ECF No. 1; *Rodriguez v. Coeytaux*, No. 3:25-cv-00225 (S.D. Tex. Jul. 20, 2025), ECF No. 1.

Massachusetts Abortion Project (MAP)

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

379. MAP launched in the fall of 2023 as a project of Cambridge Reproductive Health Consultants, a nonprofit.[270]

380. 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."[271]

381. MAP mails FDA-approved abortion drugs to women and girls who are up to 10 weeks pregnant and who are 16 or older.[272]

382. 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

[269] Ex. 68, Belluck, *supra* n. 266.
[270] 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.
[271] Ex. 64, Nadworny, *supra* n. 252.
[272] *Id.*

located."[273]

383. MAP harnesses websites like plancpills.org "to get the word out to women nationwide."[274] 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.[275]

384. 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."[276] 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.[277] Occasionally some women "talk by phone with [Dr. Angel] Foster or a prescriber."[278]

385. MAP's abortion drugs "cannot be picked up in person."[279]

386. On its website, MAP states that if a woman needs follow up care, they should turn to local providers in their 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 about 2 in 100 cases. However, if you are worried, you can get an ultrasound at an

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[273] *Id.*
[274] Ex. 1, Calvert, *supra* n. 272.
[275] Ex. 64, Nadworny, *supra* n. 252.
[276] *Id.*
[277] *Id.*
[278] Ex. 1, Calvert, *supra* n. 272.
[279] Ex. 75, Plan C, Florida; Ex. 76, Plan C, Texas.

emergency room 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."[280]

387. 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."[281]

388. On average, "MAP currently sends out about 500 prescriptions a month."[282] 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."[283]

389. NPR provided images of MAP mailing abortion drugs to women in states like Florida and Texas. These images show that MAP packing abortion drug mailers using Danco's well-known orange boxes of Mifeprex.[284]

390. In August 2024, the *Wall Street Journal* reported that MAP now hosts "pill-packing parties to help strangers in faraway states circumvent strict laws."[285]

391. At these pill-packing parties, volunteers help "mail abortion medication

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[280] Ex. 69, MAP, Frequently asked questions, https://www.cambridgereproductivehealthconsultants.org/map.
[281] Ex. 64, Nadworny, *supra* n. 252.
[282] *Id.*
[283] *Id.*
[284] *Id.*
[285] Ex. 1, Calvert, *supra* n. 272.

to women in states with strict limits." 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 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."[286]

392. 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.[287]

Abuzz

393. A third similar shield-law service is Abuzz, which serves some States with abortion bans.[288]

394. Abuzz provides abortion drugs to every state except Texas, Mississippi, Alabama, and Georgia.[289] It provides abortion drugs through 10 weeks of pregnancy and beyond.[290]

395. Abuzz's website states that it does not provide in-person care. Instead,

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[286] *Id.*
[287] *Id.*
[288] Ex. 68, Belluck, *supra* n. 266.
[289] Ex. 70, Abuzz, https://www.abuzzhealth.com/.
[290] Ex. 71, Abuzz, FAQs, https://www.abuzzhealth.com/faqs/.

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."[291] "Your FDA-approved medications (mifepristone and misoprostol) will be sent by mail."[292]

396. 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 wrong' or 'I'm pregnant and bleeding. I'm scared there's something wrong' and you should get the care you need."[293]

We Take Care of Us

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

398. Plan C reports that We Take Care of Us will provide abortion drugs to a woman or girl of any age.[294]

399. 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.[295]

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[291] Ex. 70, Abuzz.
[292] Ex. 71a, Abuzz, How it works, https://www.abuzzhealth.com/how-it-works/.
[293] Ex. 71, Abuzz, FAQs.
[294] Ex. 75, Plan C, Florida; Ex. 76, Plan C, Texas.
[295] Ex. 74, We Take Care of Us, FAQs, https://www.wetakecareof.us/faqs.

400. 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."[296] We Take Care of Us requires only a "10-15 minute online intake request."[297]

401. We Take Care of Us accepts payment by Venmo and "can arrange shipment to any U.S. state, Guam, Puerto Rico and APO addresses."[298]

402. 402. Another organization, Her Safe Harbor, ships abortion drugs to all 50 states.[299]

403. 403. Her Safe Harbor advertises processing and shipping "1 mifepristone tablet and 2 doses of 4 misoprostol tables (FDA approved)" within 4-6 days.[300]

404. 404. Her Safe Harbor ships abortion drugs in quantities that would facili-tate up to 162 abortions per week, including to cities in Texas such as Tomball, Houston, Beaumont, Fulshear, and El Paso.[301]

Online Directories

405. Online directories connect these abortion providers to women in Florida and Texas.

406. The organization Plan C describes itself as "a public health creative campaign on abortion pill access, started in 2015 by a small team of veteran public health

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[296] *Id.*
[297] Ex. 74a, We Take Care of Us, Care, https://www.wetakecareof.us/care.
[298] *Id.*
[299] Ex. 84, Her Safe Harbor, https://hersafeharbor.com.
[300] *Id.*
[301] Bridget Grumet, *Abortion pills by mail surge despite Texas' bans. Will it last?*, Austin American-Statesman (Jan. 16, 2025), https://www.statesman.com/story/opinion/columns/2025/01/16/abortion-pill-texas-ban-law-mifepristone-misoprostol-plan-c-pills/77332833007/.

advocates, researchers, social justice activists." Plan C "works to transform access to abortion in the US by normalizing the self-directed option of abortion pills by mail."[302]

407. To this end, Plan C "maintain[s] the most comprehensive online directory of abortion pill information and support services in the US."[303]

408. Plan C's directory advertises "[a]bortion pills by mail in every state."[304] Regarding Florida and Texas, the website says, "Abortion access in [your state] is restricted, but abortion pills are still available by mail from providers outside of [your state]. Show my options."[305] Under a section entitled, "Options for getting pills," Plan C identifies "[o]nline clinics that mail pills," "[w]ebsites that sell pills," and "[c]ommunity networks that mail pills."[306]

409. The "online clinics" are described as "US-licensed clinicians who ship pills to you after a brief online form or phone/video visit."[307]

410. Plan C identifies seven online clinics for Florida: Abuzz, Cambridge Reproductive Health Consultants (MAP), Aid Access, We Take Care of Us, A Safe Choice, and two international online clinics.[308]

411. For Texas, Plan C identifies seven online clinics: Cambridge Reproductive Health Consultants (MAP), Aid Access, We Take Care of Us, A Safe Choice, and

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[302] Ex. 77, Plan C, About Us, https://www.plancpills.org/about.
[303] Ex. 78, Plan C, 2024 Annual Report, https://cdn.prod.website-files.com/5f7e0692875fa8243cac6673/6765f8d1ce4a2a258784864f_Plan_C_Annual_Report_2024.pdf.
[304] Plan C, https://www.plancpills.org/; Ex. 80, Plan C, Websites That Sell Pills, https://www.plancpills.org/websites-that-sell-pills.
[305] Ex. 75, Plan C, Florida; Ex. 76, Plan C, Texas.
[306] *Id.*
[307] *Id.*
[308] Ex. 75, Plan C, Florida.

three "international online clinics." The website notes that one of the international clinics "SHIPS TO MEXICO ONLY, BUT CAN BE PICKED UP ALONG U.S. BORDER AT COURIER LOCATIONS."[309]

412. According to the website, Abuzz and MAP will mail FDA-approved abortion drugs to women aged 16+. Aid Access, We Take Care of Us, and A Safe Choice will prescribe abortion pills to women of "any age."[310]

413. Plan C also reports that each of these online clinics offer the service of providing "pills in advance"—i.e., prescribing abortion drugs to a woman who is not yet pregnant.[311]

414. Plan C also directs Texans and Floridians to AccessMA, identified as a "network[] of volunteers in the US that ship generic abortion pills for free." Plan C urges users to request pills from AccessMA by creating a protonmail.com account and sending an email to the appropriate email address listed on redstateaccess.org.[312] Requests from Florida are to be sent to sjog2010@proton.me. Requests from Texas are to be sent to texascccess@proton.me. The request must include "your name, full mailing address, estimated weeks gestation or date of last menstrual period."[313] AccessMA's "[c]lients can request pills in 1) identifiable blister packs, 2) medicine bottles, or 3) unidentifiable loose pills in sealed pill packets." AccessMA is advertised to

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[309] Ex. 76, Plan C, Texas.
[310] Ex. 75, Plan C, Florida; Ex. 76, Plan C, Texas.
[311] *Id.*; *see also* Ex. 85, Her Safe Harbor, *Buy Abortion Pills For Future Use*, https://hersafeharbor.com/buy-abortion-pills-for-future-use/.
[312] *Id.*
[313] Ex. 79, Free Medication Abortion, https://www.redstateaccess.org/.

ship pills to women of all ages.[314]

415. Under a heading entitled, "Why are online clinics listed if my state does not allow telehealth for abortion?," Plan C explains that "[t]his is possible because some states have 'shield laws' in place that protect clinicians when they provide telehealth care to someone in another state."[315]

416. Plan C is not alone. A second organization known as Abortion Finder boasts "the most comprehensive directory of trusted (and verified) abortion service providers and assistance resources in the United States,"[316] while a third organization, I Need An A, claims it was "the first comprehensive and regularly updated resource for abortion seekers in the US. Since then, we've been called the 'Quintessential Post-Roe Resource' by The Nation, appeared on John Oliver's Last Week Tonight, and, most importantly to us, have helped more than 1.4 million people learn about their options similar 'comprehensive directories' of abortion options for women in states regulating abortion."[317]

417. Plan C and affiliated groups advertise their directories on social

[314] Ex. 75, Plan C, Florida; Ex. 76, Plan C, Texas.
[315] *Id.*
[316] Abortion Finder, https://www.abortionfinder.org/.
[317] I Need An A, https://www.ineedana.com/.

media[318] and billboards[319] in Florida and Texas.

418. Mail-order abortion helps rapists 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 (Abuzz) have only a minimal screening process that are unlikely to stop a perpetrator from obtaining chemical abortion drugs.

419. This telehealth and mail-order abortion marketplace is a boon for sex traffickers. Texas has recognized that "[d]ue to the potentially high number of trafficking victims who undergo abortion procedures, abortion facility employees are uniquely situated to identify and assist victims of sex trafficking." Now, sex traffickers can obtain abortion pills for their victims without any in-person interaction.[320]

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[318] Ex. 77, Plan C, About Us ("In Winter 2022/2023 we began a research and messaging development process to support new communications campaign called 'Know Your Plan C / Conoce a Tu Plan C,' learning from grassroots organizations and audiences in six restricted states (Florida, Georgia, Kentucky, Mississippi, Oklahoma, and Texas) and rolling out content to those states designed to be educational, approachable, action-oriented, and empowering. In six months this campaign garnered 30M impressions and views, via strategic channels of social media and video platforms, radio and pod ads, and organic sharing."); Florida Access Network, *Florida Access Network Launches Statewide Campaign* (Sept. 2023), https://www.flaccessnetwork.org/in-the-streets/florida-access-network-launches-statewide-campaign-urging-floridians-to-join-the-fight-for-abortion-access.

[319] Ex. 78, Plan C, 2024 Annual Report; Kim Roberts, *Abortion Pill Website Advertising in Rio Grande Valley*, The Texan (May 3, 2024), https://thetexan.news/issues/social-issues-life-family/abortion-pill-website-advertising-in-rio-grande-valley/article_9c43a718-097a-11ef-bbab-93331fa7cc50.html; Florida Access Network, *Florida Access Network Launches Statewide Campaign*, *supra* n. 320.

[320] Ex. 67, C.S.H.B. 3446, H. Comm. Rpt., 84th Legis. (Mar. 12, 2015), https://capitol.texas.gov/tlodocs/84R/analysis/pdf/HB03446H.pdf (a subsequent, similar version was codified at Tex. Health & Safety Code § 245.025).

#WeCount Report

420. Although abortion suppliers have responded to *Dobbs* by no longer submitting the required state abortion reports, other data from non-governmental sources shows that the removal of in-person dispensing protections has harmed Plaintiffs.

421. Texas allows for nonelective abortions only, which do not occur in high numbers. So, the baseline for abortions via abortion drugs should be low or near zero beginning in mid-2022, when the state's abortion laws were allowed to take effect.

422. However, the Society of Family Planning's "#WeCount report," using data purchased from "clinics, private medical offices, hospitals, and virtual clinic providers," [321] shows that 48,460 abortions have been performed in Texas since July 2022, when the Supreme Court issued judgment in *Dobbs*.[322] All but 230 were illegal telehealth abortions.[323]

423. The report found that 10,290 telehealth abortions were performed in Florida between May 2024 and December 2024, despite telehealth abortions being illegal during that time.[324]

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[321] Ex. 93, Society of Family Planning, *#WeCount Report April 2022 through December 2024* (Jun. 23, 2025), https://societyfp.org/research/wecount/wecount-december-2024-data/.

[322] Ex. 94, Society of Family Planning, *#WeCount Report April 2022 through December 2024* (Jun. 23, 2025), https://societyfp.org/research/wecount/wecount-december-2024-data/ (Report data tables, Values tab).

[323] *Id.* For purposes of the report, a "telehealth abortion" occurs 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."

[324] *Id.*

424. The #WeCount report highlighted the skyrocketing use of telehealth abortions as a "key finding": "The proportion of abortions that were provided via telehealth increased over time from 5% in April-June of 2022 to 25% by the end of December 2024." The report explains that "[l]egal climates appear to play an important role" in this trend. Specifically, because of "abortions provided under shield laws," "[t]elehealth abortions provided into states with 6-week bans have increased; some of the increase into states with 6-week bans was due to the states switching from having telehealth restrictions to having 6-week bans during this time period. Telehealth abortions provided into states with total bans increased substantially by the end of 2024."[325]

425. These abortions, and the resulting harmful complications, are traceable to the 2021/2023 Dispensing Changes. The FDA's 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.

426. That *third parties* violate the States' laws in doing so does not matter in the standing analysis—because their conduct is not just the "predictable" response to the 2023 REMS, *Department of Commerce v. New York*, 588 U.S. 752, 768 (2019), but the *expressly intended* result of the 2023 REMS. But for the 2023 REMS, abortion providers and facilitators like Aid Access could not lawfully mail mifepristone into Florida and Texas. By eliminating the in-person dispensing requirement, the 2023

[325] *Id.*

REMS permits the "dispensing of mifepristone through the mail . . . or through a mail-order pharmacy."[326] That direct affront to Plaintiffs' laws renders Defendants directly complicit in abridging the States' sovereign prerogatives—and that "clearly [gives the states] Article III standing to challenge" the 2023 REMS. *Louisiana*, 705 F. Supp. 3d at 654.

iv. *The 2019 Generic Approval*

427. By approving a generic version of the drug, the FDA increased supply and availability, lowering cost and drastically increasing use of chemical abortions.[327]

428. "[T]hird parties [have] react[ed] in predictable ways," increasing the use of chemical abortion compared to surgical abortion. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019).

429. By causing a massive increase in the number of women obtaining chemical abortions, the 2019 Generic Approval exacerbates the difficulty that Plaintiffs face in regulating abortions performed within their borders.

CLAIMS FOR RELIEF

CLAIM ONE
THE 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

430. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 425 of this complaint.

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[326] Ex. 32, Letter from FDA to ACOG and SMFM at 2.
[327] *Supra* nn. 274-80.

431. The FDA lacked legal authority when issuing the 2016 Major Changes.

432. 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).

433. The 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.

434. 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 2016 Major Changes.

435. The 2016 Major Changes were premised on the invalid approval of Mifeprex.

436. Therefore, the 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.

CLAIM TWO
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

437. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 432 of this complaint.

438. The FDA's illegal and unreasonable rationales for the 2019 Generic Approval and shared REMS program—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).

439. 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.

440. The 2019 Generic Approval and shared REMS program were premised on the invalid approval of Mifeprex.

441. Therefore, the 2019 Generic Approval and shared REMS program 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.

CLAIM THREE
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**

442. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 437 of this complaint.

443. The FDA lacked legal authority when issuing the 2021/2023 Dispensing Changes (consisting of the 2021 non-enforcement decision and the 2023 REMS changes).

444. The FDA's 2021/2023 Dispensing Changes violate 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.

445. The FDA's 2021/2023 Dispensing Changes 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.

446. Because a federal agency cannot permit what federal law expressly prohibits, the FDA lacked legal authority when issuing the 2021/2023 Dispensing Changes.

447. The FDA's illegal and unreasonable rationales for the 2021/2023

Dispensing 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).

448. The 2021/2023 Dispensing Changes 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.

449. 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 Dispensing Changes.

450. The 2021/2023 Dispensing Changes were premised on the invalid approval of Mifeprex.

451. Therefore, the 2021/2023 Dispensing Changes 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.

CLAIM FOUR
THE 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

452. Plaintiffs re-allege and incorporate, as though fully set forth, all paragraphs 1 to 447 of this complaint.

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

454. 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.

455. 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.

456. For the reasons stated above, the challenged 2016 Major Changes must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined.

457. 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.

CLAIM FIVE
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

458. Plaintiffs re-allege and incorporate, as though fully set forth, all paragraphs 1 to 453 of this complaint.

459. Defendants lacked legal authority to issue the 2019 Generic Approval.

460. 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 Generic Approval was unlawfully approved.

461. Unable to rely on an unlawful approval, the FDA's 2019 Generic 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).

462. Therefore, the 2019 Generic Approval must be held unlawful, set aside, vacated, and preliminarily and permanently enjoined.

CLAIM SIX
2000 APPROVAL OF MIFEPREX

***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

463. Plaintiffs re-allege and incorporate, as though fully set forth, paragraphs 1 to 458 of this complaint.

I. Subpart H

464. Defendants lacked legal authority in 2000 to approve mifepristone under the FDA's Subpart H regulations for the accelerated approval of certain new drugs.

465. The FDA's Subpart H regulations apply only to "certain new drugs that have been studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy)." 21 C.F.R. § 314.500.

466. Pregnancy is not an illness.

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

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

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

II. FFDCA

470. Defendants lacked legal authority in 2000 to approve mifepristone

under the FDCA.

471. The FDA's 2000 Approval violated the FDCA because the clinical trials on which the agency relied did not use the full set of design features the agency typically requires to produce unbiased investigations of drug safety and effectiveness.

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

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

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

475. It was arbitrary, capricious, and an abuse of discretion to approve mifepristone without requiring an ultrasound and blood test to accurately assess gestational age, rule out ectopic pregnancy, and detect Rh-negative blood type.

476. Finally, the FDA violated the FFDCA and the agency's implementing regulations because the agency mandated the use of misoprostol for chemical abortion

as part of the 2000 Approval—despite the requirement that the sponsor submit an sNDA for a new use of a previously approved drug.

477. The FDA's decision to approve mifepristone—and to do so under Subpart H—did not rest on a good faith analysis of the drug's anticipated effect on public health. It was pure politics.

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

III. PREA

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

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

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

482. In 2016, despite contrary evidence in the administrative record, the FDA

sought to provide an impermissible post-hoc rationalization that it inaccurately stated in the 2000 Approval that it was "waiving" the pediatric study requirements and, instead, should have said it had found that the requirements were met for post-menarchal pediatric patients by extrapolating from studies of adult populations.

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

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

485. In addition to such a rationalization being impermissible and an

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

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

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

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

IV. Comstock Act

489. The 2000 Approval did not comply with the federal laws that expressly

prohibit the mailing or delivery by any letter carrier, express company, or other common carrier of any substance or drug intended for producing abortion. 18 U.S.C. §§ 1461–62.

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

V. Pretext

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

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

PRAYER FOR RELIEF

For these reasons, Plaintiffs 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 that:

1. sets aside and rescinds the 2000 approval of Mifeprex;
2. sets aside and rescinds the 2019 approval of generic mifepristone;
3. if applicable, 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; and

4. if applicable, restores the in-person dispensing and administration requirement.

B. Issues a permanent injunction ordering Defendants to withdraw Defendants' actions to approve and deregulate these abortion drugs.

C. Holds unlawful, sets aside, and vacates the 2000 Mifeprex Approval (NDA) and the 2019 Generic Approval (aNDA).

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

E. Holds unlawful, sets aside, and vacates the 2021/2023 Dispensing Changes.

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 22nd day of August 2025.

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*Pro hac vice application forthcoming

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

STATE OF MISSOURI, *et al.*,

Intervenor-Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants,

DANCO LABORATORIES, LLC,

Intervenor-Defendant, and

GENBIOPRO, INC.,

Intervenor-Defendant.

Case No. 2:22-cv-00223-Z

THE STATES OF FLORIDA AND TEXAS'S BRIEF IN SUPPORT OF THEIR MOTION FOR LEAVE TO INTERVENE

The States of Florida and Texas, in support of their Motion for Leave to Intervene pursuant to Rules 24(a) and 24(b), state as follows:

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INTRODUCTION

It has been nearly two years since the States of Missouri, Kansas, and Idaho ("Plaintiffs") moved to intervene in this action. For much of that time, Plaintiffs ably represented the shared interests of the States of Florida and Texas ("Movants").

In recent months, however, it has become apparent that Movants' interests may no longer be adequately represented by Plaintiffs. Missouri and Idaho banned elective abortion after *Dobbs*. But in June, an Idaho Supreme Court decision triggered the circulation of an initiative petition proposing a constitutional right to elective abortion until viability. A week later, many of Missouri's abortion regulations were enjoined under a constitutional amendment passed in 2024. These developments may threaten Plaintiffs' standing to challenge the FDA's lawless regulation of mifepristone.

Meanwhile, the severity of Movants' injuries is increasingly evident. Data released earlier this summer revealed the magnitude of illegal telehealth abortions being performed in Florida and Texas, just after a new study discovered that over 10% of women who take abortion drugs suffer a "serious adverse event" like sepsis or hemorrhaging. At the same time, legal developments in Texas and Louisiana illustrated the difficulty of enforcing abortion regulations against abortionists in "shield law" jurisdictions.

Movants therefore seek to intervene in this action to preserve their interests and promote judicial efficiency.

PROCEDURAL HISTORY

This action commenced in November 2022, when several physicians and member organizations sued the FDA and other government defendants.[1] Danco, the manufacturer of brand name mifepristone (Mifeprex), filed an unopposed motion for leave to intervene as a defendant in January 2023.[2] In November of that year, Missouri, Kansas, and Idaho moved to intervene as plaintiffs.[3] The Court granted the motion on January 12, 2024, over defendants' objection.[4] The states' original complaint in intervention challenged the FDA's approval of Mifeprex in 2000 (the "2000 Approval").[5]

On June 13, 2024, the United States Supreme Court determined that the physicians and member organizations lacked standing.[6] The states sought leave to file an amended complaint.[7] The Court granted the motion on January 16, 2025.[8] The states filed their amended complaint the same day.[9] The amended complaint

[1] Compl., ECF No. 1 (Nov. 18, 2022).
[2] Mot. to Intervene, ECF No. 19 (Jan. 13, 2023).
[3] Mot. to Intervene, ECF No. 151 (Nov. 3, 2023).
[4] Resp. and Object., ECF No. 163 (Dec. 16, 2023); Resp. and Object., ECF No. 164 (Dec. 18, 2023); Order Granting Mot. to Intervene, ECF No. 175 (Jan. 12, 2024).
[5] Compl. in Intervention, ECF No. 176 at 102-03 (Jan. 12, 2024) (requesting a declaration that mifepristone was unlawfully approved under Subpart H and a permanent injunction ordering the withdrawal of mifepristone and misoprostol as FDA-approved chemical abortion drugs).
[6] *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 374 (2024).
[7] Mot. for Leave to File Am. Compl., ECF No. 195 (Oct. 11, 2024).
[8] Order Granting Mot. for Leave to File Am. Compl., ECF No. 215 (Jan. 16, 2025).
[9] Am. Compl., ECF No. 217 (Jan. 16, 2025).

abandoned the states' challenge to the 2000 Approval. Motions to dismiss were filed by the government defendants[10] and Danco.[11] The states responded on February 20, 2025.[12]

Five days later, GenBioPro moved to intervene. The manufacturer of generic mifepristone explained that its interests were no longer adequately represented by Danco because the amended complaint challenged the 2019 approval of generic mifepristone without challenging the 2000 approval of Mifeprex.[13] The states objected.[14] The Court granted GenBioPro's motion on April 28, 2025.[15]

The FDA and Danco filed replies in favor of their motions to dismiss on May 5, 2025.[16] The Court has not ruled on those motions.

ADDITIONAL FACTS RELEVANT TO INTERVENTION

Several developments are relevant to the Court's consideration of the Motion for Leave to Intervene.

First, new data alarmed Movants to the severity of their sovereign injuries. On June 23, 2025, the Society of Family Planning released a new report detailing "national shifts in abortion volume, by state and month, following the *Dobbs v.*

[10] Mot. to Dismiss Am. Compl., ECF No. 218 (Jan. 18, 2025).
[11] Mot. to Dismiss Am. Compl., ECF No. 221 (Jan. 28, 2025).
[12] Resp. to Mot. to Dismiss Am. Compl., ECF No. 228 (Feb. 20, 2025).
[13] Mot. to Intervene, ECF No. 229 (Feb. 25, 2025).
[14] Resp. to Mot. to Intervene, ECF No. 243 (Mar. 18, 2025).
[15] Memo. Op. and Order Granting Mot. to Intervene, ECF No. 246 (Apr. 28, 2025).
[16] Reply, ECF No. 247 (May 5, 2025); Reply, ECF No. 248 (May 5, 2025); *see also* Notice Regarding Position, ECF No. 249 (May 5, 2025).

Jackson Women's Health Organization Supreme Court decision."[17] This "#WeCount report" uses data purchased from "clinics, private medical offices, hospitals, and virtual clinic providers" and reveals the number of "abortions provided under shield laws."[18]

Among its major findings is that "[t]he proportion of abortions that were provided via telehealth increased over time from 5% in April-June of 2022 to 25% by the end of December 2024."[19] The report explains that "[l]egal climates appear to play an important role" in this trend.[20] Specifically, "[t]elehealth abortions provided into states with 6-week bans have increased; some of the increase into states with 6-week bans was due to the states switching from having telehealth restrictions to having 6-week bans during this time period. Telehealth abortions provided into states with total bans increased substantially by the end of 2024."[21]

Florida and Texas are no exceptions. In Florida, it has been illegal to provide an abortion through telehealth since May 1, 2024,[22] yet #WeCount reports 10,290

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[17] Ex. 93, Society of Family Planning. *#WeCount Report April 2022 through December 2024* (June 23, 2025), available at https://societyfp.org/research/wecount/wecount-december-2024-data/. Citations to numbered exhibits refer to the appendix filed with the Motion for Leave to Intervene.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] Fla. Stat. § 390.0111(2) (effective date triggered by *Planned Parenthood of Sw. & Cent. Fla. v. State*, 384 So. 3d 67 (Fla. 2024) by operation of Laws of Fla. Ch. 2014-137 § 7).

telehealth abortions performed in Florida between May 2024 and December 2024.[23] Texas law prohibits providing abortion-inducing drugs to a pregnant woman without an in-person examination,[24] yet #WeCount reports 48,230 telehealth abortions performed in Texas between July 2023 and December 2024.[25]

These revelations come on the heels of an 865,727-sample study concluding that the incidence of sepsis, infection, hemorrhaging, or other "serious adverse event" associated with mifepristone abortion is 11%—a rate 22 times higher than disclosed by the FDA-approved label.[26]

Second, it has recently become clear that Movants will face significant difficulty in enforcing their abortion regulations against shield state abortionists. In December 2024, Texas Attorney General Ken Paxton petitioned for an injunction and civil penalties against Dr. Margaret Carpenter, a New York-based physician and abortion activist, for sending mifepristone and misoprostol to a Texas woman.[27] The woman, who did not have any physical conditions justifying the abortion under state law, suffered hemorrhaging and was taken to the hospital. On February 13, a Texas

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[23] Ex. 94, Society of Family Planning, *#WeCount Report April 2022 through December 2024* (June 23, 2025) (Report data tables, Values tab), available at https://societyfp.org/research/wecount/wecount-december-2024-data/.
[24] Tex. Health & Safety Code § 171.063.
[25] Ex. 94, Society of Family Planning, *#WeCount Report April 2022 through December 2024* (June 23, 2025) (Report data tables, Values tab).
[26] Ex. 81, Ryan T. Anderson & Jamie Bryan Hall, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Public Policy Center (Apr. 28, 2025), available at https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/.
[27] Ex. 50, Pet. and App. for Temporary and Permanent Injunctive Relief, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Dec. 12, 2024).

judge entered a default judgment ordering Carpenter to pay over $100,000 in penalties.[28] However, when Texas attempted to domesticate the judgment in July, the county clerk refused to docket Texas's filing in light of New York's shield law.[29] Texas is pursuing a mandamus action against the clerk, but New York Governor Kathy Hochul has publicly vowed to oppose Texas's efforts: "Texas Attorney General Ken Paxton has repeatedly tried to file a judgment against a New York doctor and our response has been clear: hell no."[30]

Criminal penalties have proven equally difficult to enforce. On January 31 of this year, the district attorney for West Baton Rouge indicted Dr. Carpenter for sending abortion drugs to a Louisiana woman who forced the pills on her minor daughter.[31] The girl experienced heavy bleeding, called 911, and was taken to the hospital in an ambulance. Louisiana Governor Jeff Landry issued an extradition warrant for Carpenter on February 11.[32] Two days later, Governor Hochul announced that she "will not be signing an extradition order that came from the governor of Louisiana—not now, not ever."[33] Similar criminal investigations of out-of-state abortionists are

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[28] Ex. 51, Final Judgment and Order Granting Permanent Injunction, *Texas v. Carpenter*, No. 471-08943-2024 (Tex. Collin Cnty. Feb. 13, 2025).
[29] *See* Michael Hill, *New York clerk again refuses to enforce Texas judgment against doctor who provided abortion pills*, Associated Press (July 14, 2025).
[30] *See* Alejandra O'Connell-Domenech, *Texas Attorney General Paxton sues New York county clerk over abortion ruling*, The Hill (July 28, 2025).
[31] Ex. 52, Bill of Indictment, *Louisiana v. Carpenter et al.*, No. 250187 (La. 18th Jud. Dist. Jan. 31, 2025).
[32] Ex. 53, Letter from Governor Jeff Landry to the Governor of the State of New York (Feb. 11, 2025).
[33] *See* Pam Belluck et al., *Abortion Provider Won't Be Extradited to Louisiana, N.Y. Governor Says*, The New York Times (Feb. 13, 2025).

pending in Florida. Based on Louisiana's experience, shield laws will likely pose a significant barrier to enforcing any convictions that may result.

Third, changes to Plaintiffs' abortion laws are creating an asymmetry of interests. On July 3, 2025, a circuit judge enjoined many of Missouri's abortion regulations, finding them preempted by a constitutional amendment approved in November 2024. The enjoined laws include Missouri's ban on elective abortion and a wide range of regulations regarding admitting privileges, pathological examinations, waiting periods, telemedicine, informed consent, and even facility licensing.[34]

On June 24, 2025, the Idaho Supreme Court approved a fiscal impact statement and ballot title for an initiative petition proposing a constitutional right to elective abortion through viability.[35] The decision allowed the amendment sponsor to begin collecting signatures.[36] If enough are obtained, the amendment will appear on Idaho's November 2026 general election ballot.

The Kansas Supreme Court discovered a broad, unenumerated right to elective abortion in the Kansas Constitution in 2019.[37] It "affirmed" that decision in 2024.[38]

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[34] Ex. 54, Order, *Comprehensive Health of Planned Parenthood Great Plains et al. v. Missouri*, No. 2416-CV31931 (Mo. Cir. Ct. Jackson Cnty. July 3, 2025).
[35] Ex. 55, Substitute Op., *Idahoans United for Women and Families v. Labrador et al.*, No. 52636-2025 (Idaho June 24, 2025).
[36] *See* Kyle Pfannenstiel, *'End the ban:' Idaho organizers start gathering signatures for abortion rights ballot initiative*, Idaho Capital Sun (July 3, 2025).
[37] *Hodes & Nauser, MDs, P.A. v. Schmidt*, 440 P.3d 461, 464 (2019).
[38] *Hodes & Nauser, MDs, P.A. v. Kobach*, 551 P.3d 37, 44 (2024).

ANALYSIS

I. Movants are entitled to intervene as of right under FRCP 24(a)(2).

A party must meet four criteria to intervene as of right under FRCP 24(a)(2):

> (1) the application . . . must be timely; (2) the applicant must have an interest relating to the property or transaction which is the subject of the action; (3) the applicant must be so situated that the disposition of the action may, as a practical matter, impair or impede his ability to protect that interest; [and] (4) the applicant's interest must be inadequately represented by the existing parties to the suit.

Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm., 834 F.3d 562, 565 (5th Cir. 2016). Movants satisfy each requirement.

A. The motion is timely.

In the Fifth Circuit, timeliness "is not limited to chronological considerations but is to be determined from all the circumstances." *Id.* District courts are guided by the four factors provided in *Stallworth v. Monsanto Company*:

> (1) how long the potential intervener knew or reasonably should have known of her stake in the case into which she seeks to intervene; (2) the prejudice, if any, the existing parties may suffer because the potential intervener failed to intervene when she knew or reasonably should have known of her stake in that case; (3) the prejudice, if any, the potential intervener may suffer if the court does not let her intervene; and (4) any unusual circumstances that weigh in favor of or against a finding of timeliness.

558 F.2d 257, 264 (5th Cir. 1977). These factors are "a framework and not a formula." *John Doe No. 1 v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001). While "[a] motion to intervene may still be timely even if all the factors do not weigh in favor of a finding of timeliness," *id.*, each factor supports intervention here.

i. A reasonable length of time has passed since Movants had reason to believe their interests are not adequately protected.

"The first factor focuses on the time lapse between the applicant's receipt of actual or constructive knowledge of his interest in the litigation and the filing of his motion for intervention." *Edwards v. City of Houston*, 78 F.3d 983, 1000 (5th Cir. 1996). Time is not measured from the commencement of the action. *Sierra Club v. Espy*, 18 F.3d 1202, 1206 (5th Cir. 1994). Instead, the clock starts when a party becomes aware that its interests "may be" no longer protected by the original parties. *Id*. at 1207.

Movants only recently became aware that Plaintiffs may no longer be in a position to adequately represent Movants' interests in this action. As described above, an initiative petition that would amend the Idaho Constitution to legalize elective abortion through viability was approved for circulation on June 24, 2025.[39] Then, on July 3, 2025, many of Missouri's abortion regulations—including its ban on elective abortion—were enjoined under a similar constitutional amendment adopted in 2024.[40] In Kansas, elective abortion remains legal through viability due to the Kansas Supreme Court's decision in *Hodes & Nauser, MDs, P.A. v. Schmidt*, 440 P.3d 461 (2019). These developments threaten Plaintiffs' ability to allege sovereign injuries as a basis for standing.

Plaintiffs' ability to represent Movants' interests is also hamstrung by the amended complaint. The 2000 Approval was clearly unlawful, and the FDA's

[39] Ex. 54, *Comprehensive Health of Planned Parenthood Great Plains*, *supra* n. 34.
[40] Ex. 55, *Idahoans United for Women and Families*, *supra* n. 35.

subsequent actions should be set aside for that reason alone. But the amended complaint, which was filed in January, dropped the states' requests for a declaration that mifepristone was unlawfully approved under Subpart H and a permanent injunction ordering the withdrawal of mifepristone and misoprostol as FDA-approved chemical abortion drugs.

However, Plaintiffs continued to argue that their claim against the 2019 approval of generic mifepristone depended on the invalidity of the 2000 Approval. Resp. to Mot. to Intervene, ECF No. 243 7 (Mar. 18, 2025) ("With respect to the generic approval, the States are asserting the *exact same* arguments the original Plaintiffs did."). On April 28, the Court determined that the amended complaint does not "directly challenge the lawfulness of the 2000 approval," nor does its challenge to the 2019 approval of generic mifepristone "depend on the validity of the 2000 approval." Memo. Op. and Order Granting Mot. to Intervene, ECF No. 246 10 (Apr. 28, 2025).

At that time, an administrative remedy seemed possible. The FDA had requested an extension of time to respond to the amended complaint, stating that the new administration was insufficiently familiar with the issues involved. Unopposed Mot. for Ext. of Time, ECF No. 238 ¶ 5 (Mar. 3, 2025). Movants hoped that, once familiarized, the new administration would choose not to defend its predecessors' illegal acts. However, on May 5, 2025, the FDA filed a motion to dismiss arguing that Plaintiffs' economic and sovereign injuries do not establish standing to challenge any of the FDA's actions on mifepristone. Reply, ECF No. 247 (May 5, 2025). In June and

July, Movants became aware that pursuing penalties against shield state abortionists may prove equally futile. *Supra* nn. 27-33.

June was also when the #WeCount report revealed a staggering increase in the number of illegal telehealth abortions being performed in Florida and Texas.

In sum, Movants did not learn of developments impeding Plaintiffs' ability to assert sovereign injury until June and July; did not receive clear notice that none of the amended complaint's remaining claims depend on the validity of the 2000 Approval until April; did not know whether the new administration would continue to defend the FDA's actions until May; did not know whether shield state officials would choose to obstruct enforcement of Movants' abortion laws until June and July; and did not become aware of the massive increase in illegal telehealth abortions being performed within their borders until June. Taking these developments as a whole, as instructed by the Fifth Circuit and applied by the Court when granting previous motions to intervene in this action,[41] it has been about two months since Movants became aware that their interests were no longer adequately represented by Plaintiffs.

Defendants may argue that the clock started earlier, perhaps when the amended complaint was filed in January. Even then, the delay would be reasonable under the circumstances. As explained in an affidavit submitted by the agency that manages the Florida Medicaid program, gathering evidence of economic injury is a time-consuming process. It involves filtering claims by diagnosis code, requesting

[41] *See* Suggestions in Support of Mot. to Intervene, ECF No. 152 at 13 (Nov. 3, 2023); Order Granting Mot. to Intervene, ECF No. 175 at 3 (Jan. 12, 2024).

medical records from hundreds of healthcare providers, waiting for responses, decrypting records, narrowing records through keyword searches, and manually reviewing records to determine whether treatment was related to mifepristone complications.[42] The Fifth Circuit has approved analogous delays for less compelling reasons. *See Ass'n of Pro. Flight Attendants v. Gibbs*, 804 F.2d 318, 321 (5th Cir. 1986) (reversing order finding intervention untimely based on a five-month delay and reminding district courts not to "place[] undue emphasis on the first of the *Stallworth* factors"); *Diaz v. S. Drilling Corp.*, 427 F.2d 1118, 1125 (5th Cir. 1970) ("In the context of this lengthy, complicated litigation, based on a contract signed over a decade ago, we do not think that the Government forfeited its right to intervene solely by the passage of a year.").

ii. Intervention would alleviate prejudice, not cause it.

Though it is second on the list, "[t]he most important consideration in determining timeliness is whether any existing party to the litigation will be harmed or prejudiced by the proposed intervenor's delay in moving to intervene." *McDonald v. E. J. Lavino Co.*, 430 F.2d 1065, 1073 (5th Cir. 1970). This factor "is concerned only with the prejudice caused by the applicants' delay, not that prejudice which may result if intervention is allowed." *Edwards*, 78 F.3d at 1002. "[M]ere inconvenience is not in itself a sufficient reason to reject as untimely a motion to intervene as of right." *McDonald*, 430 F.2d at 1073.

[42] Ex. 72, Declaration of Ann Dalton ¶ 11.

The Fifth Circuit's rule of thumb is that motions to intervene filed "before trial and any final judgment" do not cause prejudice. *Glickman*, 256 F.3d at 377; *see also Edwards*, 78 F.3d at 1001 ("[T]hat these motions were filed prior to entry of judgment favors timeliness, as most of our case law rejecting petitions for intervention as untimely concern motions filed after judgment was entered in the litigation."); *Wal-Mart Stores*, 834 F.3d at 565-66 ("Because the [intervenor] sought intervention before discovery progressed and because it did not seek to delay or reconsider phases of the litigation that had already concluded, the [intervenor's] motion was timely.").

This case is still at an early stage procedurally. It has not progressed to discovery, let alone trial. The Court has yet to rule on a single dispositive motion. Consequently, intervention will not prejudice existing parties. To the contrary, intervention is to the Defendants' benefit, considering "the only other realistic path for Intervenors is to file a separate lawsuit," which would duplicate effort and waste resources. Order Granting Mot. to Intervene, ECF No. 175 5 (Jan. 12, 2024); *see also Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, No. 5:21-CV-071-H, 2022 WL 974335, at *7 (N.D. Tex. Mar. 31, 2022) ("[T]he Court finds that permissive intervention will not cause undue delay or prejudice . . . . As discussed above, the state intervenors could bring their own suit against the defendants, challenging HISA on Tenth Amendment grounds. Had they done so, the time and expense of separate litigation would almost invariably cause the defendants greater prejudice, expense, and delay. They would have to defend against all of Texas's claims, largely duplicating their efforts spent in the present lawsuit.").

iii. Movants will suffer prejudice if intervention is denied.

"The third factor focuses on the prejudice the potential intervener would suffer if not allowed to intervene." *Glickman*, 256 F.3d 371. Movants' arguments on this factor are materially identical to those made in favor of Plaintiffs' motion for leave to intervene. First, an adverse ruling in this litigation could significantly affect Movants' ability to exercise their sovereign prerogatives to regulate the health and welfare of their inhabitants and protect their fiscs. *See infra* I.B. This is because any adverse decision in this action would have a "stare decisis effect" in a separate action, whether or not it creates binding precedent. *Espy*, 18 F.3d at 1207; *see infra* I.C.

In the same vein, any injunction issued in this case would necessarily affect the injunctive relief available in a separate proceeding. *See Gen. Land Off. v. Trump*, No. 24-40447, 2025 WL 1410414, at *7 (5th Cir. May 15, 2025) ("The district court's analysis failed to assess how any potential remedy will be restricted by the injunction . . . . '[I]f a state or federal judge in a separate proceeding decided that the appellants' contentions were meritorious, he would be unable to award them effective relief without generating an injunctive command that would overlap or conflict with the [prior] order.'") (quoting *Stallworth*, 558 F.3d at 268).

Relatedly, because there are certain legal rights "associated with formal intervention, namely the briefing of issues, presentation of evidence, and ability to appeal," *Espy*, 18 F.3d at 1202, denying intervention would prejudice Movants, *Glickman*, 256 F.3d at 379 (intervenor would suffer prejudice "as a nonparty [who] will not be able to participate in the trial concerning that ruling nor will it be able to appeal that ruling"); *Edwards*, 78 F.3d at 1002-03.

iv. Unusual circumstances

"The final factor in determining timeliness is the existence of unusual circumstances militating either for or against a determination that the application is timely." *Espy*, 18 F.3d at 1207. To the extent there are unusual circumstances present in this case, *see supra* I.A.i, they militate in favor of intervention.

B. Movants have an interest relating to the property or transaction which is the subject of the action.

A party seeking to intervene as of right must assert "an interest related to the property or transaction at issue in the case." *Ross v. Marshall*, 426 F.3d 745, 757 (5th Cir. 2005). The interest must be "concrete, personalized, and legally protectable." *Texas v. United States*, 805 F.3d 653, 658 (5th Cir. 2015). "Non-property interests are sufficient to support intervention when, like property interests, they are concrete, personalized, and legally protectable." *Brumfield v. Dodd*, 749 F.3d 339, 343 (5th Cir. 2014).

Preserving a "regulatory system" is one such interest. *See Wal-Mart Stores*, 834 F.3d at 566; *see also Sierra Club v. City of San Antonio*, 115 F.3d 311, 315 (5th Cir. 1997) (holding that a state's "important sovereign interest in protecting [its] self-governing authority" and "in seeing that the scheme passed by [its] legislature is properly enforced" supports intervention as of right). A state's interest is "judged by a more lenient standard if the case involves a public interest question." *Brumfield*, 749 F.3d at 344.

Movants have both property and "regulatory system" interests in this action. As explained in the proposed complaint in intervention, the FDA's actions inflict (1)

economic injuries by, *inter alia*, requiring Movants to pay for emergency medical treatment through Medicaid, and (2) sovereign harms by frustrating enforcement of Movants' abortion laws. Any adjudication of the lawfulness of the FDA's actions will have a direct effect on these interests. And because the fate of chemical abortion is of great public interest, Movants are entitled to even greater lenience than is ordinally given under FRCP 24(a)(2). *See id.* ("Although the movant bears the burden of establishing its right to intervene, Rule 24 is to be liberally construed.").

C. The disposition of this action may impair or impede Movants' ability to protect their interests.

"The third criterion that an applicant for intervention must satisfy is that the disposition of the case into which he seeks to intervene 'may, as a practical matter, impair or impede his ability to protect [that] interest.'" *Ross*, 426 F.3d at 760. Intervenors "do not need to establish that their interests *will* be impaired . . . only that the disposition of the action 'may' impair or impede their ability to protect their interests." *Brumfield*, 749 F.3d at 344 (emphasis in original). After all, "[i]t would indeed be a questionable rule that would require prospective intervenors to wait on the sidelines until after a court has already decided enough issues contrary to their interests." *Id.*

The "stare decisis effect" of a district court's judgment is sufficient to "supply the requisite disadvantage to satisfy" the third *Strickland* factor. *Espy*, 18 F.3d at 1207. It matters not that a decision may not bind other district courts because "[t]he district court's ruling . . . will undoubtedly, unless changed, be relied upon as a precedent in future actions." *Heaton v. Monogram Credit Card Bank of Georgia*, 297 F.3d

416,424 (5th Cir. 2002). And any injunction issued in this case would necessarily affect the injunctive relief available in a separate proceeding. *See Gen. Land Off. v. Trump*, 2025 WL 1410414, at *7; *Stallworth*, 558 F.3d at 268. Thus, the disposition of this case may impair or impede Movants' ability to protect their interests in a separate action.

D. Movants' interests are inadequately represented by Plaintiffs.

"The final requirement for intervention as a matter of right is that the applicant's interest must be inadequately represented by the existing parties to the suit." *Espy*, 18 F.3d at 1207. "The applicant need only show that representation 'may be' inadequate." *Id.* This burden "is not a substantial one." *Brumfield*, 749 F.3d at 345.

Movants satisfy this "minimal" burden. *Id.* Pending litigation in Missouri, an initiative petition circulating in Idaho, and state supreme court precedent in Kansas may compromise Plaintiffs' ability to establish standing for their claims. *See supra* I.A.i. Even if Missouri or Idaho's ban on elective abortion survive, Plaintiffs' abandonment of their claim against the 2000 Approval undermines their remaining claims and shows that Plaintiffs and Movants do not share the "same ultimate objective." *Wal-Mart Stores, Inc.*, 834 F.3d at 569; *compare* Am. Compl., ECF No. 217 (Jan. 16, 2025) (seeking a return to the pre-2016 REMS) *with* Ex. A, Proposed Compl. in Intervention (seeking to set aside the FDA's approval of mifepristone).

Additionally, the #WeCount report shows that the volume of telehealth abortions in Florida (16,820 since July 2023) and Texas (48,230) and is much larger than in Missouri (3,010), Kansas (3,020), and Idaho (1,010). These figures suggest that Movants have "more extensive interests" in this action than Plaintiffs. *See Brumfield*,

749 F.3d at 346 ("We cannot say for sure that the state's more extensive interests will in fact result in inadequate representation, but surely they might, which is all that the rule requires.").

Because Movants satisfy each *Strickland* factor, they are entitled to intervene.

II. In the alternative, the Court should allow permissive intervention under FRCP 24(b)(1)(B).

Permissive intervention "is appropriate when: (1) timely application is made by the intervenor, (2) the intervenor's claim or defense and the main action have a question of law or fact in common, and (3) intervention will not unduly delay or prejudice the adjudication of the rights of the original parties." *Texas v. United States*, No. 4:18-CV-00167-O, 2018 WL 10562846, at *2 (N.D. Tex. May 16, 2018) (citing *Kneeland v. Nat'l Collegiate Athletic Ass'n*, 806 F.2d 1285, 1289 (5th Cir. 1987)). While permissive intervention is discretionary, the Fifth Circuit encourages district courts to "allow intervention where no one would be hurt and the greater justice could be obtained." *Texas*, 805 F.3d at 657.

A. The motion is timely.

Movants acted promptly upon becoming aware that their interests in this action may no longer be adequately represented by Plaintiffs. *See supra* I.A.

B. Movants' claims share questions of law and fact in common with the main action.

To intervene under Rule 24(b)(1)(B), a party must have a "claim or defense that shares with the main action a common question of law or fact." This aspect of the rule "has been construed liberally" in favor of intervention. *Newby v. Enron Corp.*, 443 F.3d 416, 422 (5th Cir. 2006).

The amended complaint challenges three categories of action taken by the FDA: its 2016 REMS changes, its 2019 approval of generic mifepristone, and its 2023 REMS changes. Plaintiffs claim these actions are arbitrary, capricious, not in accordance with law, and therefore invalid under the Administrative Procedure Act. Movants seek to challenge the same actions on the same grounds. Ex. A, Proposed Compl. in Intervention.

C. Permissive intervention will not result in undue delay or prejudice to existing parties.

"The analysis as to whether the intervention will cause undue delay or prejudice is essentially the same as the timeliness analysis." *Students for Fair Admissions, Inc. v. Univ. of Texas at Austin*, 338 F.R.D. 364, 372 (W.D. Tex. 2021). As with intervention as of right, courts in the Fifth Circuit find motions to intervene nonprejudicial when filed before discovery, trial, and final judgment. *See, e.g., U.S. Equal Emp. Opportunity Comm'n v. Wellpath LLC*, No. 5:20-CV-1092-DAE, 2021 WL 4096556, at *2 (W.D. Tex. Mar. 15, 2021) ("[T]he Court finds that granting intervention here will not delay or prejudice the adjudication of the original parties' rights. Babineaux filed her motion to intervene at the beginning of discovery . . . and before a trial date has been set."). This case has not progressed to discovery, let alone trial. Permitting intervention at this juncture would not prejudice existing parties. *See supra* I.A.ii.

Defendants may argue that Movants' challenge to the 2000 Approval will unduly delay resolution of this case. Not so. Movants' arguments against the 2000 Approval are the same arguments made by the original physician and member organization plaintiffs and by Missouri, Kansas, and Idaho in their original complaint in

intervention. Ex. A, Proposed Compl. in Intervention. Defendants have briefed the issue in this Court, the Fifth Circuit, and the Supreme Court. Thus, the claim "will not inject significant unrelated questions of law and fact." *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, 2024 WL 1260639, at *7 (N.D. Tex. Jan. 12, 2024).

The Fifth Circuit's recent opinion in *General Land Office v. Trump* supports this conclusion. That case began as a challenge by the General Land Office of Texas ("GLO") against President Biden's proclamation of new "priorities" for border wall funding. *Gen. Land Off. v. Trump*, 2025 WL 1410414, at *1. GLO challenged the proclamation under several provisions of the United States Constitution. *Id.* After the district court entered a preliminary injunction, a private landowner, two environmental organizations, and three federal contractors moved to intervene. The intervenors raised new claims ranging from "contract disputes" to "property damage" to "environmental issues." *Gen. Land Off. of State of Texas v. Biden*, No. 7:21-CV-00272, 2024 WL 2753253, at *2 (S.D. Tex. May 28, 2024). The existing parties opposed the motion, arguing that the "inject[ion of] a wide range of new fact-specific interests" would unduly delay the litigation. The district court agreed and denied the motions to intervene. *Id.*

The Fifth Circuit reversed. The district court's analysis was "flawed," the panel said, because it confused inconvenience for prejudice. *Gen. Land Off.*, 2025 WL 1410414 at *6. The Fifth Circuit explained that "would-be intervenors have no right to relitigate issues already decided" and "no prejudice can come from renewed

discovery or pretrial proceedings, because an intervenor must accept the proceedings as he finds them." *Id.* (quoting *Glickman*, 256 F.3d at 378; *Espy*, 18 F.3d at 1206 n.3). Therefore, the appellate court found it "difficult to understand how [the existing parties] could have been harmed." *Id.*

Movants do not seek to relitigate issues already decided. The validity of the 2000 Approval, though thoroughly and repeatedly briefed, has not been decided. While the reintroduction of this issue may cause a new round of motions to dismiss, "such is the nature of nearly any intervention." *Nat'l Horsemen's*, 2022 WL 974335, at *7. Movants also note that intervention would likely eliminate other time-consuming issues, such as whether this Court is a proper venue for Plaintiffs' claims. *See* Reply, ECF No. 247 1-6 (May 5, 2025); Reply, ECF No. 248 1-4 (May 5, 2025).

D. The Court should exercise its discretion to allow Movants to intervene.

While Movants meet the requirements of FRCP 24(b)(1)(B), permissive intervention still lies within the discretion of the Court. Movants submit that permitting intervention would "obtain the greater justice" and further judicial economy. Rule 24 is designed to facilitate a single adjudication of claims arising from the same underlying facts, as duplicative litigation "waste[s] the parties and the Court's time and resources." *See E.E.O.C. v. Commercial Coating Service, Inc.*, 220 F.R.D. 300, 302–03 (S.D. Tex. 2004). This case presents the "classic example" in which "the rights asserted by two groups . . . should be adjudicated in one action, rather than in two." *Stallworth*, 558 F.2d at 270. "With little strain on the court's time and no prejudice to the litigants, the controversy can be stilled and justice completely done." *Id.*

CONCLUSION

For the foregoing reasons, the States of Florida and Texas respectfully request that the Court grant their Motion for Leave to Intervene as of right or, in the alternative, exercise its discretion to permit intervention in this action.

Respectfully submitted this 22nd day of August 2025.

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