

October 9, 2026

The Honorable Kyle Diamantas
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas:

I write with concern that FDA’s long-promised safety study of the abortion drug mifepristone may be using incomplete data. On October 7, the Department of Justice filed a status report on FDA’s behalf in *Louisiana v. FDA*, the litigation challenging FDA’s 2023 removal of the in-person dispensing requirement for mifepristone during the Biden Administration. According to the filing, FDA’s safety study of the drug relies in part on “a variety of data sources contained within Sentinel,” the agency’s distributed database of insurance claims and health records.¹ Yet the filing does not provide the time horizon for its source data. To ensure credibility, FDA must confirm its review includes data from the period *after* the Biden Administration gutted safety regulations in 2023.

As you know, in April 2021, FDA announced that it would not enforce its in-person dispensing requirement for mifepristone during the COVID-19 public health emergency. And on January 3, 2023, it formally modified the mifepristone REMS (Risk Evaluation and Mitigation Strategy) to eliminate in-person dispensing and to allow certified retail pharmacies to dispense the drug. Louisiana and other states have challenged that 2023 decision in court. A recent independent study has shown that nearly 11% of women have suffered a serious adverse health event within 45 days of using mifepristone.²

FDA’s confirmed reliance on Sentinel data, along with ambiguity as to whether FDA acquired other commercially available data, raises questions about whether FDA’s study can adequately assess the impact of the Biden Administration’s 2023 REMS. According to the Sentinel Initiative, the date range of available data varies by source. For example, the end date of Sentinel’s Medicaid data appears to be 2021—leading to a nearly 50 percent drop in database enrollment after that year—while data from 2024 “and possibly 2023” appear incomplete from publicly available sources.³

Compounding the uncertainty, FDA’s filing states that its study confirmed adequate exposures and outcomes “across relevant time periods,” but it never identifies those periods.⁴ This suggests that if the agency primarily relies on data from Sentinel, its analysis may rest largely on procedures

¹ Fed. Defs.’ Status Report ¶ 2, *Louisiana v. FDA*, No. 6:25-cv-01491 (W.D. La. Oct. 7, 2026), ECF No. 278.

² <https://media.eppc.org/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf>

³ Sentinel Initiative, *Key Database Statistics*, <https://www.sentinelinitiative.org/about/key-database-statistics> (last updated Oct. 13, 2025).

⁴ Status Report ¶¶ 3–4.

that occurred *before* the 2023 REMS took effect and possibly exclude analysis of a large Medicaid population after that date. If the FDA’s review does not capture this population, the study may not properly inform the agency’s analysis about whether to modify the REMS by excluding women who have received the drug by mail. Other commercially available data from all-payer claims could help fill the gap left by Sentinel’s time-limited Medicaid data. Yet according to the DOJ status report, while the FDA “continues to gather and analyze additional data” outside Sentinel, it does not say what those datasets are or even what years they cover.⁵

To resolve these issues and provide assurance to patients that FDA is reviewing *all* relevant data, please answer the following questions in writing by October 22, 2026:

1. Does the FDA’s Sentinel database include all data after 2021 or 2023, such as that of the Medicaid population?
2. Has the FDA sought to acquire this data? If not, why not?
3. Identify the “additional data” outside Sentinel that FDA is gathering and analyzing, and the precise period each source covers.
4. Did the FDA originally plan to acquire a broader set of insurance data? If so, when and why did the agency change to reviewing primarily Sentinel data?

Thank you for your prompt attention to this request.

Sincerely,

A handwritten signature in black ink, appearing to read "Josh Hawley", with a large, stylized flourish at the end.

Josh Hawley
United States Senator

⁵ Status Report ¶ 2.