IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI SOUTHEASTERN DIVISION

THE STATE OF MISSOURI, *et al.*,	)	
	)	
Intervenor Plaintiffs,	)	
	)	Case No. 4:25-cv-01580-CMS
v.	)	
	)	
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
Defendants.	)	

[PROPOSED] SUPPLEMENTAL COMPLAINT

INTRODUCTION

1. Plaintiffs State of Missouri, State of Kansas, and State of Idaho filed the operative Amended Complaint in this action on January 16, 2025. Am. Compl., ECF No. 217.

2. Plaintiffs' Amended Complaint named as defendants the U.S. Food and Drug Administration; Robert M. Califf, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration;[1] Patrizia Cavazzoni, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration;[2] U.S. Department of Health and Human Services;

[1] Pursuant to Federal Rule of Civil Procedure 25(d)(1), Martin A. Makary, M.D. has been substituted for Robert M. Califf in his official capacity as Commissioner of Food and Drugs.

[2] Pursuant to Federal Rule of Civil Procedure 25(d)(1), Richard Pazdur, M.D., has been substituted for Patrizia Cavazzoni in his official capacity as Director, Center for Drug Evaluation and Research.

and Xavier Becerra, in his official capacity as Secretary, U.S. Department of Health and Human Services[3] (Defendants). Plaintiffs' Amended Complaint pleaded four counts against Defendants for disregarding federal statutes and FDA regulations when approving unsafe and high-risk chemical abortion drugs for over-the-counter use. *Id.*

3. Pursuant to Federal Rule of Civil Procedure 15(d), Plaintiffs file this Supplemental Complaint for the purpose of setting forth events "that happened after the date of the pleading to be supplemented." Specifically, Plaintiffs wish to address the recent decision of Defendant U.S Food and Drug Administration (FDA) to grant Evita Solutions, LLC's (Evita) amended new drug application (ANDA) for a generic form of Mifeprex, Mifepristone Tablets, 200mg, despite mounting evidence that the drug poses serious, even life-threating harm to pregnant women.

4. Mifepristone is a high-risk drug that the FDA continues to green-light despite its devastating effects on pregnant women and girls. Studies of the real-world use of mifepristone concluded that significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient.[4] And, as the FDA reports on its label, roughly one in 25 women who take abortion drugs will end up in the emergency

[3] Pursuant to Federal Rule of Civil Procedure 25(d)(1), Robert F. Kennedy, Jr. has been substituted for Xavier Becerra in his official capacity as Secretary, U.S. Department of Health and Human Services.

[4] Ex. 4, Am. Compl., ECF No. 217, Harrison Compl. Decl. ¶ 16; *see also* Am. Compl. ¶ 64, ECF No. 217.

room.[5] Many women who end up in the emergency room after taking abortion drugs suffer severe injuries. *See* Am. Compl. ¶ 66, ECF No. 217.

5. In spite of these realities, the FDA cut corners when it removed safeguards from this dangerous drug.

6. In 2016, the FDA engaged in a large-scale rollback of the safety precautions it put in place when it approved mifepristone in 2000 (2016 Major Changes). Through these changes, the FDA haphazardly stripped away vital safety precautions, which it characterized as "interrelated,"[6] without conducting a single study evaluating the impact of a simultaneous rollback. Instead, the FDA relied only on studies that evaluated one or some of the changes, and many such studies included additional safeguards not required under the 2016 Major Changes. *See* Am. Compl. ¶¶ 141–43, ECF No. 217. Sticking its head in the sand, the FDA eliminated non-fatal reporting requirements for abortion providers based on data collected under the originally approved safety standards,[7] leaving no way to fully evaluate the effects of the newly deregulated regime.

7. The 2016 Major Changes failed to satisfy the rigorous scientific standards of the Federal Food, Drug, and Cosmetic Act (FDCA).

8. In 2019, the FDA continued to ignore growing evidence of danger to

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[5] Ex. A, FDA-Approved Label for Mifepristone (Mifeprex) (March 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf (Mifeprex March 2023 Label).

[6] Ex. 2, Am. Compl., ECF No. 217, FDA, Center for Drug Evaluation and Research, Summary Review of Application Number: 020687Orig1s020, at 6 (Mar. 29, 2016) (2016 Summary Review).

[7] Ex. 2, Am. Compl., ECF No. 217, 2016 Summary Review, *supra* note 6, at 6.

pregnant women and girls and approved the first generic version of mifepristone ("2019 ANDA Approval"), produced by GenBioPro, Inc. ("GenBioPro").[8] This approval increased the supply and availability of mifepristone, lowered the cost of the drug, and increased the use of chemical abortions.[9] As a result of the 2019 ANDA Approval, "the number of women experiencing medical complications after taking mifepristone has risen." *All. For Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 241 (5th Cir. 2023).

9. In conjunction with this approval, the FDA adopted a single, shared system risk evaluation and mitigation strategy (REMS) for all mifepristone products used for "the medical termination of intrauterine pregnancy" through 70 days (known as the "Mifepristone REMS Program").[10] Thus creating a uniform REMS for brand and generic mifepristone.

10. The 2016 Major Changes left intact the REMS requirement that abortion providers dispense mifepristone only in certain healthcare settings, specifically clinics, medical offices, and hospitals.[11] In 2021, under the Biden-Harris administration, the FDA issued a non-enforcement decision on this in-person

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[8] Ex. 30, Am. Compl., ECF No. 217, 2019 FDA ANDA Approval Letter to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

[9] Ex. 108, Am. Compl., ECF No. 217, Solanky Affidavit; *see also* Am. Compl. ¶¶ 753–55, ECF No. 217.

[10] Ex. 30, Am. Compl., ECF No. 217, 2019 FDA Supplemental Approval Letter to Danco Laboratories, LLC (Apr. 11, 2019), Supplement Approval, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/020687Orig1s022ltr.pdf.

[11] *See* Ex. 34, Am. Compl., ECF No. 217, 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, 25 (Dec. 16, 2021) (2021 FDA Response).

dispensing protection. This decision subverted statutes expressly disallowing such conduct. 18 U.S.C. § 1461.

11. Doubling-down on its failure to consider the increasing evidence of the serious harms mifepristone causes pregnant women and girls, the Biden-Harris FDA announced it would gut the in-person dispensing protection from the Mifepristone REMS Program in December of 2021. The FDA also added a requirement allowing permitted pharmacies to become certified to dispense mifepristone.[12] The FDA made these decisions without any evidence that removing the in-person dispensing protection was safe for women's health. *See* Am. Compl. ¶¶ 181–198, ECF No. 217. Moreover, this relaxation effectively "allowed mifepristone to be prescribed remotely and sent via mail," *All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 226 (5th Cir. 2023), rev'd, 602 U.S. 367, 226 (2024), in violation of longstanding federal law prohibiting mailing abortion drugs, 18 U.S.C. § 1461.

12. In 2023, the FDA formalized the removal of in-person dispensing protections and expanded the REMS program to allow retail pharmacies to dispense mifepristone (the 2021/2023 Removal of the In-Person Dispensing Protection),[13] in blatant disregard for federal law, 18 U.S.C. § 1461.

13. The FDA's actions attempt to create a 50-state mail-order abortion drug

[12] Ex. 33, Am. Compl., ECF No. 217, 2021 FDA Center for Drug Evaluation & Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021).
[13] Ex. 3, Am. Compl., ECF No. 271, FDA, Center for Drug Evaluation and Research, Mifepristone Summary Review, dated Jan. 3, 2023 at 21 (FDA 2023 Summary Review).

economy, undermining state abortion laws in Plaintiff states.[14] It also enabled providers to dispense abortion drugs to residents of Plaintiff States later in pregnancy without follow-up care—causing women to seek emergency services in Plaintiff States for treatment of resulting complications. *See* Am. Compl. ¶¶ 258–78, ECF No. 217.

14. On September 30, 2025, the FDA continued its pattern of ignoring the dangerous effects of mifepristone on pregnant women and girls and, relying on the 2016 Major Changes, approved a second generic version of the drug. This approval marks the FDA's most recent violation in a long string of unlawful decisions.

15. This generic drug, produced by Evita Solutions LLC (Evita) is subject to the same REMS and labelling as the brand drug, Mifeprex which is produced by Danco Laboratories, LLC (Danco). The generic drug is chemically identical to Danco's Mifeprex and GenBioPro, Inc.'s generic mifepristone. Consequently, this generic drug produces the same side effects, the same consequences, and the same devastating impact on women and girls nationwide.

16. In this Supplemental Complaint, Plaintiffs plead additional facts and claims related to the FDA's misguided and unlawful approval of Evita's generic version of mifepristone against the Defendants.

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[14] The Missouri statute, Mo. Rev. Stat. § 118.021.1, requiring in-person administration of mifepristone for the purpose of an abortion is currently the subject of ongoing litigation, but remains in effect. *See Comprehensive Health of Planned Parenthood Great Plains v. State*, 2416-CV31931 (Mo. Cir. Jackson Cnty.). The same goes for Idaho's statute. Idaho Code § 18-622' *see St. Luke's Health System, Ltd.* v. *Labrador*, 1:25-cv-15 (D. Idaho). The Kansas statute, K.S.A. 65-4a10, was struck down by the Kansas Supreme Court in 2024. *See Hodes & Nauser, MDs, P.A. v. Stanek*, 318 Kan. 995 (S. Ct. Kan. 2024).

JURISDICTION OVER SUPPLEMENTAL CLAIM

17. The grounds for this Court's subject matter jurisdiction over the claim pleaded below are the same as the grounds set forth in the Amended Complaint. *See* Am. Compl.¶¶ 27–33, ECF No. 217.

18. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391 because at least one party resides in the district. *See* Order Transferring to Another District 26, ECF No. 273. Venue is also proper because a substantial part of the facts, events or omissions giving rise to the claims occurred in this district.

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

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

SUPPLEMENTAL FACTUAL ALLEGATIONS

21. A generic drug manufacturer may submit an ANDA to introduce into commerce and to distribute a generic version of an approved drug. 21 U.S.C. § 355(j); *see also id.* at ¶ 87.

22. In the ANDA, the generic drug manufacturer must show, among other things, that (a) the conditions of use prescribed, recommended, or suggested in the

labeling proposed for the new drug have been previously approved for a drug listed and (b) the drug product is chemically identical to the approved drug. This allows the generic drug manufacturer to rely on the FDA's finding of safety and effectiveness for the reference drug. The route of administration, dosage form, and strength for the generic must also be identical to the approved drug. 21 U.S.C. § 355(j); 21 C.F.R. § 314.94; *see also* Am. Compl. ¶ 88, ECF No. 217.

23. On September 30, 2025, eight months after Plaintiffs filed their Amended Complaint, the FDA approved Evita's ANDA for its generic version of Danco's Mifeprex, "Mifepristone Tablets, 200 mg" (2025 ANDA Approval).[15] The FDA "concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act."[16] The FDA determined Evita's Mifepristone Tablets, 200 mg "to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mifeprex (mifepristone) Tablets, 200 mg, of Danco Laboratories, LLC."[17]

24. Evita and GenBioPro sell the only generic mifepristone and misoprostol.

25. Evita's generic drug is subject to the same labeling and REMS requirements as Danco's Mifeprex and GenBioPro's generic mifepristone. In 2019, the FDA approved a single, shared REMS Program for brand and generic mifepristone. The program ensures that *all* mifepristone products for "the medical

[15] Ex. B, 2025 FDA ANDA Approval Letter to Evita Solutions, LLC p. 1 (September 30, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.
[16] *Id.*
[17] *Id.*

termination of intrauterine pregnancy" through 70 days follow a single REMS program to manage the risks associated with the drugs.[18] All mifepristone products are also subject to the same labeling requirements.[19]

26. The labeling and REMS requirements governing mifepristone products are not based on rigorous review of health and safety risks the drug pose. To approve Evita's generic drug, the FDA relied on only the unlawful and untested 2016 Major Changes labeling and the unlawful 2021/2023 Removal of the In-Person Dispensing Protection. In addition, despite the agency's elimination of non-fatal reporting requirements in 2016, the FDA did not require any additional investigations or studies that evaluated the drug's safety nor any specific assessments on the impact of the drug on the health of pregnant women and girls.

27. Evita's generic mifepristone tablets are chemically identical to Danco's Mifeprex and GenBioPro's generic mifepristone. Accordingly, Evita's generic mifepristone brings with it the same side effects, risks, and harms to pregnant women and girls as Mifeprex and GenBioPro. Just as the FDA's unlawful 2019 ANDA Approval led to an increase in the number of women obtaining chemical abortions, the FDA's 2025 ANDA Approval will increase accessibility to chemical abortions.[20]

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[18] Ex. 30, Am. Compl., ECF No. 217, 2019 FDA Supplemental Approval Letter to Danco Laboratories, LLC (Apr. 11, 2019), Supplement Approval, *supra* note 10.

[19] In 2000, the FDA stated that "[L]abeling is now part of a total risk management program," and "the professional labeling, Medication Guide, Patient Agreement, and Prescriber's Agreement will together constitute the approved product labeling to ensure any future generic drug manufacturers will have the same risk management program." Ex. 18, Am. Compl., ECF No. 217, 2000 FDA Approval Memo. to Population Council re: NDA 20-687 Mifeprex (mifepristone) at 2 (Sept. 28, 2000).

[20] *See* Ex. 108, Am. Compl., ECF No. 217, Solanky Affidavit.

The supply of mifepristone will increase, the cost will decrease, and the number of chemical abortions will rise in Plaintiff States and across the nation.[21]

28. Plaintiffs experience harm from the use of chemical abortions. Am. Compl. ¶¶ 525–756, ECF No. 217. Accordingly, the FDA's approval of another generic drug with the same chemical composition as Danco's Mifeprex and GenBioPro's generic mifepristone, aggravates and worsens Plaintiffs' harms as it increases the accessibility of this dangerous drug to the detriment of pregnant women and children.

SUPPLEMENTAL CLAIMS FOR RELIEF

SIXTH CLAIM

2025 ANDA APPROVAL

***ULTRA VIRES;* ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)**

IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

29. Plaintiffs re-allege and incorporate paragraphs 1–28 above and all paragraphs in the Amended Complaint as if fully set forth in this paragraph.

30. The FDA lacked legal authority when issuing the 2025 ANDA Approval.

31. The FDA's actions seek to enable the violation of state laws restricting abortion, as described in the Amended Complaint. But a federal agency cannot disregard applicable state law or seek to enable and encourage what state law

[21] Evita has expressed that it believes abortion should be "accessible to all"—"regardless of their . . . age, . . . income, or where they live." Evita Solutions, *Making generic mifepristone available and accessible today*, perma.cc/BW83-MUE4.

expressly prohibits, so the FDA lacked legal authority and acted arbitrarily and capriciously when issuing the 2025 ANDA Approval.

32. Therefore, the 2025 ANDA Approval must be held unlawful, stayed, set aside, vacated, and preliminarily and permanently enjoined under the APA and the Court's inherent equitable power to enjoin ultra vires actions, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

SEVENTH CLAIM

2025 ANDA APPROVAL

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)

IN EXCESS OF STATUTORY JURISDICTION, AUTHORITY, OR LIMITATIONS, OR SHORT OF STATUTORY RIGHT; ARBITRARY, CAPRICIOUS, AN ABUSE OF DISCRETION, OR OTHERWISE NOT IN ACCORDANCE WITH LAW

33. Plaintiffs re-allege and incorporate paragraphs 1–32 above and all paragraphs in the Amended Complaint as if fully set forth in this paragraph.

34. Defendants lacked legal authority to issue the 2025 ANDA Approval.

35. Because the FDA relied on the unlawful 2016 Major Changes labeling and the 2021/2023 Removal of the In-Person Dispensing Protection as a means to approve Evita's generic drug, Mifepristone Tablets, 200 mg, the 2025 ANDA Approval was unlawfully approved.

36. Unable to rely on an unlawful approval, the FDA's 2025 ANDA Approval violated the FDCA because it lacked the clinical investigations, adequate testing, sufficient information, and substantial evidence to show the safety and effectiveness

of mifepristone under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof as required by 21 U.S.C. § 355(d).

37. Therefore, the 2025 ANDA Approval must be held unlawful, set aside, vacated, and preliminarily and permanently enjoined.

38. Evita may submit an application with proposed labeling consistent with the pre-2016 Major Changes labeling, but, unlike Danco, Evita cannot simply revert to a previously approved label.

SUPPLEMENTAL PRAYER FOR RELIEF

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

A. Issues a preliminary injunction, or stay of the effective dates, that rescinds the 2025 ANDA Approval;

B. Holds unlawful, sets aside, and vacates the 2025 ANDA Approval;

C. Any other relief the Court deems proper.

Date: November 19, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 19, 2025, a true and accurate copy of the foregoing was electronically filed by using the Court's CM/ECF system to be served on all counsel of record entered in the case.

/s/ *Louis J. Capozzi, III*
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