DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

September 19, 2025

Dear Attorneys General:

Thank you for your letter of July 31, 2025, regarding the review of mifepristone by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS). We write to provide an update on this review.

As you noted, the FDA first approved Mifeprex (mifepristone) in September 2000 for medical termination of pregnancy (abortion) through seven weeks gestation. In 2016, the FDA extended this window to ten weeks gestation, and relaxed certain other requirements under the drug's Risk Evaluation and Mitigation Strategy (REMS). Most recently, in 2023, the FDA modified the REMS program again by removing the in-person dispensing requirement.

Since its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone. As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, takes necessary action. The FDA continuously reviews reports of adverse events to determine, among other things, whether they are known risks or whether they are signals of emerging safety concerns.

Under the Food and Drug Administration Amendments Act, the Secretary is authorized to require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a). For drugs that are "inherent[ly] toxic[] or potential[ly] harmful[]," the Secretary "may require that the [REMS] include such elements as are necessary to assure safe use of the drug." *Id.* § 355-1(f)(1). The Secretary is also authorized to require modifications to an existing REMS when he, among other things, "determines that 1 or more goals or elements should be added, modified, or removed from the [current REMS] to … ensure the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(g)(4)(B).

HHS is committed to studying the adverse consequences reported in relation to mifepristone to ensure the REMS are sufficient to protect women from unstated risks. Therefore, through the FDA, HHS will conduct a study of the safety of the current REMS, in order to determine whether modifications are necessary. HHS's decision to do so is informed by the lack of adequate consideration underlying the prior REMS approvals, and by recent studies raising concerns about the safety of mifepristone as currently administered.

To that end, HHS—through the FDA—is conducting its own review of the evidence, including real-world outcomes and evidence, relating to the safety and efficacy of the drug. Given the 2016 FDA decision to eliminate the REMS requirement for certified prescribers to report non-fatal serious adverse events to the mifepristone sponsors, this review will contribute to the understanding of the drug's safety profile.

Recent studies—such as the study by the Ethics and Public Policy Center (EPPC), which you highlighted in your letter—indicate potential dangers that may attend offering mifepristone without sufficient medical support or supervision. FDA's own data collected between 2000 to 2012 indicated 2,740 adverse events, including 416 events involving blood loss requiring transfusions. Since then, safeguards for women regarding the administration of mifepristone have been significantly reduced.

The concerns you have raised in your letter merit close examination. This Administration will ensure that women's health is properly protected by thoroughly investigating the circumstances under which mifepristone can be safely dispensed.

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HHS and FDA remain committed to protecting the health and safety of pregnant women. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

Thank you again for your continued engagement in this matter. We will keep you informed as the FDA's review of mifepristone progresses.

Sincerely,

/s/

Robert F. Kennedy, Jr.
Secretary

/s/

Martin A. Makary, MD, MPH
Commissioner of Food and Drugs