IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

THE STATE OF LOUISIANA, *et al.*,

Plaintiffs,

v.

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

Federal Defendants,

and

DANCO LABORATORIES, *et al.*,

Intervenor Defendants.

No. 6:25-cv-01491-DCJ-DJA

FEDERAL DEFENDANTS' STATUS REPORT

On April 7, 2026, this Court denied Plaintiffs' motion for preliminary relief and granted Federal Defendants' motion to stay proceedings "pending completion of [the U.S. Food and Drug Administration's] ongoing review of the mifepristone REMS and issuance of any resulting agency decision." ECF No. 258 at 36. The Court directed FDA to file a report within six months "providing the Court with the status of its review in terms of process and any updated timeframe for completion of the review." *Id.* Accordingly, FDA reports as follows:

1. FDA is conducting a study to assess the safety of mifepristone, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy

though 70 days gestation.[1] FDA has several ways of evaluating the safety profile of mifepristone (in a regimen with misoprostol), which include, but are not limited to, comparing its profile to that of surgical abortion through 70 days gestation. FDA is also performing a "TreeScan" analysis (a statistical data mining method), which will allow FDA to discover unknown safety concerns (if any) contained in the data regarding the use of mifepristone through 70 days gestation.

2. FDA is using a variety of data sources contained within Sentinel, a distributed database, to conduct the study.[2] Sentinel datasets reside with the individual data partners. FDA also continues to gather and analyze additional data that is outside of the Sentinel system.

3. There are many steps involved in conducting a safety study, one of which is an assessment of study feasibility, which has been completed. Assessing the feasibility of conducting the study was an iterative process, which included checking the available data for adequate study power by determining whether there are enough exposures (the number of persons who receive the interventions of interest) and outcomes (the adverse events of interest) available for the study across relevant time periods. Feasibility work also included determining and validating appropriate

[1] Throughout this report, all references to mifepristone concern the drug's approved use, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy though 70 days gestation.

[2] *See generally* FDA's Sentinel Initiative, available at https://www.fda.gov/safety/fdas-sentinel-initiative.

measurement algorithms for key components of the study, including exposures, outcomes, and important confounding factors.

4. FDA's study allows agency experts to assess comparative safety outcomes for mifepristone and the comparator group consisting of approximately 100,000 women in each group. FDA will conduct detailed safety analyses, which will consist of measuring the frequency of a variety of safety outcomes and comparing the frequency of those outcomes between women who use mifepristone and the comparator group, adjusting for baseline differences in both groups of women.

5. FDA is on track to obtain study results by mid-December 2026. FDA will then need to review and evaluate/interpret the results and draft a report. FDA expects to complete that process not later than March 2027. The agency also plans to complete its TreeScan analysis in the same time frame.

6. In addition to these studies, FDA is conducting a review of the Mifepristone REMS Program. Among other things, that review encompasses consideration of arguments and information submitted to the Agency in multiple pending Citizen Petitions. These Petitions advocate for a wide range of agency actions, including reinstating certain REMS requirements previously removed from the REMS, such as the requirement that the drug be dispensed only in certain healthcare settings (the "in-person dispensing requirement"). Collectively, the petitioners cite more than 170 articles and publications in support of their respective positions, and hundreds of public comments have been submitted to the dockets for these petitions. FDA must review all of these materials before rendering its petition decisions and as part of the

REMS review. In addition, FDA has been directed to reconsider the 2023 decision modifying the REMS in two other cases. *See Purcell v. Kennedy*, Civ. No. 17-00493, 2025 WL 310785 (D. Haw. Oct. 30, 2025); *Whole Woman's Health Alliance v. U.S. Food and Drug Admin.*, Civ. No. 3:23-00019, 2026 WL 2125567 (W.D. Va. July 23, 2026). Among other things, those decisions require FDA to apply statutory factors in 21 U.S.C. § 355-1(a)(1) that, based on the Agency's interpretation of the statutory requirements, it has not previously evaluated in approving modifications to the REMS; compare mifepristone to certain other drugs with comparable risks under 21 U.S.C. § 355-1(f)(2)(D)(i); consider publications beyond those that FDA evaluated in reaching its 2023 decision; and consider the views of patients, providers, and pharmacists if the Agency is considering imposing elements to assure safe use (also known as ETASU) under 21 U.S.C. § 355-1(f)(2) as part of the Mifepristone REMS Program.

7. Following completion of its study[3] and review, FDA will decide whether changes to the Mifepristone REMS Program are necessary and, if applicable, initiate any such changes in accordance with established processes. FDA anticipates that it will be able to provide an update to its estimated date of completion as more information becomes known, particularly in March 2027 when it expects to complete its report on the final study results.

[3] In response to the Court's direction to describe "FDA's authority to issue interim orders addressing the prescribing or distribution of a drug if confronted with concerning information during its review," ECF No. 229, the government previously outlined FDA's authorities regarding approval suspension, labeling changes, and REMS modifications. *See* ECF No. 250.

October 7, 2026

Respectfully submitted,

BRETT A. SHUMATE
Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Noah T. Katzen
NOAH T. KATZEN
Assistant Branch Director
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L St., NW
Washington, DC 20005
202-305-2428
Noah.T.Katzen@usdoj.gov

Counsel for Defendants