December 11, 2025

The Honorable Bill Cassidy, M.D.
Chairman
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Cassidy:

Thank you for your letter of October 16, 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).

Your letter poses several questions and asks for responses on a question-by-question basis. Since mifepristone for medical termination of early pregnancy is the subject of pending litigation, and because we continue to deliberate on potential actions to protect the health and safety of pregnant women, we are unable to fully respond to these questions at the present time. However, I assure you that the FDA is reviewing the evidence and we will keep you informed as the review progresses. This review will help ensure that the FDA's decisions are grounded in Gold Standard Science and rigorous, transparent, and objective evidence.

You cited our response to the state attorneys general, and I would like to reiterate several important points included in that response.

Our review 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. Our review includes 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.

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.

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.

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Thank you again for your leadership on this important matter. We will keep you informed and will share additional details on our review as they become available.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs