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

State of Missouri, *et al.*,

Intervenor-Plaintiffs, and

State of Florida, State of Texas,

Proposed Intervenor-Plaintiffs, and

Rosalie Markezich and **State of Louisiana**, by and through its Attorney General, **Liz Murrill**,

Proposed Intervenor-Plaintiffs,

v.

United States Food and Drug Administration, *et al.,*

Defendants, and

Danco Laboratories, LLC,

Intervenor-Defendant, and

GenBioPro, Inc.,

Intervenor-Defendant.

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

COMPLAINT

1. The fight for life is far from over.

2. In *Dobbs v. Jackson Women's Health Organization*, the United States Supreme Court "return[ed] the issue of abortion to the people's elected representatives." 597 U.S. 215, 232 (2022). That decision empowered each state to

"evaluate the competing interests and decide how to address this consequential issue." *Id.* at 339 (Kavanaugh, J., concurring). And as a result, voters and their representatives may enact and enforce laws "based on their belief that abortion destroys an 'unborn human being.'" *Id.* at 256 (majority op.).

3. So it was in Louisiana. Before *Dobbs* overruled *Roe v. Wade*, 410 U.S. 113 (1973), Louisianans adopted a pro-life law—to become effective immediately upon *Roe*'s overruling—that would prohibit abortion with narrow exceptions. La. Stat. Ann. § 40:1061. After *Dobbs*, therefore, Louisiana's pro-life law took immediate effect, protecting the unborn in Louisiana.

4. Or so Louisiana thought. Shortly after *Dobbs*, pro-abortion activists and doctors launched a nationwide effort to effectuate abortions in pro-life states like Louisiana—all without setting foot in those states. How? By mail. Every year, doctors and activists in states like California and New York mail a U.S. Food and Drug Administration (FDA)-approved abortion drug called mifepristone to thousands of Louisiana residents for the express purpose of causing abortions in Louisiana that are blatantly unlawful.

5. But some of the women who ingest the drugs do not want an abortion. Since FDA effectively allowed "blind" dispensing without the in-person care of a doctor, bad actors have been able to obtain FDA-approved abortion drugs from prescribers in other states and then secretly spike women's drinks without their knowledge or force women into taking these drugs against their will.

6. This is what happened to Rosalie Markezich. In October 2023, under immense pressure and fearing for her safety, Rosalie took abortion drugs that her boyfriend obtained via the U.S. Postal Service from a doctor in California. Rosalie did not want to have an abortion. But far from empowering Rosalie to make her own choice and preserving her autonomy, mail-order abortion drugs had Rosalie feeling trapped and terrified. She grieves the loss of her child and endures lasting emotional trauma. But for FDA's 2023 REMS, Rosalie would have received the protection of a private in-person medical appointment. And if she had been able to tell a doctor that she did not want an abortion, the drugs that took her baby's life would never have been provided.

7. The reality on the ground is striking. The pro-abortion Society of Family Planning's 2024 #WeCount report states that, from April to June 2024 alone, mail-order abortion drugs—sent into Louisiana from doctors and activists in other states—accounted for an average of 617 abortions in Louisiana *per month*.[1] And #WeCount data released in June 2025 describes that number as topping *800 abortions* in Louisiana in *December 2024 alone*.[2]

8. This extra-territorial mailing of abortion drugs is illegal under state law—and it is the direct result of the Biden Administration's 2023 agency action expressly facilitating this scheme. That action is the subject of this lawsuit.

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[1] Ex. 1, Society of Family Planning, #WeCount Report April 2022 to June 2024 at 10 (Oct. 22, 2024), perma.cc/WRW3-PMWK, App. 0011.

[2] Ex. 2, Society of Family Planning, #WeCount Report April 2022 to December 2024 at PowerPoint slide 35 (Jun. 23, 2025), perma.cc/RM6F-H2Q9, App. 0093.

9. For years, Defendant FDA required mifepristone to be dispensed in person. For good reason: As FDA continues to acknowledge today, mifepristone poses serious risks to women—so much so that the FDA-required label says that roughly 1 in 25 women who use mifepristone *as directed* will end up in the emergency room.

10. In 2023, however, the Biden Administration removed the in-person dispensing requirement from its Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. The Biden Administration did so for avowedly political reasons. President Biden had ordered his Administration to "identify all ways" to make abortion available in those states that, after *Dobbs*, opted to choose life for the unborn. And the 2023 REMS was a banner achievement in carrying out that directive for—as FDA freely noted—the 2023 REMS now allows the "dispensing of mifepristone through the mail ... or through a mail-order pharmacy."[3] In other words, but for the 2023 REMS, activists in New York and California could not blanket pro-life states like Louisiana with mifepristone by mail.

11. There is no serious dispute that the 2023 REMS is unlawful on Administrative Procedure Act grounds—five Fifth Circuit judges already have recognized as much.

12. *First*, the 2023 REMS is arbitrary and capricious, not least because it rests on FDA's unsupported determination that mifepristone is safe—a determination based on the absence of any adverse events reported *in a system FDA*

[3] Ex. 3, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS, at 2 (Apr. 12, 2021), App. 0128.

already gutted. 5 U.S.C. § 706(2)(A). Said Judges Oldham and Engelhardt: The "ostrich's-head-in-the-sand approach" reflected in the reasoning adopted by the 2023 REMS "suggests FDA's actions are well 'outside the zone of reasonableness.'" *All. for Hippocratic Med. v. FDA*, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023) (*Alliance I*). Chief Judge Elrod (for herself and Judges Ho and Wilson) echoed that sentiment, stating that the earlier panel "aptly" concluded that FDA's 2023 REMS is likely arbitrary and capricious. *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 249–51 (5th Cir. 2023) (*Alliance II*). The unanimous panel also determined that the 2023 REMS "was not reasonable" because the agency relied on published literature "despite FDA's admission that the literature did not affirmatively support its position." *Id.* at 250. So the Court here need only cite the Fifth Circuit's own conclusions to hold that the 2023 REMS is arbitrary and capricious.

13. *Second*, as Judge Ho recognized in *Alliance II*, the 2023 REMS also is contrary to law because it "violate[s] the Comstock Act, 18 U.S.C. §§ 1461–62, and [thus is] 'not in accordance with law' for that reason as well." *Id.* at 267 (Ho, J., concurring in part and dissenting in part) (quoting 5 U.S.C. § 706(2)(A)). Among other things, the Comstock Act prohibits the mailing of "[e]very article or thing designed, adapted, or intended for producing abortion." 18 U.S.C. § 1461. The Act also prohibits the use of "any express company or other common carrier or interactive computer service" for "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." *Id.* § 1462. Each one of these provisions covers, of course, precisely the mailing of mifepristone that the Biden Administration intentionally

sought to facilitate through the 2023 REMS. So for that additional reason, the Court need only cite Judge Ho's concurrence to "set aside the [2023 REMS] because it violates the Comstock Act." *Alliance II*, 78 F.4th at 270 (Ho, J., concurring in part and dissenting in part).

14. Now, to be sure, the Supreme Court itself did not pass on these arguments because it ultimately disposed of the original *Alliance* plaintiffs on standing grounds. *See FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 374 (2024). But this case supplies the standing piece that the Supreme Court found lacking in *Alliance*. Specifically, for example, Louisiana has incontrovertible evidence that, because of the 2023 REMS, doctors and others are (as the Biden Administration intended) sending streams of mifepristone by mail into Louisiana for the express purpose of causing thousands of abortions in Louisiana every year. That conduct directly violates Louisiana's abortion laws and prevents Louisiana from protecting the lives of unborn babies despite the promise of *Dobbs*. That conduct also has directly generated emergencies that harm Louisiana women and emergency room visits that harm the State. For these points, look no further than a pending indictment in Louisiana, which charges Dr. Margaret Carpenter of New York with mailing FDA-approved mifepristone into Louisiana that ultimately sent a teenage girl to a Louisiana emergency room.[4]

15. This is an extraordinarily serious case, but it is also an extraordinarily easy case: Through the 2023 REMS, the Biden Administration attempted to

[4] Ex. 4, Dr. Margaret Carpenter indictment, App. 0130–31.

undermine *Dobbs* by facilitating the mailing of mifepristone into every pro-life state, thus harming Louisiana and causing women like Rosalie immense suffering. But the Fifth Circuit has twice recognized the likely illegality of the reasoning embraced by the 2023 REMS. Accordingly, the Court need only follow the Fifth Circuit's guidance in deeming unlawful, setting aside, vacating, and enjoining the enforcement of the 2023 REMS.

JURISDICTION AND VENUE

16. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1346(a), 1361 because this action against the United States' agencies and its officers in their official capacities 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*.

17. 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. § 706, Fed. R. Civ. P. 57, and this Court's inherent equitable powers. *See Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

18. 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). Proposed Intervenor-Plaintiffs bring this intervention action in the same district and division in which an action involving the same subject matter is already pending.

PARTIES

Plaintiffs

19. Plaintiff Rosalie Markezich is a resident of Louisiana. She became a victim of FDA's mail-order abortion scheme in October 2023 when her boyfriend ordered FDA-approved abortion drugs from a California doctor and, by her boyfriend's actions, she felt coerced to take them. The abortion drugs killed her child.

20. Plaintiff State of Louisiana is a sovereign State of the United States of America. Liz Murrill is the Attorney General of the State of Louisiana. She is authorized by Louisiana law to sue on the State's behalf. La. Const. art. IV, § 8. Her offices are located at 1885 North Third Street, Baton Rouge, Louisiana 70802. Louisiana sues to vindicate its sovereign, quasi-sovereign, and proprietary interests.

Defendants

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

22. 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.

23. Defendant George Francis Tidmarsh, M.D., Ph.D., named in his official capacity, is the Director of FDA's Center for Drug Evaluation and Research. Dr. Tidmarsh is tasked with regulating drugs throughout their lifecycle, approving and evaluating new and existing drugs, monitoring post-marketing drug safety, and taking enforcement actions necessary to protect the public from harmful drugs. Dr. Tidmarsh's official address is 10903 New Hampshire Avenue, Silver Springs, Maryland 20993.

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

25. Defendant Robert F. Kennedy, Jr., is the Secretary of HHS and is named in his official capacity. Secretary 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.

26. Collectively and as applicable, all Defendants are referred to herein as "FDA" or "Defendants." Plaintiff State of Louisiana also sues Defendants' employees, agents, and successors in office.

27. Defendants are subject to the APA. 5 U.S.C. § 701(b); 5 U.S.C. § 551(1).

FACTUAL ALLEGATIONS

28. *Dobbs* portended a sea change in America when, for the first time in a half century, the Supreme Court "return[ed] the issue of abortion to the people's elected representatives." 597 U.S. at 232. Indeed, for many pro-life states like Louisiana and others, *Dobbs* meant protecting unborn babies from abortion (with narrow exceptions) within their borders.

29. That promise, however, has not been realized in Louisiana and its sister pro-life states. That is because a nationwide movement of pro-abortion doctors and other activists are *mailing* the abortion drug mifepristone into Louisiana for the express purpose of causing abortions in Louisiana and circumventing Louisiana's pro-life laws. That mail-order abortion effort is possible only because of the Biden Administration's 2023 REMS, which attempts to thwart *Dobbs* by facilitating the mailing of FDA-approved mifepristone into pro-life states where abortions are prohibited or significantly curtailed. Such mailing is blatantly unlawful, not least because the 2023 REMS is arbitrary and capricious (as five Fifth Circuit judges have recognized) and the Comstock Act independently bans the mailing of abortion drugs. As a consequence, hundreds of unlawful abortions occur every month in Louisiana.

30. The allegations below (I) provide a brief explanation of mifepristone; (II) offer an overview of FDA's regulation of mifepristone; (III) describe the Biden Administration's 2023 REMS, which facilitated mail-ordered mifepristone as a response to *Dobbs* and as a means of circumventing pro-life states' laws; (IV) outline the nature of the resulting extra-territorial effort for mailing mifepristone into pro-

life states; (V) identify data and examples of how that effort is playing out in Louisiana; and (VI) articulate the specific harms that give Rosalie and Louisiana standing to file this suit challenging the 2023 REMS.

I. A Brief Overview of Mifepristone.

31. A French pharmaceutical company called Roussel Uclaf S.A. first developed and tested mifepristone under the name RU-486 (also called "Mifeprex" today). In 1988, it was approved as an abortion drug in France.[5]

32. Mifepristone is a synthetic steroid and endocrine disruptor that blocks progesterone receptors in the uterus. Progesterone is necessary to maintain a pregnancy and support a growing baby. By blocking progesterone receptors, mifepristone causes the uterine lining to deteriorate, starving the baby of oxygen and nutrition and eventually killing the baby.[6]

33. Today, mifepristone generally is administered as part of a two-drug regimen involving a second drug called misoprostol. Mifepristone is first introduced, killing the baby. And then misoprostol is introduced, which induces contractions to expel the baby from her mother's womb.[7]

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[5] Ex. 5, Center for Drug Evaluation and Research, Application Number: 20-687 Medical Review(s) at 1–2 (Jan. 27, 2000), App. 0134–35.

[6] Ex. 6, Blake M. Autry & Roopma Wadhwa, *Mifepristone*, StatPearls (Feb. 28, 2024), perma.cc/K2CL-CKP3; Ex. 7, *The Facts on Mifepristone*, Planned Parenthood, perma.cc/A7UB-P2DZ, App. 0177–78.

[7] Ex. 7, *The Facts on Mifepristone*; Ex. 8, *Medication Abortion: Your Questions Answered*, Yale Med. (Sept. 11, 2023), perma.cc/NA6N-GL2N, App. 0191.

34. The side effects from mifepristone are serious and undisputed. They include severe cramping and heavy bleeding.[8] In fact, FDA's own label states that roughly 1 in 25 women who take mifepristone will end up in the emergency room,[9] with up to 7% requiring a "surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding."[10] The label also includes a black box warning that "serious and sometimes fatal infections or bleeding" may occur.[11]

35. The risks of complications and emergency surgeries increase with gestational age.[12] For example, FDA's label notes that the percentage of surgical interventions for ongoing pregnancies is ten times higher for women at 64–70 days' gestation than for women at less than or equal to 49 days' gestation.[13] And one study on which FDA previously relied[14] found that—as compared to those who take

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[8] Ex. 9, FDA-Approved Label for Mifepristone (Mifeprex) at 7 (Jan. 2023), perma.cc/2UJ5-8WVF ("Mifeprex 2023 Label") ("Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most patients can expect bleeding more heavily than they do during a heavy menstrual period."), App. 0202.

[9] *Id.* at 7, Table 2, App. 0203.

[10] *Id.* at 17, App. 0212.

[11] *Id.* at 1, App. 0196.

[12] Ex. 10, 2021 FDA Letter to AAPLOG and Am. Coll. of Pediatricians denying in part and granting in part 2016 Citizen Petition, Docket No. FDA-2019-P-1534 at 9 (Dec. 16, 2021), App. 0224 ("We agree that the failure rate of medical abortion regimens, including the currently approved regimen, generally increases with increasing gestational age."); Ex. 9, Mifeprex 2023 Label at 13, Table 4, App. 0208.

[13] Ex. 9, Mifeprex 2023 Label at 13, Table 4, App. 0208.

[14] Ex. 11, Center for Drug Evaluation and Research, Application Number: 020687Orig1s020 Summary Review at 19 (Mar. 29, 2016) ("FDA 2016 Summary Review"), App. 0276.

mifepristone *before* nine weeks' gestation—almost four times as many women who take it *after* nine weeks' gestation experience an incomplete abortion, nearly twice as many suffer an infection, and over six times as many require surgical evacuation.[15]

36. Remotely dispensed abortion drugs present even greater risks to women because, without an in-person examination, prescribers cannot confirm and therefore are more likely to misdate the gestational age of a baby or fail to detect an ectopic pregnancy—with potentially fatal consequences.

37. A more recent review of large-scale insurance data concluded that the "real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of 'less than 0.5 percent' in clinical trials reported on the drug label."[16] Nearly 11% of women "experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion."[17]

38. Of the women who end up in the emergency room after taking abortion drugs, many suffer severe injuries. A study testing the severity of emergency department visits for Medicaid-eligible women following various pregnancy outcomes found that "an [emergency department (ED)] visit following a [mifepristone] abortion

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[15] Ex. 12, Maarit Niinimaki et al., *Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study*, BMJ at 5 (April 20, 2011). App. 0290.

[16] Ex. 13, Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Pub. Pol'y Ctr. at 1 (Apr. 28, 2025), perma.cc/YH5F-9R6C, App. 0294.

[17] *Id.*

was significantly more likely to have a severe or critical acuity rating than a visit following surgical abortion, live birth, or an ED visit at any time by a woman who was never pregnant."[18] The study also found that ED visits coded severe or critical for women who underwent a chemical abortion increased by 4,041.1% between 2004 and 2015, compared to a 450.6% increase for surgical abortion subjects and 20.9% for live birth subjects.[19] (And all this assumes accurate reporting in the ED, notwithstanding that some abortion activists encourage women to tell emergency room staff that they are having a miscarriage if they suffer abortion-drug complications requiring urgent care.[20])

39. That is not all. Without an in-person doctor visit, abortion drugs also present heightened risks for women with an Rh-negative blood type, which accounts for about 15% of North Americans.[21] If these women are not simultaneously administered Rhogam, they may experience isoimmunization, which threatens future pregnancies. If an Rh-negative woman is left untreated, her future baby will have a 14% chance of being stillborn and a 50% chance of suffering neonatal death or a brain

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[18] Ex. 14, James Studnicki et al., *Comparative Acuity of Emergency Department Visits Following Pregnancy Outcomes Among Medicaid Eligible Women, 2004–2015*, Int'l J. Epidemiology & Pub. Health Rsch., Apr. 2024, at 1, App. 0301.

[19] *Id.* at 2, App. 0302.

[20] *See, e.g.*, Ex. 15, *Will a doctor be able to tell if you've taken abortion pills?*, Women Help Women (Sept. 23, 2019), perma.cc/E89M-HUCG, App. 0306–07; Ex. 16, *How do you know if you have complications and what should you do?*, Aid Access, perma.cc/764Z-QBZQ, App. 0310.

[21] Ex. 17, *Am. Coll. of Obstetricians and Gynecologists Practice Bulletin No. 181: Prevention of Rh D Alloimmunization,* 130 Obstetrics & Gynecology 481 (Aug. 2017), App. 0312.

injury.[22] In addition, beyond these physical risks, women have described their abortion-drug experiences as harming their mental health and leaving them feeling unprepared, silenced, regretful, or trapped.[23]

II. FDA's Regulation of Mifepristone.

40. After obtaining the American patent rights to mifepristone, the Population Council, "a nonprofit founded in 1952 by John D. Rockefeller III to address supposed world overpopulation,"[24] conducted clinical trials in the United States.[25] The Population Council granted Danco Laboratories, LLC ("Danco")—incorporated in the Cayman Islands in 1995—an exclusive license to manufacture, market, and distribute mifepristone under the brand name Mifeprex in the United States.[26] Danco remains "one of the most enigmatic companies in the pharmaceutical industry,"[27] but its sole business of distributing abortion drugs has "been extremely profitable."[28]

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[22] *See id.*

[23] *See* Ex. 18, 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), App. 0330–33.

[24] Ex. 19, Population Council, perma.cc/2YFW-FP5S, App. 0338.

[25] Ex. 5, Center for Drug Evaluation and Research, Application Number: 20-687 Medical Review(s) at 2, App. 0135.

[26] Ex. 20, 2002 Citizen Petition of AAPLOG to FDA at 9 (Aug. 8, 2002) ("2002 Citizen Petition"), App. 0361.

[27] Ex. 21, Robert O'Harrow Jr., *Drug's U.S. Marketer Remains Elusive*, Wash. Post (Oct. 11, 2000), perma.cc/MY3N-83F8, App. 0446.

[28] Ex. 22, Hannah Levintova, *The Abortion Pill's Secret Money Men*, Mother Jones (March–April 2023), perma.cc/283E-UALT, App. 0457.

41. FDA's regulation of mifepristone began with its handling of the Population Council's new drug application for "Mifepristone Tablets, 200 mg" filed on March 18, 1996.[29]

42. FDA approved mifepristone in 2000 "for the medical termination of intrauterine pregnancy through 49 days' pregnancy."[30] Because FDA had previously concluded that "restrictions ... on the distribution and use of mifepristone are needed to assure safe use of this product,"[31] FDA approved the Population Council's application with distribution restrictions "to assure safe use" under an accelerated approval program found at 21 C.F.R. § 314 Subpart H.[32]

43. FDA's 2000 approval contained a few requirements in addition to gestational age that are key here. *First*, FDA required at least three in-person doctor visits, including in-person dispensing of mifepristone: (1) the Day 1 dispensing and administration of mifepristone; (2) the Day 3 dispensing and administration of misoprostol; and (3) the Day 14 follow-up visit to confirm no fetal parts or tissue

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[29] Ex. 23, Letter from Center for Drug Evaluation and Research to Ann Robbins, Ph.D. (Sept. 18, 1996), perma.cc/579K-KZ8B, App. 0463.

[30] Ex. 24, 2000 FDA Approval Letter for Mifeprex (mifepristone) Tablets at 1 (Sept. 28, 2000), App. 0472. In 2019, FDA approved GenBioPro, Inc.'s generic version of Mifeprex, and thus GioBioPro's generic mifepristone has the same labeling and is subject to the same regulation as Danco's mifepristone; Ex. 25, 2019 FDA ANDA Approval Letter to GenBioPro, Inc. at 1 (Apr. 11, 2019), perma.cc/QY87-UKNG, App. 0476.

[31] Ex. 26, FDA Center for Drug Evaluation & Research Letter to Population Council re: NDA at 5 (Feb. 18, 2000), App. 0487.

[32] Ex. 27, 2000 FDA Approval Memo. to Population Council re: NDA 20-687 Mifeprex (mifepristone) at 6 (Sept. 28, 2000), App. 0496; Ex. 26, FDA Center for Drug Evaluation & Research Letter to Population Council re: NDA at 5, App. 0487.

remain.[33] *Second*, FDA required that the dispensing be done by a certified physician.[34] And *third*, FDA stated that mifepristone's "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."[35] To that end, FDA required mifepristone's label to include a "black box warning for special problems, particularly those that may lead to death or serious injury."[36]

44. Congress thereafter codified FDA's post-marketing regulations under Subpart H in the Food and Drug Administration Amendments Act of 2007 (FDAAA) and authorized FDA to require drug sponsors to submit and implement a REMS if the agency determines that one is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a). In 2008, FDA followed Congress's mandate under the FDAAA to convert mifepristone's Subpart H post-marketing restrictions into a REMS under Section 909(b)(1).[37]

45. In 2011, FDA approved a REMS for mifepristone that included the previous Subpart H restrictions, noting that "a REMS is necessary for MIFEPREX

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[33] Ex. 27, FDA 2000 Approval Memo. at 2–3, App. 0492–93.

[34] *Id.* at 6, App. 0496.

[35] *Id.* at 2, App. 0492.

[36] *Id.*

[37] Ex. 28, Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008), App. 0501.

(mifepristone) to ensure the benefits of the drug outweigh the risks of serious complications[.]"[38] The REMS consisted of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments.[39] The REMS also 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."[40] The 2011 REMS warned that women should not take mifepristone if they "cannot easily get emergency medical help [for] 2 weeks" after taking the drug.[41] The REMS required prescribers "to assure patient access to appropriate medical facilities"[42] that were "equipped to provide blood transfusions and resuscitation, if necessary."[43] And the agency instructed women to take the Medication Guide with them "[w]hen [they] visit an emergency room."[44] In 2016, 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.[45]

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[38] Ex. 29, 2011 FDA Supplemental Approval Letter to Danco Laboratories, LLC at 1 (June 8, 2011) ("2011 Approval Letter"), App. 0503.

[39] *Id.*; Ex. 30, 2011 REMS for NDA 20-687 Mifeprex (mifepristone) Tablets, 200mg (June 8, 2011) ("2011 REMS"), App. 0508–10.

[40] Ex. 29, 2011 Approval Letter at 1, App. 0503; Ex. 30, 2011 REMS, 0508–10.

[41] Ex. 30, 2011 REMS at 5, App. 0512.

[42] *Id.* at 1, App. 0508.

[43] *Id.* at 7, App. 0514.

[44] *Id.* at 4, App. 0511.

[45] Ex. 31, 2016 FDA Letter to AAPLOG, Christian Medical & Dental Associations, and Concerned Women for America denying 2002 Citizen Petition, Docket No. FDA2002-P-0364 at 21 (Mar. 29, 2016) ("2016 Petition Denial"), App. 0539.

46. In 2016, FDA authorized "major changes" to the mifepristone REMS, including, as relevant here, extending the maximum gestational age from 49 days to 70 days, removing the requirement for in-person follow-up examinations on Day 3 and Day 14 after an abortion, and allowing "healthcare providers" other than physicians to dispense and administer abortion drugs.[46] FDA did not, however, eliminate the Day 1 in-person dispensing requirement for mifepristone.

47. In addition to these new changes to the conditions of use, FDA eliminated the requirement that prescribers report nonfatal, serious adverse events, asserting that "after 15 years of reporting serious adverse events, the safety profile for Mifeprex is essentially unchanged."[47] FDA acknowledged that "[i]t is important that the Agency be informed of any deaths with Mifeprex to monitor new safety signals or trends."[48]

48. During the COVID-19 pandemic, the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) sent a joint letter to FDA asking the agency to abandon the in-person dispensing requirement for mifepristone and to allow remote dispensing for the duration of the pandemic.[49] One month later, ACOG and others sued to enjoin FDA's in-person dispensing requirement during the pandemic. *Am. Coll. of Obstetricians &*

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[46] Ex. 11, FDA 2016 Summary Review at 5–10, App. 0262–67.

[47] *Id.* at 26, App. 0283.

[48] *Id.*

[49] Ex. 32, 2020 Letter from ACOG & SMFM to FDA about Mifepristone REMS (Apr. 20, 2020) ("2020 ACOG-SMFM Letter"), App. 0553–54.

Gynecologists v. FDA, 472 F. Supp. 3d 183 (D. Md. 2020). The district court there granted ACOG's request, *id.* at 233, *order clarified*, 2020 WL 8167535 (D. Md. Aug. 19, 2020), and the Fourth Circuit denied FDA a stay of the injunction, Court Order Denying Mot. for Stay Pending Appeal, *Am. Coll. of Obstetricians & Gynecologists v. FDA*, No. 20-1824 (4th Cir. Aug. 13, 2020), ECF No. 116.

49. Under President Trump's first administration, FDA then requested an emergency stay from the U.S. Supreme Court. Appl. for Stay, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, No. 20A34 (U.S. Aug. 26, 2020). In its filing, the agency affirmed that in-person dispensing was both "minimally burdensome" and "necessary" to preserve the safety of women who take abortion drugs. *Id.* at 4, 13. FDA added 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 in-person dispensing was "necessary to mitigate [those] serious risks." *Id.* at 4, 7, 21. The U.S. Supreme Court granted the requested stay in January 2021. *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (2021).

50. After President Biden took office, however, FDA reversed course, stating that it "intends to exercise enforcement discretion" regarding the in-person dispensing requirement during the COVID-19 pandemic (2021 Non-Enforcement Decision).[50] By refusing to enforce that requirement, FDA authorized abortion drugs

[50] Ex. 3, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS at 2, App. 0128.

to be prescribed remotely and sent via mail. Indeed, FDA expressly recognized that its Non-Enforcement Decision would allow "dispensing of mifepristone through the mail ... or through a mail-order pharmacy."[51]

51. Later that year, in December 2021, FDA denied a 2019 citizen petition's request to preserve the in-person dispensing requirement and stated its intention to permanently remove that requirement.[52]

52. In a separate December 2021 letter, FDA said it had "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."[53] The letter identified 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

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[51] *Id.*

[52] Ex. 10, 2021 FDA Letter to AAPLOG at 25, App. 0240. FDA likewise denied a similar petition filed in December 2022 by Students for Life of America that asked the agency to restore in-person dispensing. Ex. 33, Students for Life of America, Citizen Petition to FDA (Dec. 13, 2022), App. 0557–70. FDA rejected the petition on the grounds that it requested "the same or substantially the same" relief as the 2019 citizen petition. Ex. 34, 2023 FDA Letter to Students for Life of Am. denying 2022 SFLA Petition, Docket No. FDA-2022-P-3209, at 2 (Jan. 3, 2023), App. 0626.

[53] Ex. 35, 2021 FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021), App. 0628.

that dispense the drug be specially certified," signaling that FDA would soon allow pharmacies to dispense abortion drugs.[54]

III. The Biden Administration Responds to *Dobbs* with the 2023 REMS.

53. FDA's regulation of mifepristone (or lack thereof) took on a whole new life after *Dobbs* overruled *Roe* in 2022. The pro-abortion activists within FDA anticipated as much. As Ruth B. Merkatz (Director of FDA's Office of Women's Health (1994–1996) and later a director at the Population Council) explained, "[w]e knew [mifepristone] 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."[55]

54. Following the U.S. Supreme Court's refusal to block a Texas pro-life bill in September 2021, President Biden directed HHS and the Department of Justice (DOJ) to explore steps to "ensure access to safe and legal abortion."[56] Officials were to "use every lever at their disposal to ensure … access" for "every woman … across the country."[57]

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[54] *Id.*

[55] Ex. 36, FDA, Oral History Interview with Ruth B. Merkatz at 39 (Oct. 16, 2019), perma.cc/6JRY-DR92, App. 0668.

[56] Ex. 37, White House, Readout of White House Roundtable Meeting with Women's Rights and Reproductive Health Leaders (Sept. 3, 2021), perma.cc/CN85-AZM2, App. 0730.

[57] Ex. 38, White House, Press Briefing by Press Secretary Jen Psaki and Deputy National Security Advisor for Cyber and Emerging Technologies Anne Neuberger, September 2, 2021 (Sept. 2, 2021), perma.cc/6CVF-3MMQ, App. 0750.

55. FDA had planned its action in response to *Dobbs* for over a year. The *Dobbs* oral argument on December 1, 2021, indicated that *Roe v. Wade* was "doomed."[58] So just over two weeks later, on December 16, 2021, FDA announced sua sponte that it would permanently authorize a nationwide, mail-order abortion-drug regime and directed the drug sponsors to make the associated changes.

56. After *Dobbs*, the Biden Administration kicked its efforts into high gear. President Biden called *Dobbs* "an extreme decision"[59] by "not a normal Court"[60] and recommitted to "doing everything in his power" to "protect access" to abortion.[61] He noted: "Some states are saying that they'll try to ban or severely restrict access to these medications."[62]

57. To that end, President Biden issued multiple executive orders mandating access to abortion.[63]

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[58] Ex. 39, Ian Millhiser, *It sure sounds like Roe v. Wade is doomed*, Vox (Dec. 1, 2021), perma.cc/M4EU-DSC2, App. 0771.

[59] Ex. 40, White House, Remarks by President Biden Before Meeting with His Task Force on Reproductive Healthcare Access (Jan. 22, 2024), perma.cc/N9KR-TKX9, App. 0784.

[60] Ex. 41, White House, Remarks by President Biden on the Supreme Court's Decision on Affirmative Action (June 29, 2023), perma.cc/7XU8-3KL4, App. 0794.

[61] Ex. 42, White House, FACT SHEET: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care Services (July 8, 2022), perma.cc/F5ZZ-XGL8, App. 0796.

[62] Ex. 43, White House, Remarks by President Biden on the Supreme Court Decision to Overturn *Roe v. Wade* (June 24, 2022), perma.cc/B8Y3-EWUZ, App. 0808.

[63] Ex. 44, Exec. Order No. 14076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42053 (July 8, 2022), App. 0811; Ex. 45, Exec. Order No. 14079, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49505 (Aug. 3, 2022), App. 0815; *see also* Ex. 46, Presidential Memorandum, Further Efforts

58. 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 FDA's determination that the drug is safe and effective—including when prescribed through telehealth and *sent by mail*."[64]

59. The same day, HHS Secretary Becerra announced HHS's "commitment to ensure every American has access to … medication abortion" and promised to "double down and use every lever we have to protect access to abortion care."[65] He noted a few days later that "HHS will take steps to increase access to medication abortion" and "will leave no stone unturned."[66]

60. President Biden then issued a follow-up executive order again directing HHS "to protect and expand access to abortion care, including medication abortion."[67]

To Protect Access to Reproductive Healthcare Services, 88 Fed. Reg. 4895 (Jan. 22, 2023), App. 0820 ("My Administration remains committed to supporting safe access to mifepristone.").

[64] Ex. 47, 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), perma.cc/66T6-BL87, App. 0824 (emphasis added).

[65] Ex. 48, Press Release, HHS, HHS Secretary Becerra's Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), perma.cc/89AZ-RFL4, App. 0826.

[66] Ex. 49, Press Release, HHS, Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of *Roe v. Wade* (June 28, 2022), perma.cc/KW6H-KF7D, App. 0828.

[67] Ex. 44, Exec. Order No. 14076, App. 0820.

61. These directives culminated in the permanent 2023 REMS, which made two key moves.

62. *First*, and perhaps most significant, the 2023 REMS permanently removed the in-person dispensing requirement, which had required that mifepristone must "be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals."[68] This move now allows doctors and other activists to dispense mifepristone *by mail*, and also expands the program to allow mifepristone to be dispensed by certified pharmacies, including retail pharmacies.[69]

63. FDA acknowledged in its 2023 Summary Review that it had "determined" on "12/16/2021" that "the REMS must be modified to remove the in-person dispensing requirement."[70] FDA added 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."[71] FDA thus imported its 2021 rationale when it implemented the 2023 changes.

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[68] Ex. 50, Center for Drug Evaluation and Research, Application Number: 020687Orig1s025 Summary Review at 3 (Jan. 3, 2023) ("FDA 2023 Summary Review"), App. 0835.

[69] *Id.* at 3, 12–13, App. 0835, 0844–45.

[70] *Id.* at 6, App. 0838.

[71] *Id.* at 9, 16, App. 0841, 0848.

64. FDA's 2021 REMS Modification Rationale Review relied on the "small" number of adverse events voluntarily reported in the FDA Adverse Event Reporting System (FAERS) database, even though FDA had years before *abandoned* the requirement that abortion providers report nonfatal adverse events.[72]

65. 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."[73]

66. 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."[74] Compounding the problem, the complicated FAERS electronic submission process itself erodes its reliability, since it takes FDA 48 pages of guidance to instruct users

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[72] Ex. 51, Center for Drug Evaluation and Research, Application Numbers: 020687 and 91178 Rationale Review at 21 (Dec. 16, 2021) ("FDA 2021 Rationale Review"), App. 0943.

[73] Ex. 52, FDA Adverse Events Reporting System (FAERS) Public Dashboard, perma.cc/CZ2G-4S75, App. 0974, 0976.

[74] Ex. 53, 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 Issues in L. & Med., no. 1, Nov. 1, 2021, at 25–26, App. 1013–14.

how to use it.[75] For all of these reasons, reporting "discrepancies render the FAERS inadequate to evaluate the safety of mifepristone abortions."[76]

67. In addition to FAERS data, FDA evaluated "assessment data" concerning healthcare provider certification, program utilization, and non-compliance. It noted that the eight reported cases of adverse events from these data were also identified in the FAERS database.[77]

68. FDA also claimed support from published literature evaluating mail-order dispensing by pharmacies and clinics.[78] Yet the agency conceded that it was unable to "generalize" the results to the United States population and that "the usefulness of the studies is limited in some instances by small sample sizes and lack of follow-up information on outcomes."[79] FDA thus acknowledged that "[t]he studies [it] reviewed are *not adequate on their own* to establish the safety of the model of dispensing mifepristone by mail[.]"[80] Instead, the studies were merely "not

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[75] *See* Ex. 54, Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments (Apr. 2021), perma.cc/CAD8-N4EM, App. 1017–64.

[76] Ex. 55, Christiana A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Rsch & Managerial Epidemiology 1, 1 (2021), App. 1066.

[77] Ex. 51, FDA 2021 Rationale Review at 21–23, 38–39, App. 943–45, 0960–61.

[78] *Id*. at 38, App. 0960.

[79] *Id*.

[80] *Id.* at 39. App. 0961 (emphasis added).

inconsistent with" FDA's conclusion that removing the initial in-person visit would be safe.[81]

69. FDA reviewed three studies for "mail order pharmacy dispensing."[82] One (Hyland) alarmingly reported that 3% of the participants needed to be hospitalized—a 330% increase over the rate on the approved label.[83] FDA disregarded this dramatic increase, saying it could not make any "conclusions about [that study's] safety findings."[84] Another study (Upadhyay) had "numerous deviations" from abortion practices in the United States, "limited follow-up information, and small sample size"—all of which "limit[ed] [its] usefulness."[85] And a third study, an "interim analysis" (Grossman), was largely irrelevant because it evaluated outcomes for "dispens[ing] by mail-order pharmacy after in-person clinical assessment."[86]

70. FDA also cited five studies that "evaluated clinic dispensing by mail."[87] In one (Raymond), 7% of participants "had clinical encounters in [emergency department (ED)] and urgent care centers."[88] In another (Chong), "6[%] [of] participants had unplanned clinical encounters in ED/urgent care," and "[s]urgical

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[81] *Id.*

[82] *Id.* at 28, App. 0950.

[83] *Id.* at 27–28, App. 0949–50.

[84] *Id.* at 28, App. 0950.

[85] *Id.* at 27, App. 0949.

[86] *Id.* at 26, App. 0948.

[87] *Id.* at 28, App. 0950.

[88] *Id.* at 29, App. 0951.

interventions were required in 4.1[%] to complete abortion."[89] A third study (Anger) revealed that 12.5% "had an unplanned clinical encounter."[90] In the fourth study (Kerestes), 5.8% in the "telemedicine [plus] mail group" had "ED visits," a rate exceeding the range on the label (2.9% to 4.6%) and almost three times higher than the 2.1% for women who had an "in-person" visit.[91] The final study (Aiken) had "limitations" because "investigators were unable to verify the outcomes" and "the study's design did not capture all serious safety outcomes."[92]

71. FDA conceded that "the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic[.]"[93] The agency similarly acknowledged that the Anger study "suggests a pre-abortion examination may decrease the occurrence of procedural intervention and decrease the number of unplanned visits for postabortion care."[94]

72. Still, FDA concluded that, while the studies "suggest more frequent encounters with healthcare providers, they generally support a conclusion that dispensing by mail is safe"[95] and that mifepristone would "remain safe and effective for medical abortion if the in-person dispensing requirement is removed[.]"[96] And

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[89] *Id.* at 30, App. 0952.

[90] *Id.* at 31, App. 0953.

[91] *Id.* at 31–32, App. 0953–54.

[92] *Id.* at 33–34, App. 0955–56.

[93] *Id.* at 34, App. 0956.

[94] *Id.*

[95] *Id.* at 39, App. 0961.

[96] *Id.*

"[w]ith the removal of the in-person dispensing requirement," mifepristone is "no longer required to be dispensed only in a clinic, medical office or hospital. Under the REMS as modified, mifepristone can be dispensed through a pharmacy[.]"[97] (One year after the 2023 REMS took effect, Walgreens and CVS announced they had completed certification requirements and would begin dispensing mifepristone in their stores.[98])

73. *Second*, in addition to eliminating the in-person dispensing requirement, the 2023 REMS 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."[99]

74. 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[.]"[100] This requirement ensured that a third-party physician will effectively diagnose and treat a woman's abortion-drug complication.[101]

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[97] Ex. 50, FDA 2023 Summary Review at 40, App. 0911.

[98] Ex. 56, Pam Belluck, *CVS and Walgreens Will Begin Selling Abortion Pills this Month*, N.Y. Times (Mar. 1, 2024), perma.cc/AV5J-TTXF, App. 1072–76.

[99] Ex. 50, FDA 2023 Summary Review at 11, App. 0843.

[100] Ex. 57, 2019 REMS Single Shared System for Mifepristone 200MG at 8 (Apr. 2019), App. 1085.

[101] Ex. 30, 2011 REMS at 4–5, App. 0511 ("When you visit an emergency room or a provider who did not give you your Mifeprex, you should give them your

75. 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 provider] who did not give [her] mifepristone so the emergency room or HCP will understand that the patient is having a medical abortion."[102] Despite the Guide's longstanding role in the 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."[103]

76. FDA did not address the health risks associated with misdiagnosing an abortion-drug complication, or the common practice among abortion-drug dispensers of encouraging women to tell emergency staff that they are having a miscarriage when they present with complications.[104]

77. After the 2023 REMS, HHS issued a report called *Marking the 50th Anniversary of Roe: Biden-Harris Administration Efforts to Protect Reproductive Health Care*. HHS identified the 2023 REMS' removal of the in-person dispensing requirement as one of the critical actions it took since *Dobbs* to push abortion

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MEDICATION GUIDE so that they understand that you are having a medical abortion with Mifeprex.").

[102] Ex. 50, FDA 2023 Summary Review at 20, App. 0852.

[103] *Id.* at 12, App. 844.

[104] *See, e.g.*, Ex. 15, *Will a doctor be able to tell if you've taken abortion pills?,* App. 306; Ex. 16, *How do you know if you have complications and what should you do?,* App. 0310.

throughout the country.[105] In an accompanying press release, HHS highlighted FDA's REMS modification as one of the Department's "six core priorities" to "protect and expand access" to abortion post-*Dobbs*.[106]

78. The White House likewise identified FDA's 2023 permanent removal of the in-person dispensing requirement as a key response to President Biden's July 8, 2022, executive order directing HHS to "protect and expand access to abortion care, including medication abortion."[107]

IV. The Nationwide, Extra-Territorial Abortion Effort.

79. The Biden FDA's 2023 REMS has had its intended effect—facilitating a nationwide effort to mail FDA-approved mifepristone into states like Louisiana where abortion is prohibited (with narrow exceptions) and causing hundreds of unlawful abortions in those states every month.

80. The scheme is simple. Take one abortion facilitator, Abuzz, whose website tells Louisianans that they need only fill out a "short form" to obtain abortion

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[105] Ex. 58, HHS, Marking the 50th Anniversary of *Roe*: Biden-Harris Administration Efforts to Protect Reproductive Health Care (Jan. 19, 2023), perma.cc/8EB4-P7US, App. 1088 (HHS "continue[s] to activate all divisions of the Department in service to [its] commitment to ensuring" access to abortion).

[106] Ex. 59, Press Release, HHS, HHS Releases Report Detailing Biden-Harris Administration Efforts to Protect Reproductive Health Care Since *Dobbs* (Jan. 19, 2023), perma.cc/6CE3-J7DD, App. 1094.

[107] Ex. 60, White House, FACT SHEET: The Biden-Harris Administration's Record on Protecting Access to Medication Abortion (Apr. 12, 2023), perma.cc/78TT-3J2G, App. 1099 (citing Exec. Order No. 14076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42053 (July 8, 2022)); Ex. 61, HHS, Secretary's Report, Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care (Aug. 2022), perma.cc/WWV5-CSFY, App. 1104.

drugs "discreetly packaged and delivered by mail."[108] "In most cases," Abuzz promises, "providers do not require a phone call or video visit."[109] Similarly, another abortion facilitator, A Safe Choice, promises mifepristone by mail after a person fills out a "quick" online form, "no phone call required."[110] Another facilitator, Choices Rising, assures Louisianans that "[t]here is no need to have a telehealth consultation" before receiving the "FDA-approved abortion pill" in "a few days."[111] And the Massachusetts Medication Abortion Access Project says their form can be completed in "less than 5 minutes," after which "[t]he pills [will] arrive in the mail and you take them at home or wherever is comfortable for you!"[112] Each of these facilitators states that it sends FDA-approved mifepristone into all fifty states, or to Louisiana specifically, through the mail to induce abortions.

81. And the scheme unfolds with activists hosting "pill-packing parties to help strangers in faraway states circumvent strict laws," preparing Danco's signature orange Mifeprex boxes for mailing while eating pizza and "sipp[ing] Chardonnay in red plastic cups":[113]

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[108] Ex. 62, Abuzz, *Abortion Pill Access in Louisiana*, perma.cc/BDY4-5MX9, App. 1125.

[109] Ex. 63, Abuzz, *Need abortion care at home?*, perma.cc/ERK3-D97B, App. 1132.

[110] Ex. 64, A Safe Choice, *Home,* perma.cc/HCQ7-WYC6, App. 1136; Ex. 65, A Safe Choice, *Online Consultation Form*, perma.cc/NSA6-HGPQ, App. 1142–43.

[111] Ex. 66, Choices Rising, *Abortion Pill*, perma.cc/7NKQ-BYRU, App. 1147.

[112] Ex. 67, MAP, *Frequently asked questions*, perma.cc/3HNJ-ZFTC, App. 1150.

[113] Ex. 68, Scott Calvert, *The Parties Where Volunteers Pack Abortion Pills for Red-State Women*, Wall St. J. (Aug. 12, 2024), perma.cc/57KX-MD3V, App. 1154.

82. The sheer scale of this nationwide, extra-territorial abortion effort is striking. According to one report, in less than a month after *Dobbs* was decided, seven United States-based abortion-drug facilitators mailed approximately 3,500 doses of mifepristone and its generic equivalent to states that prohibit their use and distribution.[114]

83. Consider Aid Access, which has explained how FDA's removal of in-person dispensing has enabled its prescribers to frustrate state abortion restrictions and mail FDA-approved abortion drugs "to people in all 50 states, even those that have banned it."[115] When FDA imposed a temporary moratorium in 2021 on the "in-person dispensing requirement for mifepristone,"[116] Aid Access began sending FDA-

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[114] Ex. 69, Rachel Roubein, *'Shield' Laws Make it Easier to Send Abortion Pills to Banned State*s, Wash. Post. (July 20, 2023), perma.cc/A8MP-VXLJ, App. 1165.

[115] Ex. 70, Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States That Ban It*, The Guardian (July 23, 2023), perma.cc/49J6-3CZS, App. 1168; Ex. 71, Aid Access, *Get Abortion Pill Online in Louisiana*, perma.cc/J65J-M5LF, App. 1172.

[116] Ex. 70, Rebecca Grant, App. 1168.

approved abortion drugs by mail to certain states. "For the first time, legally prescribed medication abortion could be put in the mail."[117]

84. Then, after FDA permanently removed in-person dispensing in the 2023 REMS, Aid Access expanded its scope and began sending FDA-approved abortion drugs by mail to *all* states—including from states like New York that have adopted so-called "shield laws," which purport to protect from liability activists who use pro-abortion states as their home base to mail mifepristone into other states where abortion is prohibited.[118] All thanks to FDA, says Aid Access, women "feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline."[119] So today, because of FDA's removal of the in-person dispensing requirement, Aid Access has become the largest of the current abortion-drug facilitators.[120]

85. Dr. Linda Prine, a New York City-based abortion-drug prescriber for Aid Access, explained the scale of Aid Access's FDA-enabled operations by mid-2024. Within one month after New York's shield law passed, Aid Access "sent about 4,000

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[117] *Id.*

[118] *Id.*

[119] *Id.* at App. 1169.

[120] Ex. 72, Elissa Nadworny, *Inside a medical practice sending abortion pills to states where they're banned*, NPR (Aug. 7, 2024), perma.cc/3XWU-PEXT, App. 1180.

pills into restricted states, and now [as of April 2024] we're up to around 10,000 pills a month."[121]

86. Said Rachel Rebouché, the dean of Temple University Law School, to *The New York Times*: "Thousands 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."[122]

87. Finally, the dangerous disregard for women's health is undeniable. In another interview with the *Washington Post*, Dr. Prine said that when women call her for advice about complications, she 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."[123] 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.'"[124]

88. The *Washington Post* shared Dr. Prine's comments with other doctors. It reported: "A woman in that situation could have hemorrhaged or become septic,

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[121] Ex. 73, Abigail Brooks & Dasha Burns, *How a network of abortion pill providers works together in the wake of new threats*, NBC News (April 7, 2024), perma.cc/7ER7-BB7G, App. 1187.

[122] Ex. 74, Pam Belluck, *Abortion Shield Laws: A New War Between the States,* N.Y. Times (Feb. 22, 2024), perma.cc/6YVK-5YCQ, App. 1196.

[123] Ex. 75, Caroline Kitchener, *Alone in a bathroom: The fear and uncertainty of a post-*Roe *medication abortion*, Wash. Post (April 11, 2024), perma.cc/N66P-FTWU, App. 1224.

[124] *Id.* at App. 1226.

according to five OB/GYNs interviewed for this article."[125] Keri Garel, an OB/GYN at Boston Medical Center, said, "Whenever there is something inside the uterus that is trying to come out and won't come out, the risk of bleeding and infection gets higher with every passing moment," and so she would advise someone in this woman's situation to go to the hospital immediately. "At that point, your life is the most important thing."[126]

89. Dr. Prine also described how a "quiet and scared" 15-year-old girl 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." [127] The article states, "Unable to flush the fetus down the toilet, the girl asked about throwing it away."[128] Dr. Prine's main response: "There's nothing in there that's traceable back to you … As long as you don't tell anybody."[129]

90. Another Aid Access nurse practitioner also admitted to the *Washington Post* "that this system is far from perfect."[130] And she confessed there are "occasions her patients in restricted states require in-person care" that she cannot provide.[131]

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[125] *Id*. at App. 1232.

[126] *Id.* at App. 1233.

[127] *Id*. at App. 1221.

[128] *Id*.

[129] *Id*.

[130] Ex. 107, Caroline Kitchener, *Blue-state doctors launch abortion pill pipeline into states with bans*, Wash. Post (July 19, 2023), perma.cc/85E8-RVML, App. 2058.

[131] *Id*.

91. And these are not isolated instances. Prescribers and facilitators like Aid Access actively shroud their operations and disregard the serious risks women face when taking these drugs. Take Her Safe Harbor, for example.[132] Debra Lynch, the nurse practitioner who runs Her Safe Harbor, 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."[133] And "[s]he doesn't ask patients in states with abortion bans or restrictions to provide identification like a driver's license."[134] If women ask what they should do if they want or need to visit an emergency room, Lynch "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."[135]

92. Similarly, Abuzz tells women 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

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[132] Ex. 76, Her Safe Harbor, *Abortion Pills Online*, perma.cc/8JCL-7DQU, App. 1246.

[133] Ex. 77, Pam Belluck, *A day with one abortion pill prescriber*, N.Y. Times (Jun. 9, 2025), perma.cc/8Y85-E7UJ, App. 1258–59.

[134] *Id.* at App. 1259.

[135] *Id.* at App. 1260.

bleeding. I'm scared there's something wrong' and you should get the care you need."[136]

93. These abortion providers will not stop in response to state pro-life laws; only a change in federal regulation will stop them. As Angel Foster, who runs Massachusetts-based The MAP, which mails abortion drugs to "women in every state," said, "her organization will keep sending pills to women in Texas, as it has about 10,000 times in the past two years." "'We really don't change things unless we're legally required to,' she said."[137]

V. This Extra-Territorial Abortion Effort Is Playing Out in Louisiana.

94. Louisiana well knows the direct effects of this campaign—for it is living that reality every day.

95. Consider one recent high-profile example from Louisiana involving Dr. Margaret Carpenter. In 2022, Dr. Carpenter and Dr. Prine launched the Abortion Coalition for Telemedicine (ACT)—a group that "directly supports clinicians who" provide mail-order abortions to women "in all 50 states."[138] ACT works "directly with clinicians to launch shielded practices" so more women in pro-life states like Louisiana can receive mail-order abortions.[139] ACT is "committed" to enabling mail-

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[136] Ex. 78, Abuzz, *FAQs*, perma.cc/9LQ7-QZVL, App. 1276.

[137] Ex. 106, The Associated Press, *Texas Has a New Abortion Pill Law. But At Least One Provider Plans to Keep Shipping Them There*, Newsday (Sept. 18, 2025), perma.cc/84NU-BALB, App. 2041.

[138] Ex. 79, ACT, *Who We Are*, perma.cc/EX5M-RFUX, App. 1280.

[139] Ex. 80, ACT, *What We Do*, perma.cc/E3CM-SLYC, App. 1285.

order abortions "across state lines" and even helps "shielded practices" obtain "malpractice insurance."[140]

96. ACT promotes sending FDA-approved abortion drugs across state lines. Its website states that "[t]he two-step process of mifepristone and misoprostol is an FDA-approved method for terminating early pregnancies up to 12 weeks and can be done in the comfort of a patient's home with the support of a telemedicine provider."[141] ACT defines "medication abortion" as "FDA-approved mifepristone."[142]

97. ACT partners with several notorious out-of-state facilitators, including Aid Access.[143] As an abortion-drug prescriber, Dr. Carpenter has worked with Aid Access "to help facilitate access to abortion drugs in states where it's illegal."[144]

98. Dr. Carpenter's actions have revealed a dark consequence of remote dispensing: people other than pregnant women can order abortion drugs with ease. In April 2024, Dr. Carpenter allegedly prescribed and mailed abortion drugs to a woman in Louisiana who was not even pregnant.[145] The woman then allegedly forced her pregnant teenage daughter to take the drugs alone at home—even though the

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[140] *Id.* at App. 1286.

[141] *Id.*

[142] Ex. 81, ACT, *FAQs,* perma.cc/55HW-PJ56, App. 1291.

[143] Ex. 82, ACT, *Resources*, perma.cc/A9ND-USQL, App. 1295.

[144] Ex. 83, Alaa Elassar, *New York Doctor Indicted in Louisiana Abortion Case Recognized as a Leader in Women's Reproductive Health*, CNN (Feb. 23, 2025), perma.cc/8F88-6BYA, App. 1302.

[145] Ex. 84, Rosemary Westwood, *After Historic Indictment, Doctors Will Keep Mailing Abortion Pills Over State Lines*, NPR (Mar. 19, 2025), perma.cc/CQ6Z-SVL7, App. 1315.

daughter reportedly wanted to keep the baby and even planned a gender reveal party.[146] After the daughter took the drugs, she experienced a medical emergency, called 911, and was taken to the hospital in an ambulance.[147]

99. On January 31, 2025, a Louisiana grand jury indicted Dr. Carpenter, her medical practice, and the girl's mother for knowingly causing an abortion by delivering, dispensing, distributing, or providing a pregnant woman with an abortion-inducing drug in violation of Louisiana law.[148] But not even criminal charges have deterred Dr. Carpenter's coalition or its allies. Despite the Louisiana indictment, New York Governor Kathy Hochul has refused to extradite Dr. Carpenter, citing New York's shield law: "I'm respecting the laws of New York. Am I supposed to make those subservient to laws of another state?"[149] For its part, ACT issued a press release conveying that the coalition "has and continues to stand behind New York and other shield laws across the country that enable the distribution" of mail-order abortion drugs.[150]

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[146] *Id.*; Ex. 85, Katherine Donlevy, *Louisiana DA Warns There's Trove Of Evidence Against NY Doctor Who Allegedly Mailed Abortion Pills To Teen – Who Was Planning Gender Reveal Party: Report*, N.Y. Post (Feb. 15, 2025), perma.cc/N6UV-2VF5, App. 1326.

[147] Ex. 86, Lorena O'Neil, *Louisiana Mother Pleads Not Guilty Following Abortion Pill Indictment*, La. Illuminator (Mar. 11, 2025), perma.cc/TWX7-9FPS, App. 1331.

[148] Ex. 4, Dr. Carpenter indictment, App. 0131; Ex. 86, Lorena O'Neil, App. 1330.

[149] Ex. 85, Katherine Donlevy, App. 1327.

[150] Ex. 87, Press Release, ACT, Statement on Governor Hochul's Response to Louisiana Extradition Order (Feb. 13, 2025), perma.cc/S7PG-NNAM, App. 1334.

100. In response to Dr. Carpenter's indictment, New York enacted a law further shielding abortion-drug prescribers from liability by allowing them to list the name of their clinic instead of their own name on prescription labels—an attempt to make it more difficult to prosecute individual doctors in New York who illegally dispense abortion drugs to states that prohibit them.[151] Other states—including California, Colorado, Maine, Massachusetts, Rhode Island, Vermont, and Washington—have passed similar laws. In a troubling shift, California's newly enacted law (September 11, 2025) permits abortion drug prescriptions to be issued without identifying either the provider *or* the recipient. This is "to make it harder for states with abortion bans to develop evidence to make legal cases against doctors and others operating under shield laws."[152] But it also makes it harder, if not impossible, for women to build an evidentiary record to pursue providers and abusers for wrongdoing. These legal developments naturally and foreseeably follow the availability of mail-order abortion drugs.

101. Louisiana is also investigating a second case against Dr. Carpenter—this time for allegedly mailing mifepristone to a woman who was 20 weeks pregnant, wrapped her aborted baby's remains in a towel, and threw the baby in a garbage

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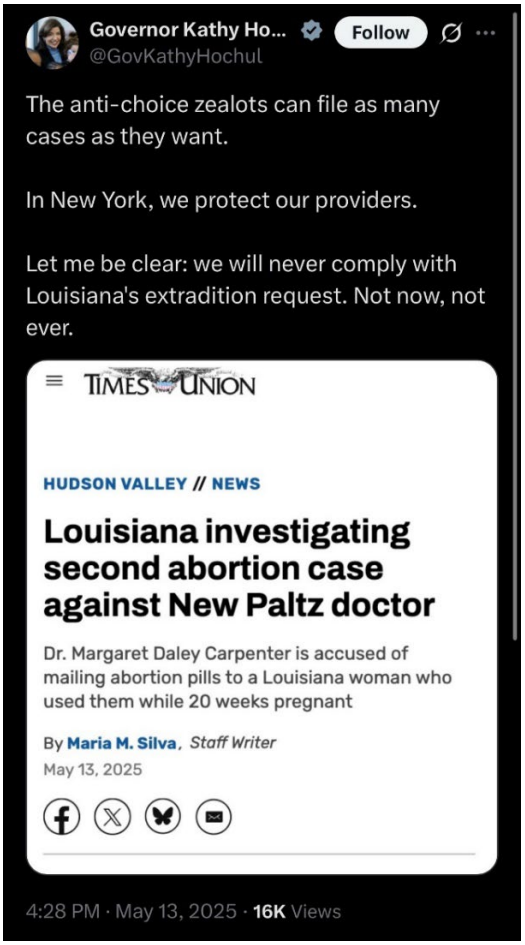
[151] Ex. 88, Press Release, Protecting Reproductive Freedom: Governor Hochul Signs Legislation Affirming New York's Status as a Safe Haven for Reproductive Health Care (Feb. 3, 2025), perma.cc/ZSH6-J6HW, App. 1337.

[152] Ex. 105, Pam Belluck, *California Passes Bill Allowing Omission of Patients' Names from Abortion Pill Bottles*, N.Y. Times (Sept. 11, 2025), perma.cc/U25B-S4M2, App. 2036.

can.[153] Louisiana Attorney General Murrill cited the "problem" with "activists who are intent on sending these pills to people through the mail."[154] Governor Hochul doubled down on her defiance of Louisiana law on X[155]:



[153] Ex. 89, Rosemary Westwood, *Louisiana Investigates Second Case Against New York Doctor Over Mailing Abortion Pills*, La. Illuminator (May 13, 2025), perma.cc/D4BR-RKFC, App. 1347.

[154] *Id.* at 1348.

[155] Ex. 90, Governor Kathy Hochul (@GovKathyHochul), X (May 13, 2025, 4:28 PM), perma.cc/ZA4U-G2CY, App. 1350.

102. As these examples show, FDA's removal of the in-person dispensing requirement in the 2023 REMS has had its intended effect. Pro-abortion activists credit the 2023 REMS for their ability to blanket pro-life states with mifepristone—with impunity and without any fear of liability.

103. And the resulting numbers are shocking. A Society of Family Planning #WeCount report states that, "between July 2023 to June 2024," they observed a range of "from 310 to 620" mail-order abortions per month in Louisiana. From April to June 2024, the average number of mail-order abortions reached 617 per month in the State.[156] In December 2024 alone, it reached 800.[157]

104. In fact, FDA's approval of mifepristone-by-mail *increased* the number of abortions Louisiana residents obtained—even *after* Louisiana's abortion prohibition (with narrow exceptions) took effect.[158]

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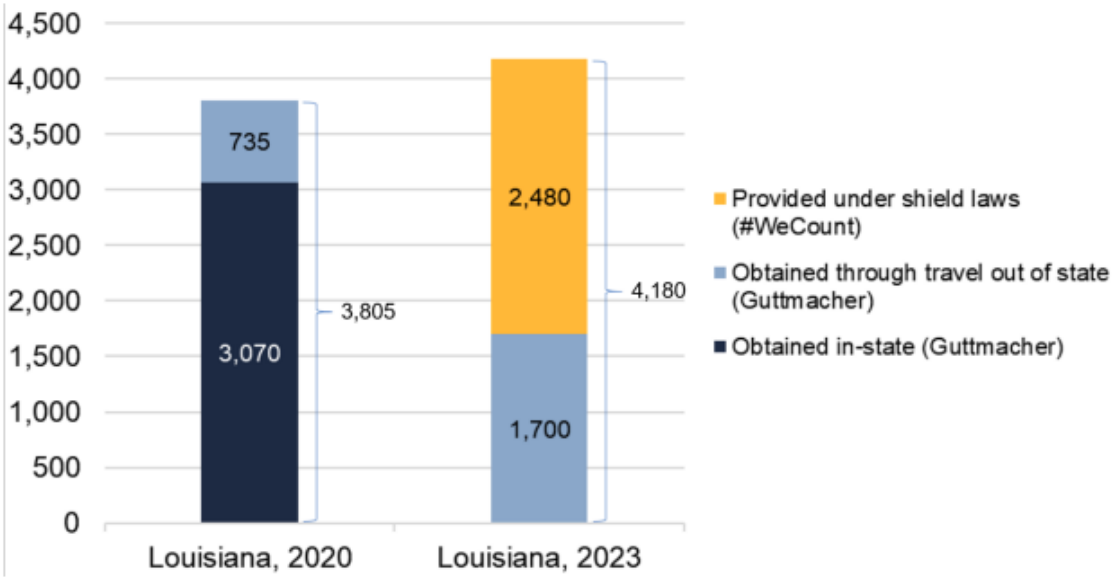
[156] Ex. 1, Society of Family Planning, #WeCount Report April 2022 to June 2024 at 10, App. 0011.

[157] Ex. 2, Society of Family Planning, #WeCount Report April 2022 to December 2024 at PowerPoint slide 35, App. 0093.

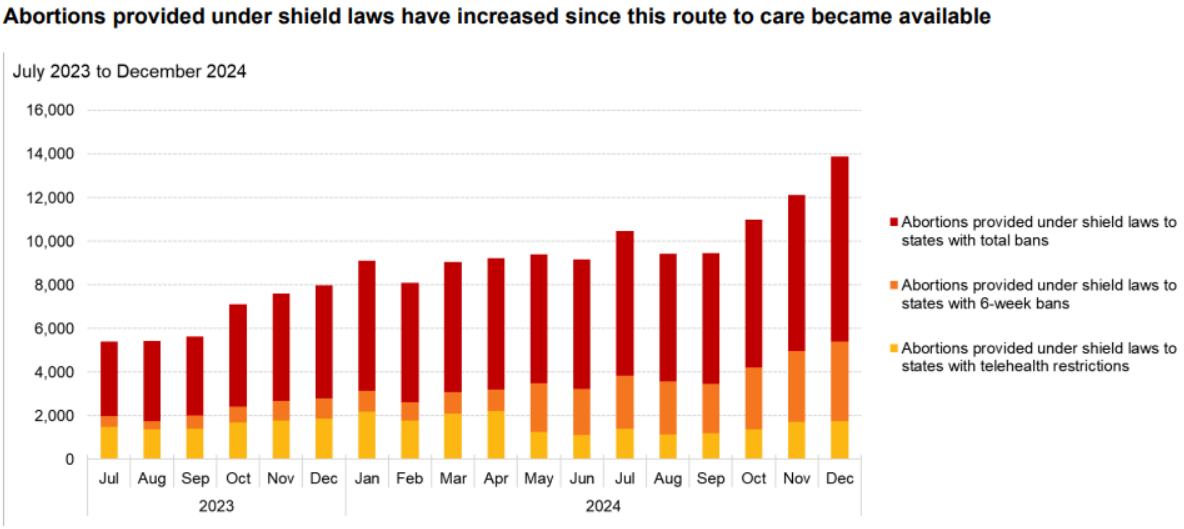
[158] Ex. 1, Society of Family Planning, #WeCount Report April 2022 to June 2024 at 16, App. 0017.

Figure 13. Louisiana, six months of 2020 and 2023, respectively



105. That trend coincides with national reported data, which show that the mailing of mifepristone under the 2023 REMS accounts for *thousands* of abortions every month in pro-life states:[159]

[159] Ex. 91, Society of Family Planning, #WeCount Report April 2022 to December 2024 at 11. (Jun. 23, 2025), perma.cc/859P-G4FV, App. 1362.



VI. Rosalie Has Standing to Challenge the 2023 REMS.

106. In October 2023 Rosalie Markezich felt coerced by her boyfriend to take FDA-approved abortion drugs that he ordered from an out-of-state prescriber in her name and had delivered to her home through the U.S. Postal Service.[160]

107. Rosalie told her boyfriend that she wanted to keep her baby. But he had other plans.[161]

108. When Rosalie refused the drugs, her boyfriend became angry and shouted at her. Rosalie had suffered domestic abuse before, and she knew the signs of a dangerous man.[162] Her boyfriend had a criminal record.[163] Yet she was alone with him in a car, and her friends were unaware of her whereabouts.[164] She was

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[160] *See* Ex. 92, Rosalie Markezich Decl. ¶¶ 10–13 App. 1372.

[161] *Id.* ¶¶ 5, 11, App. 1371–72.

[162] *Id.* ¶ 12, App. 1372.

[163] *Id.*

[164] *Id.*

terrified.[165] To pacify him, Rosalie agreed to take the drugs.[166] And he watched her swallow them.[167] Although she intended to throw them up as soon as she could get away from him, she was unsuccessful, and she lost her baby.[168]

109. Rosalie did not want to have an abortion.[169] Had she received the drugs in person, she would have told the doctor that she did not want to take the drugs—she would have sought help and support.[170] Rosalie now faces prolonged emotional trauma and mourns the loss of her child.[171] No woman should have to experience that heartbreak and devastating loss.

110. Rosalie suffered and continues to suffer concrete, particularized injuries. She lost her unborn child. She endured physical pain and heavy bleeding from ingesting unwanted abortion drugs. And she continues to suffer mental-health effects from the trauma she experienced for which she seeks counseling and receives medication.

111. Rosalie is also at risk of future injury. Without a requirement for an in-person office visit to prevent coercion, Rosalie could be placed in the same position for future pregnancies. Under FDA's current regime, anyone can obtain mifepristone and

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[165] *Id.*

[166] *Id.* ¶¶ 12–13, App. 1372.

[167] *Id.* ¶ 13, App. 1372.

[168] *Id.* ¶¶ 12–14, App. 1372–73.

[169] *Id.* ¶ 16, App. 1373.

[170] *Id.* ¶ 19, App. 1373.

[171] *Id.* ¶ 18, App. 1373.

pressure or trick a woman into taking it. Rosalie has a strong interest in reinstating the in-person dispensing requirement to prevent future coercion.

112. The 2023 REMS caused Rosalie's injuries, and her injuries are traceable to the 2023 REMS. If FDA had required an in-person office visit, a medical professional would have screened Rosalie for coercion and abuse. But the 2023 REMS allowed abortion drugs to be provided through the mail—enabling abusers to order them in others' names and coerce pregnant women like Rosalie to take them. Had the FDA required in-person dispensing, Rosalie's boyfriend would not have been able to access the drugs and compel Rosalie to take them.[172] She could have told a doctor that she did not want them.

113. Rosalie's injuries are redressable. It is not just speculation that the Court can remedy her situation by removing the risk of future abortion-drug coercion: if the 2023 REMS is rolled back and FDA's actions ruled unlawful, the in-person dispensing requirement will be reinstated. This legally vindicates Rosalie, who has an interest in FDA following lawful procedure to ensure high-risk drugs do not harm her.

114. Rosalie was hurt by government agencies who turned a blind eye to the risks that mail-order abortion drugs pose to women like her. A judicial acknowledgment that FDA unlawfully failed her would mitigate the ongoing pain and suffering that she experiences as she attempts to heal. Most importantly, a final judgment reduces the risk that she will be subject to the same coercion and bodily

[172] *Id.*

injury in the future by removing the means by which others could order these drugs without her full and free consent during a future pregnancy. Rosalie has an interest, as a matter of bodily autonomy, in not being subjected to abortion-drug coercion again—coercion that is only possible because of the 2023 REMS. Rosalie has a right to protect her future unborn children.

115. The State found out about Rosalie's circumstances in 2024, and it has issued a warrant for the arrest of the California-based doctor from whom Rosalie's boyfriend ordered the abortion drugs. That warrant is still outstanding. Rosalie learned about this case and the opportunity to seek relief against FDA in 2025.

VII. Louisiana Has Standing to Challenge the 2023 REMS.

116. As outlined above, the 2023 REMS is the direct cause of extensive harm that Louisiana suffers every day that the REMS is in effect. Indeed, this was the *intended* effect of the Biden Administration's 2023 REMS: to permit "dispensing of mifepristone through the mail ... or through a mail-order pharmacy"[173]—specifically to target those pro-life states like Louisiana where abortion is prohibited (with narrow exceptions) or narrowly circumscribed.

117. It is thus unsurprising that Louisiana has standing to sue in at least three separate respects: (A) the 2023 REMS harms Louisiana in its sovereign capacity because it predictably, and by design, enables third parties to violate Louisiana's pro-life laws, preventing Louisiana from effectively enforcing its

[173] Ex. 3, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS at 2, App. 0128.

prohibition on abortion and preventing the State from protecting the lives of unborn babies despite the promise of *Dobbs*; (B) the 2023 REMS harms Louisiana in its quasi-sovereign capacity by subjecting untold numbers of Louisiana women to injuries and risks of injuries caused by mifepristone; and (C) the 2023 REMS causes Louisiana textbook pocketbook injuries through the Medicaid payments Louisiana must make to cover the predictable increase in mifepristone-induced harms and the ordinary costs that arise when uninsured or underinsured patients seek services at public hospitals. For any of these reasons, Louisiana has standing to sue.

A. The 2023 REMS Causes Sovereign Harms.

118. First and foremost is the direct sovereign harm inflicted by the 2023 REMS upon Louisiana.

119. A court in this circuit has recently reaffirmed that "states [hold] a sovereign interest in creating and enforcing their own laws and public policy." *Louisiana v. EEOC*, 705 F. Supp. 3d 643, 654 (W.D. La. 2024). Put differently, they "have an interest in 'the exercise of sovereign power over individuals and entities within the relevant jurisdiction—this involves the power to create and enforce a legal code, both civil and criminal.'" *Id.* at 653 (quoting *Texas v. Cardona*, 2024 WL 2947022, at *11 (N.D. Tex. June 11, 2024) (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982))). And central among the "direct stake[s] necessary to satisfy standing" is a state's objection to federal agency "interefere[nce] with the States' ability to enforce their laws and implement the chosen public policies of their citizens." *Id.* (citation omitted).

120. Case in point: 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. *Id.* at 653–54.

121. That is the case here. Louisiana has enacted sovereign laws prohibiting (with narrow exceptions) abortion. *See, e.g.*, La. Stat. Ann. § 40:1061(C) ("No person may knowingly administer to, prescribe for, procure for, or sell to any pregnant woman any medicine, drug, or other substance with the specific intent of causing or abetting the termination of the life of an unborn human being."); *id.* § 14:87.9(A) ("Criminal abortion by means of an abortion-inducing drug is committed when a person knowingly causes an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant woman with an abortion-inducing drug."); *id.* § 40:1061.11(A) ("When any drug or chemical is used for the purpose of inducing an abortion, the physician who prescribed the drug or chemical shall be in the same room and in the physical presence of the pregnant woman when the drug or chemical is initially administered, dispensed, or otherwise provided to the pregnant woman."). So each pill of mifepristone that is mailed directly to a person in Louisiana for the purpose of causing an abortion directly violates Louisiana's laws.

122. That *third parties* violate Louisiana's laws in doing so does not matter in the standing analysis—because their conduct is not just the "predictable" response to the 2023 REMS, *Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019), but the *expressly intended* result of the 2023 REMS. But for the 2023 REMS, abortion

facilitators like Aid Access could not lawfully mail mifepristone into Louisiana. But, by eliminating the in-person dispensing requirement, the 2023 REMS permits the "dispensing of mifepristone through the mail ... or through a mail-order pharmacy."[174] That direct affront to Louisiana's laws renders Defendants directly complicit in abridging Louisiana's sovereign prerogatives—and that "clearly [gives the states] Article III standing to challenge" the 2023 REMS. *Louisiana*, 705 F. Supp. 3d at 654.

123. In fact, the case for standing here on sovereignty grounds is even stronger than it was in cases like *Louisiana* because Plaintiff Louisiana already has been forced to expend time and resources prosecuting the violations of its laws. Take Dr. Carpenter's pending indictment—there is no question that the charged conduct violated Louisiana law. As a result, Louisiana spent significant time and money investigating the case, interviewing witnesses, drawing up filings, and pressing toward Dr. Carpenter's indictment. That whole-of-government effort transcended not just the local district attorney's office but also the Attorney General's office and other State law enforcement partners. A state's active defense and enforcement of its own laws—precipitated by the federal government's own unlawful action—plainly implicates the states' "sovereign interest in creating and enforcing their own laws and public policy." *Id.* This is a straightforward case for standing.

124. But Louisiana's sovereign harms don't end there. Preemption of state law is itself an injury. *Deanda v. Becerra*, 96 F.4th 750, 760 (5th Cir. 2024). And more

[174] Ex. 3, 2021 FDA Letter to ACOG and SMFM About Mifepristone REMS at 2, App. 0128.

than one federal court has determined that state abortion-drug regulations are preempted by FDA's REMS.

125. For example, in a case brought by GenBioPro (the generic manufacturer of mifepristone), the Southern District of West Virginia held that FDA's "2023 REMS reflects a determination by FDA that when mifepristone is prescribed, it may be prescribed via telemedicine." *GenBioPro, Inc. v. Sorsaia*, No. CV 3:23-0058, 2023 WL 5490179, at *10 (S.D.W.Va. Aug. 24, 2023). On that basis, and before the underlying claim was dropped, the court ruled that West Virginia's law prohibiting remote dispensing of abortion drugs was preempted. *Id.*

126. Similarly, the Middle District of North Carolina enjoined some of North Carolina's abortion-drug regulations because "[w]hen a state imposes a restriction on the sale or distribution of an FDA-approved drug that is designed to reduce the risks associated with the drug even though the FDA explicitly considered and rejected that restriction as unnecessary for safe use under the statutory regime imposed and required by Congress, then that state law is preempted." *Bryant v. Stein*, 732 F.Supp.3d 485, at 505 (M.D.N.C. 2024), appeal filed, Nos. 24-1576, 1600, 1617 (4th Cir. 2024). According to the district court, "North Carolina cannot second-guess the FDA's explicit judgment on how to manage risks from and safely prescribe, dispense, and administer REMS drugs, including mifepristone." *Id.* at 508.

127. To be clear, Louisiana disagrees with these district court decisions and, instead, contends that FDA sets the "regulatory floor" for drug safety standards—while states are free to require more. *GenBioPro, Inc. v. Raynes*, 144 F.4th 258, 274

(4th Cir. 2025). But because both Defendant HHS[175] and GenBioPro argue otherwise, Louisiana maintains that its sovereign interests in creating and enforcing its laws are impeded, threatened, and potentially preempted.

B. The 2023 REMS Causes Quasi-Sovereign Harms.

128. Not only that, but the 2023 REMS also causes Louisiana quasi-sovereign harms in the form of injuries to Louisiana women—and their unborn babies.

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

130. In fact, *Dobbs* itself recognized these basic principles, crediting states' ability to regulate abortion with an eye toward "legitimate interests" such as: "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

[175] Ex. 61, HHS, Secretary's Report Health Care Under Attack: An Action Plan to Protect and Strengthen Reproductive Care 8, App. 1108 (stating in a section titled "Federal Preemption—Protecting Access to Medication Abortion" that "states may not ban mifepristone based on disagreement with FDA's expert judgment").

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*, 597 U.S. at 301 (citation omitted).

131. Louisiana has enacted the laws detailed above and others like them—yet the State faces unquestionable quasi-sovereign harm each time a woman or her unborn child endures an unlawful abortion.

132. Consider not only Rosalie Markezich, but also stories of Louisiana women who have faced complications from unlawful abortions induced by mifepristone that was mailed into Louisiana. One Lafayette OB/GYN treated a woman suffering complications after taking remotely dispensed mifepristone this year. He performed a dilation and curettage (D&C) procedure to resolve an incomplete abortion and bleeding at five weeks' gestation. Another teenage woman and her mother requested from the Lafayette doctor an ultrasound to confirm the teen's uterus was empty following an elective abortion and brought with them the envelope that had contained the abortion drugs they received in the mail from New York.

133. Another New Orleans OB/GYN and ACOG fellow has personally treated at least fourteen patients for abortion-drug complications—including roughly eleven for incomplete abortion and three for infection and sepsis—since Louisiana's pro-life law went into effect in 2022. One patient took the drugs at 19 weeks' gestation. Roughly half of the patients this doctor treats are Medicaid recipients. This doctor's staff saw roughly 30 serious abortion-drug complications, including bleeding,

hemorrhaging, suction D&C, blood transfusions, and hospital stays, in just a two-month span (from April through May 2025). The total number of abortion-drug complications treated by this doctor's hospital system is roughly 30 per month.

134. In addition to women who suffer from and are treated for complications, many more call local hospitals concerned about heavy bleeding or taking multiple doses without knowing how far along they are in their pregnancies or whether they have an ectopic or molar pregnancy.

135. The State is also aware of many women who have sought the assistance and support of pregnancy care centers after taking abortion drugs received through the mail, including from out-of-state prescribers and facilitators of FDA-approved mifepristone like Dr. Margaret Carpenter and Aid Access.

136. For example, one pregnancy center in North Central Louisiana receives at least one call per week asking for a follow-up ultrasound after taking abortion drugs. The pregnancy center has also encountered several women on Louisiana Medicaid who have suffered abortion-drug complications, including a woman who sought emergency medical care to treat excessive bleeding after passing out.

137. And these are just direct injuries to pregnant Louisiana women that Louisiana law prohibits but the 2023 REMS now permits. Consider also the fatal injuries to the unborn babies that are the subject of hundreds of unlawful mifepristone abortions every month in Louisiana. By Louisiana law, an unborn child is "considered [] a natural person for whatever relates to its interests from the moment of conception." La. Civ. Code art. 26.

138. In seeking to protect such natural persons by generally prohibiting all abortions, including mifepristone-induced abortion, Louisiana has precisely sought to regulate the "legitimate" interest *Dobbs* credited: "respect for and preservation of prenatal life at all stages of development." *Dobbs*, 597 U.S. at 301. And by directly overriding Louisiana's sovereign prerogative in that respect by facilitating the deaths of thousands of unborn Louisiana children every year, the 2023 REMS directly and irreparably harms the State itself. *See, e.g.*, *Kansas v. United States*, 249 F.3d 1213, 1227 (10th Cir. 2001) (holding that Kansas suffered an irreparable harm where a federal agency's decision "places [Kansas'] sovereign interests and public policies at stake[.]"); *see also State of Ohio ex rel. Celebrezze v. U.S. Dep't of Transp.*, 766 F.2d 228, 233 (6th Cir. 1985) ("The threatened injury to a State's enforcement of its safety laws is within the zone of interests of the Administrative Procedure Act[.]").

139. To be clear, this quasi-sovereign theory of harm is not a *parens patriae* theory because Louisiana is not asserting the rights of its citizens. *Cf. Murthy v. Missouri*, 603 U.S. 43, 76 (2024). Instead, Louisiana is invoking the direct harm from the 2023 REMS to Louisiana's *own* sovereign right to regulate for the protection of its citizens.

C. The 2023 REMS Causes Economic Harms.

140. Last but not least are the economic harms caused by the 2023 REMS. As recounted above, FDA itself has long recognized the serious risks that mifepristone poses to women. Relevant here is FDA's recognition—on the required label itself—that approximately 1 in 25 women who use mifepristone *as directed* will

end up in the emergency room.[176] Also relevant is FDA's recognition—reflected in the black box warning—that mifepristone can cause "[s]erious and sometimes fatal infections and bleeding" warranting emergency attention.[177] And these warnings appeared on FDA's label for mifepristone before the 2023 REMS action when the agency acknowledged that "the literature suggests that there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail."[178]

141. It is thus no surprise that, as reflected in the various Louisiana accounts above, women who use mifepristone mailed into Louisiana—facilitated by the 2023 REMS—are being treated in emergency settings for serious complications resulting from such use. Indeed, as the number of mifepristone-induced abortions continues to increase in states like Louisiana, the overall number of women seeking emergency care in Louisiana hospitals will only grow larger. That reality reveals basic pocketbook injuries to Louisiana.

142. *First*, Louisiana is on the hook for any Medicaid-related expenses arising from these emergency room and other hospital visits. Louisiana Medicaid historically swallows 44.4% of the State's total budget—dwarfing other budget items like secondary education (16.8%) and higher education (8.6%).[179] The State is set to spend

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[176] Ex. 9, Mifeprex 2023 Label at 8, 17, App. 0203, 0212.

[177] *Id.* at 1, App. 0196.

[178] Ex. 50, FDA 2023 Summary Review at 34, App. 0905.

[179] Ex. 93, *Exhibit 5: Medicaid as a Share of States' Total Budgets and State-Funded Budgets, SFY 2021*, Medicaid and CHIP Payment and Access Commission (MACPAC) (2023), perma.cc/KUQ2-9ZAY, App. 1376. The Medicaid and CHIP Payment and Access Commission (MACPAC) is a non-partisan federal legislative branch agency

about $19 billion on Medicaid next year, with the help of $14.2 billion in federal funding.[180]

143. As of January 1, 2023, 534,294 women from ages 15–44 were enrolled in Louisiana Medicaid and 538,139 women from ages 15–44 were recipients of Louisiana Medicaid.[181] The State has reason to believe that it has already expended Medicaid dollars on treating abortion-drug complications. And the State ultimately covers medical expenses for treating abortion drug-related complications.

144. HHS estimates that the average cost of a Medicaid-covered ER visit in 2021 was $600—and that has likely since increased from inflation and increasing medical costs.[182] A Medicaid "covered charge" may only be a fraction of total costs for that visit.

145. For example, one common method of treating abortion-drug complications is a D&C (dilation and curettage) to evacuate the contents of the uterus. Louisiana Medicaid covers D&Cs in an inpatient setting for incomplete or missed abortions, provided that the unborn child is not alive at the time of the D&C and the documentation indicates that the D&C procedure is not itself an abortion or

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that provides data analysis on Medicaid to Congress, HHS, and the States; *see* 42 U.S.C. § 1396(b)(3).

[180] Ex. 94, Julie O'Donoghue, *Louisiana Medicaid Set to Grow Under Landry, Even as D.C. May Force Cuts*, La. Illuminator (Mar. 26, 2025), perma.cc/S2Y8-B8JE, App. 1380.

[181] Ex. 95, Louisiana Department of Health, Medicaid Annual Report 2022/2023 at 26, App. 1419.

[182] Ex. 96, Marc Roemer, HHS, Agency for Healthcare Research and Quality, *Costs of Treat-and-Release Emergency Department Visits in the United States, 2021* (September 2024), perma.cc/WDE2-CV77, App. 1515.

pregnancy termination.[183] D&C costs vary slightly by practice setting. Louisiana Medicaid reimburses up to $552.64 for an outpatient D&C at a state hospital,[184] up to $535.50 for an outpatient D&C at a rural hospital,[185] and up to $550.32 for an outpatient D&C at a non-rural and non-state hospital.[186]

146. Louisiana Medicaid also covers both inpatient and outpatient emergency room services.[187] Louisiana Medicaid reimburses all outpatient emergency room services at a cost-to-charge ratio (CCR) that divides the provider's total costs by its total charges.[188]

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[183] Ex. 97, Hospital Services Provider Manual: Chapter Twenty-Five of the Medicaid Services Manual, State of Louisiana Bureau of Health Services Financing, § 25.2 at PDF 16 (July 1, 2011), App. 1540.

[184] Ex. 98, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: State Hospitals (Effective Jan. 1, 2025), at PDF 58, App. 1683.

[185] Ex. 99, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Rural Hospitals (Effective Jan. 1, 2025), at PDF 57, App. 1750.

[186] Ex. 100, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Non-Rural and Non-State Hospitals (Effective Jan. 1, 2025), at PDF 58, App. 1819.

[187] Ex. 101, Medicaid Services, Louisiana Department of Health, perma.cc/T8L3-FGGP, App. 1834–36.

[188] Ex. 102, State Hospitals Outpatient Services Fee Schedule (Effective Jan. 1, 2025), at PDF 5, App. 1846; Ex. 103, Small Rural Hospital Outpatient Services Fee Schedule (Effective Jan. 1, 2025), at PDF 5, App. 1942.

147. Louisiana Medicaid also covers blood transfusions.[189] And Medicaid covers some vaginal hysterectomies at rates ranging from $1,405.95 to $1,450.94[190] and other vaginal hysterectomies at a CCR rate.[191]

148. Louisiana Medicaid likewise covers miscarriage treatment. Patients often present their abortion-drug complications as miscarriages for several reasons, including mistaken fear of legal reprisal and (as discussed above) prescribers' advice that patients do not disclose the fact that they took abortion drugs and rather let emergency-room doctors assume they are treating a miscarriage.[192] Medicaid reimburses miscarriage treatment and care at rates ranging from $752.85 to $776.94.[193]

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[189] Ex. 102, State Hospitals Outpatient Services Fee Schedule at PDF 30, App. 1871.

[190] Ex. 100, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Non-Rural and Non-State Hospitals at PDF 57, App. 1818; Ex. 99, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Rural Hospitals at PDF 56, App. 1749; Ex. 98, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: State Hospitals at PDF 57, App. 1682.

[191] Ex. 103, Small Rural Hospital Outpatient Services Fee Schedule at PDF 37, App. 1974; Ex. 102, State Hospitals Outpatient Services Fee Schedule at PDF 37, App. 1878.

[192] *See supra* sec. IV.

[193] Ex. 100, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Non-Rural and Non-State Hospitals at PDF 58, App. 1818; Ex. 99, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: Rural Hospitals at PDF 57, App. 1749; Ex. 98, Louisiana Medicaid Hospital Ambulatory Surgery Fee Schedule: State Hospitals at PDF 58, App. 1682.

149. These figures do not include the standard per diem rate for hospital stays, if needed. Per diem rates for Louisiana Medicaid providers range from $213.60 to $4,382.07.[194]

150. As detailed above, Louisiana has experienced actual emergency-room visits by patients who took mifepristone received by mail and whose care costs will likely ultimately fall to Medicaid and the State.

151. This "effect on the states' fiscs" is a concrete, economic injury. *Texas v. United States*, 809 F.3d 134, 152 (5th Cir. 2015), *as revised* (Nov. 25, 2015) (cleaned up); *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); *U.S. v. Texas*, 599 U.S. 670, 687–88 (2023) (Gorsuch, J., concurring in the judgment) (acknowledging that the same principle of concrete, monetary injury applies to states challenging the federal government under the APA).

152. Louisiana thus satisfies Article III in this way as well. *See California v. Azar*, 911 F.3d 558, 571–73 (9th Cir. 2018) (finding that the state had standing based

[194] Ex. 104, Louisiana Medicaid Hospital Provider Inpatient Per Diem Rates (effective 7/1/2024), App. 2033–38.

on an injury to its economic interests where the state was responsible for reimbursing women who seek contraception through state-run programs).

153. *Second*, Louisiana and other states with pro-life laws, though not "directly regulated parties," are effectively the objects of the regulations here because the Biden Administration "explicitly" used FDA's 2023 REMS to "target" pro-life states and "impede" the enforcement of their laws in response to the *Dobbs* decision. *See Diamond Alternative Energy LLC v. EPA*, 145 S. Ct. 2121, 2135–36 (2025). The 2023 REMS "pose[s] a legal barrier" to meaningful pro-life state laws and "den[ies] [states like Louisiana] the opportunity to [enforce abortion prohibitions] without government interference." *Id*. at 2136.

154. Indeed, this case can be viewed as "a typical APA suit" where "[a]n unregulated plaintiff ... will sue under the APA to challenge an allegedly unlawful agency rule that regulates others but also has adverse downstream effects on the plaintiff." *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 826 (2024) (Kavanaugh, J., concurring). "One example" is *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 103 (1983), where "several insurance companies challenged a federal agency's *rescission* of safety standards for new motor vehicles." *Id.* (emphasis added).

155. That is also the case here. Louisiana has standing to seek redress from a deregulatory action—*i.e.*, the 2023 REMS' elimination of the in-person dispensing requirement—which has resulted, and continues to result, in more expenses paid through public insurance claims and at state-run hospitals. Because even if FDA does

not directly regulate the State itself, the State can "obtain relief from the downstream effects of the agency's rescission of the safety standards only if" the State can "obtain vacatur of that rescission." *Corner Post*, 603 U.S. at 834–35 (Kavanaugh, J., concurring). And here, vacating the 2023 REMS would disable out-of-state actors from sending FDA-approved abortion drugs into Louisiana against state law, thereby forestalling the presently existing harms to women in Louisiana and the state resources needed to address them.

156. *Third*, and last, separate and in addition to the regular payments public hospitals receive for providing inpatient care to Medicaid beneficiaries, Louisiana Medicaid also pays a determined rate to public hospitals that serve a disproportionate share of uninsured or indigent patients. In some cases, these payments may be lower than the hospital's costs. Those public hospitals agree to accept the payment as payment in full, even if it is less than their actual cost.

157. If the State pays only a portion of a medical bill related to a mifepristone-induced abortion, the public hospital will incur as an expense the difference between the full amount of the medical bill and what was paid. In that way, too, the State suffers a monetary injury every time a public hospital foots the remainder of a bill that Medicaid does not cover.

CLAIMS FOR RELIEF

COUNT ONE

The 2023 REMS Is Arbitrary and Capricious and an Abuse of Discretion

(5 U.S.C. § 706)

158. Rosalie and the State re-allege and incorporate, as though fully set forth, paragraphs 1 to 157 of this complaint.

159. As five Fifth Circuit judges already have indicated, the 2023 REMS is arbitrary and capricious and an abuse of discretion. 5 U.S.C. § 706(2)(A).

160. That is principally so because the 2023 REMS eliminated the in-person dispensing requirement—based on sources that the agency conceded did not independently support its decision. For example, it was arbitrary and capricious for FDA to conclude that adverse event reports supported the 2023 REMS. The agency acknowledges that voluntary FAERS data *cannot be used* to indicate drug safety or calculate the incidence of adverse events. Yet FDA used mifepristone FAERS data for expressly those purposes.

161. It was also arbitrary and capricious for FDA to conclude that scientific literature supported the 2023 REMS. FDA conceded that the studies it relied on were "not adequate on their own to establish the safety of ... dispensing mifepristone by mail." The studies the agency relied on could not be generalized to the United States population because of small sample sizes, lack of information about safety outcomes, and the inclusion of pre-abortion safeguards like in-person examinations and ultrasounds. The studies also uniformly showed that emergency room visits would go

up without in-person dispensing. And one study found that hospitalizations would likewise increase.

162. Not only that, but prior to its 2021 Non-Enforcement Decision, the agency asserted and repeatedly reaffirmed over two decades that in-person dispensing was "minimally burdensome" and "necessary" to preserve safety.

163. FDA's unlawful and unreasonable rationales for the 2023 REMS—particularly in light of the *Dobbs* decision that the Biden Administration actively was trying to undermine—illustrate that the supposed justifications for the 2023 REMS were all just pretext.

164. Again, this should not be controversial, since five Fifth Circuit judges have written along the same lines. Judges Oldham and Engelhardt expressed disbelief that, "[a]fter eliminating th[e] adverse-event reporting requirement [in 2016], FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" *Alliance I*, 2023 WL 2913725, at *17. "This ostrich's-head-in-the-sand approach is deeply troubling," they said, "especially on a record that, according to applicants' own documents, necessitates a REMS program, a 'Patient Agreement Form,' and a 'Black Box' warning." *Id.* "And it suggests FDA's actions are well 'outside the zone of reasonableness.'" *Id.* (citation omitted). For those reasons, Judges Oldham and Engelhardt emphasized that "[i]t's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision"—and thus "it [is] unlikely that plaintiffs' arbitrary-and-capricious challenges will fail on the merits." *Id.* at *17–18.

165. Chief Judge Elrod (writing for herself and Judges Ho and Wilson) agreed: "FDA's decision to rely so heavily on data from FAERS 'runs counter to' the critical limitations associated with that data." *Alliance II*, 78 F.4th at 250. And that says nothing of "[t]he second defect ... [which] is that [FDA] relied on various literature relating to remote prescription of mifepristone—despite FDA's admission that the literature did not affirmatively support its position." *Id.* "Especially in light of the unreliability of the adverse-event data, it was not reasonable for FDA to depend on the published literature to support its decision." *Id.*

166. "Courts must set aside agency action where there are 'shortcomings in the agency's explanations' or where '[n]o record evidence affirmatively makes' the agency's case." *Id.* "That is the case here. In the face of concededly limited data, and lacking more probative information from prescribers, FDA fell back on studies that were merely 'not inconsistent' with its intended conclusion." *Id.* at 250–51. But FDA "did not refer to any literature that affirmatively supported the notion that mifepristone would remain safe and effective even without the in-person dispensing requirement." *Id.* at 251. Thus, Chief Judge Elrod had no trouble "conclud[ing] that the [plaintiffs] are likely to succeed in showing that this action violated the APA."[195] *Id.* All the same here.

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[195] "This action" technically referred to the 2021 Non-Enforcement Decision in *Alliance II*; however, as Chief Judge Elrod explained, the 2023 REMS "formaliz[ed] [] the policy" and, in fact, that formalization kept the case alive since "[t]he decision that FDA made in 2021—to permanently not enforce in-person prescription and dispensing requirements—remains in force." 78 F.4th at 248. Because "the effect is the same," her reasoning directly applies to the 2023 REMS as well. *Id.*

167. That fatal defect arising from the 2023 REMS' elimination of the in-person dispensing requirement goes hand-in-glove with two related defects. *First*, as FDA recognized, its handling of the in-person dispensing requirement was directly related to FDA's simultaneous decision to allow certified pharmacies—including retail pharmacies—to dispense abortion drugs. For all the reasons why the elimination of the in-person dispensing requirement was arbitrary and capricious, therefore, the certification decision was likewise arbitrary and capricious. *Second*, and in the same vein, FDA contemporaneously removed the Medication Guide Protection from the Patient Agreement—an independently arbitrary-and-capricious action because FDA relied solely on a subjective view of whether a woman would be likely to follow the Agreement's directive and failed to address serious safety concerns. Indeed, FDA did not base its conclusion on any reasoned explanation or data, nor did it attempt to address the health risks associated with (1) complication misdiagnosis or (2) the common practice of conflating abortion-drug adverse events with miscarriage.

168. For these reasons, the 2023 REMS—in its entirety—must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA.

COUNT TWO

The 2023 REMS Is Contrary to Law

(5 U.S.C. § 706)

169. Rosalie and the State re-allege and incorporate as though fully set forth, paragraphs 1 to 157 of this complaint.

170. The 2023 REMS is "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

171. That is because the "[t]he text of the Comstock Act prohibits the mailing of abortifacient drugs." *See Alliance II*, 78 F.4th at 267 (Ho, J., concurring part and dissenting in part); *see* 18 U.S.C. § 1461 ("Every article or thing designed, adapted, or intended for producing abortion ... [and every] drug ... calculated to lead another to use it or apply it for producing abortion ... [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier.").[196] "Congress later extended the mailing prohibition to cover common carriers as well," and then included "interactive computer service[s]." *Alliance II*, 78 F.4th at 267 (Ho, J., concurring part and dissenting in part); *see* 18 U.S.C. § 1462 (prohibiting the use of "any express company or other common carrier or interactive computer service" for "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion"). "So it's also illegal to use the internet to ship or

[196] Because Chief Judge Elrod resolved the case on arbitrary-and-capricious grounds, she did "not consider" the alternative Comstock Act argument. *Alliance II*, 78 F.4th at 251 n.8.

receive abortifacients." *Alliance II*, 78 F.4th at 267 (Ho, J., concurring part and dissenting in part).

172. The 2023 REMS "violates the Comstock Act" because it expressly "authorizes the dispensing of mifepristone 'through the mail ... or through a mail-order pharmacy.'" *Id.* "But 'us[ing] the mails for the mailing of a 'drug ... for producing abortion' is precisely what the Comstock Act prohibits." *Id.* at 267–68. To be clear, the 2023 REMS "doubles down on this violation by permanently eliminating the in-person dispensing requirement" so that "pharmacies [can] ship mifepristone to its users" and "distributors [like] Danco and GenBioPro [can] '[s]hip mifepristone ... to certified pharmacies.'" *Id.* at 268. This is exactly what "violates the Comstock Act." *Id.*

173. Because a federal agency cannot permit what federal law expressly prohibits, FDA lacked legal authority to permanently remove the in-person dispensing requirement through the 2023 REMS. *See FCC v. Next Wave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003) ("The Administrative Procedure Act requires federal courts to set aside federal agency action that is 'not in accordance with law,' 5 U.S.C. § 706(2)(A)—which means, of course, any law, and not merely those laws that the agency itself is charged with administering.") (citation omitted). The 2023 REMS thus must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA.

PRAYER FOR RELIEF

For these reasons, Rosalie Markezich and Louisiana 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. Holds unlawful, stays, sets aside, and vacates the 2023 REMS.

B. Issues a preliminary and permanent injunction ordering Defendants to withdraw the 2023 REMS.

C. Retains jurisdiction of this matter to enforce this Court's order.

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

E. Grants any other relief this Court considers equitable, just, and appropriate.

Dated: September 19, 2025

Respectfully submitted,

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