United States Senate
WASHINGTON, DC 20510

October 16, 2025

The Honorable Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Commissioner Makary:

We write to express significant concerns with the Food and Drug Administration's (FDA) approval of another generic form of the chemical abortion drug, mifepristone,[1] and to request information about the safety studies currently being conducted on the chemical abortion regimen.

During your confirmation hearing before the Senate HELP Committee, multiple Republican senators expressed concerns with the safety of mifepristone and actions taken by the Biden and Obama administrations to remove longstanding Risk Evaluation and Mitigation Strategies (REMS) safeguards for the drug. In response to these concerns, you reiterated your commitment to "take a solid hard look at the data and to meet with the professional career scientists who have reviewed the data at the FDA and to build an expert coalition to review the ongoing data which is required to be collected as a part of the REMS program."[2] Additionally, Department of Health and Human Services (HHS) Secretary Kennedy told senators in his confirmation hearing before the Senate Finance Committee that "President Trump . . . asked [him] to study the safety of mifepristone" and that he would "ask NIH and FDA to do that."[3]

Despite making these commitments to senators in the beginning of the year, FDA waited nearly six months after your confirmation before announcing any concrete action to evaluate and mitigate the safety risks of mifepristone, and even then, did so in a non-public letter to state attorneys general[4] without any press release or public acknowledgement of the letter until a post on X by

[1] *See* Letter from Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin, to Evita Solutions, LLC (Sept. 30, 2025), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.
[2] *Nomination of Martin Makary to serve as Commissioner of Food and Drugs: Hearing Before the S. Comm. on Health, Educ., Lab. & Pensions*, 119th Cong. (2025) (statement of Dr. Martin Makary).
[3] *Hearing to consider the nomination of Robert F. Kennedy, Jr., of California, to be Secretary of Health and Human Services: Hearing Before the S. Comm. on Fin.*, 119th Cong. (2025) (statement of Robert F. Kennedy, Jr.) [hereinafter RFK Jr. Finance Committee Confirmation Hearing].
[4] *See* Letter from Robert F. Kennedy, Jr., Sec'y, U.S. Dep't of Health & Hum. Servs. & Martin A. Makary, Comm'r of Food & Drugs, U.S. Food & Drug Admin., to Attorneys General (Sept. 19, 2025) [hereinafter Letter to Attorneys General] (available at https://www.thegatewaypundit.com/2025/09/trump-admin-rfk-jr-moves-address-assess-safety/).

Secretary Kennedy on October 2, 2025.[5] The letter stated that "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."[6] However, it does not provide any further information on the scope or other potential details of this review.

As you know, and acknowledge in the letter to the state attorneys general,[7] the Obama administration in 2016 removed the REMS requirement for prescribers to report non-fatal adverse events to the drug manufacturers,[8] depriving FDA of much needed evidence to ensure the mifepristone REMS sufficiently protects women. Secretary Kennedy acknowledged the harm this decision caused, saying in his confirmation hearing that removing the requirement to report adverse events is "against everything we believe in this country" and that "it's immoral to have a policy where patients are not allowed to report adverse events and where doctors are discouraged from doing that."[9] He further stated that "[w]e need to know what the adverse events are."[10]

On top of the fact that non-fatal adverse events have not been required to be reported since 2016, leaving FDA without critical insights into the safety of the drug, the Biden administration in 2021 caved to radical left-wing activists to temporarily halt enforcement of the in-person dispensing requirement for mifepristone under the guise of the COVID-19 pandemic.[11] Then, in case it was not already obvious that the COVID-19 justification was a ruse, the Biden FDA permanently removed the in-person dispensing requirement in 2023 to further its push for abortion-on-demand across the country.[12] All of this happened without any evidence to justify the departure from 20 years of precedent requiring this dangerous drug to be dispensed in-person where a proper medical examination could be conducted to ensure a woman does not have an undiagnosed ectopic pregnancy, does not take the chemical abortion drugs too late in pregnancy, and does not have Rh-factor incompatibility that could put future pregnancies at risk, among others. You noted this fact

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[5] *See* Secretary Kennedy (@SecKennedy), X (Oct. 2, 2025, at 5:44 PM), https://x.com/SecKennedy/status/1973866621245567344.
[6] Letter to Attorneys General, *supra* note 4, at 1.
[7] *Id.*
[8] *Contrast* U.S. Food & Drug Admin, Reference ID: 2957855, Mifeprex Risk Evaluation and Mitigation Strategy (2011), https://www.fda.gov/media/164648/download?attachment (requiring providers to report any hospitalization, transfusion, or other serious event to the manufacturer), *with* U.S. Food & Drug Admin., Reference ID: 3909592, Mifeprex Risk Evaluation and Mitigation Strategy (2016), https://www.fda.gov/media/164649/download?attachment (removing the requirement for providers to report non-fatal adverse events to the manufacturer and requiring providers only to report any deaths).
[9] RFK Jr. Finance Committee Confirmation Hearing, *supra* note 3.
[10] *Id.*
[11] *See* Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, U.S. Food & Drug Admin., to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists (Apr. 12, 2021), https://prochoice.org/wp-content/uploads/FDA-Acting-Commissioner-Letter-to-ACOG-April-12-2021.pdf (announcing that FDA's Center for Drug Evaluation and Research intended to exercise enforcement discretion during the COVID-19 Public Health Emergency with respect to the in-person dispensing requirement of the Mifepristone REMS Program).
[12] *See* U.S. Food & Drug Admin., Reference ID: 5103833, Risk Evaluation and Mitigation Strategy Single Shared System for Mifepristone 200 MG (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Document.pdf.

in your letter to the state attorneys general, stating that there was a "lack of adequate consideration underlying the prior REMS approvals."[13]

The in-person dispensing requirement also helped guard women from being coerced into having chemical abortions against their will. Since its removal in 2021, multiple news reports indicate that women have been forced to take chemical abortion pills or even given them without their knowledge. In one case in Texas, a man was convicted of repeatedly attempting to kill his unborn child by secretly spiking his pregnant wife's drinks seven times with chemical abortion drugs.[14] In another case in Louisiana, a woman was charged with obtaining chemical abortion drugs through the mail and forcing her teenage daughter to take them to end her unborn child's life.[15] Tragically, these are just some of the many stories of the danger caused by removing the in-person dispensing requirement.

In light of the FDA's approval of another means of chemical abortion under the same flawed REMS framework, it is imperative that you provide an update on your review of mifepristone and your plans to reinstate necessary safeguards. To be clear: this approval fails to mitigate the risks to women that have been identified and fails to protect women from the coercive use of the drug. It also flies in the face of President Trump's strong statement that he is "the most pro-life president" in history[16] and his dedication to protecting the lives of unborn children and keeping women safe. To help inform our understanding of FDA's work on the chemical abortion drug, please respond to the following questions, on a question-by-question basis, no later than **October 30, 2025**.

1. Under section 505-1(g)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. § 355-1(g)(2)(C)), FDA has the authority to require an application holder to submit an assessment and proposed modification to a REMS if FDA determines it necessary to evaluate whether the benefits of a drug outweigh its risks. Since January 21, 2025, has FDA requested an assessment of, or proposed modification to, a REMS assessment from any of the application holders for mifepristone and its generic manufacturers?

    a. If yes, please describe what led to FDA's determination that a REMS assessment was needed and provide the status of that assessment.

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[13] Letter to Attorneys General, *supra* note 4, at 1.
[14] Minyvonne Burke, *Texas attorney who poisoned pregnant wife with abortion medication sentenced to 180 days in jail*, NBC NEWS (Feb. 9, 2024), https://www.nbcnews.com/news/us-news/texas-attorney-poisoned-pregnant-wife-abortion-medication-sentenced-18-rcna138065.
[15] Rosemary Westwood, *Louisiana mother, NY doctor indicted for giving minor abortion pills*, WWNO (Jan. 31, 2025), https://www.wwno.org/public-health/2025-01-31/louisiana-mother-ny-doctor-indicted-for-giving-minor-abortion-pills.
[16] Adam Shaw, *Trump says he's 'proud to be the most pro-life president' in US history on anniversary of Roe v. Wade overturn*, FOX NEWS (June 24, 2023), https://www.foxnews.com/politics/trump-says-hes-proud-most-pro-life-president-history-anniversary-roe-v-wade-overturn.

b. If no, why not?

2. In a September 4, 2025, hearing, Secretary Kennedy stated that the Biden administration twisted data to bury one of the safety signals for mifepristone and that the signal showed an approximately 11 percent adverse event risk.[17] What safety signal was Secretary Kennedy referring to and what was the source of the data that led to this conclusion?

3. In your letter to the state attorneys general, you said that "[s]ince its original approval, the FDA has received reports of serious adverse events in patients who took mifepristone."[18] Please provide a complete and unredacted copy of all studies and reports in FDA's possession that document adverse events related to mifepristone.

4. In the same September 4, 2025, hearing, Secretary Kennedy stated that he spoke to you the day before and that studies relating to the safety of mifepristone are "progressing and . . . ongoing."[19] What studies was Secretary Kennedy referring to?

    a. Please explain the details of these studies, including the scope, expected timeframe, agencies involved, and type of study.

5. How has the removal of the requirement for prescribers to report non-fatal adverse events affected FDA's ongoing work to "continuously review[] reports of adverse events to determine . . . whether they are known risks or whether they are signals of emerging safety concerns?"[20]

6. Does FDA currently have any ongoing studies looking at the safety concerns resulting from the removal of the in-person dispensing requirement?

    a. If yes, please explain the details of these studies, including the scope, expected timeframe, agencies involved, and type of study.

    b. If no, why not and do you plan to conduct any such studies?

7. Section 505(j)(5)(A) of the FDCA (21 U.S.C. § 355(j)(5)(A)) requires the HHS Secretary (acting through FDA) to approve or disapprove an Abbreviated New Drug Application (ANDA) within 180 days after the initial receipt of an application or within an additional period if agreed upon by the Secretary (acting through FDA) and the applicant. Yet, Evita

[17] *The President's 2026 Health Care Agenda: Hearing Before the S. Comm. on Fin.*, 119th Cong. (2025) (statement of Sec'y Robert F. Kennedy, Jr.) [hereinafter RFK Jr. Finance Committee September Hearing].
[18] Letter to Attorneys General, *supra* note 4, at 1.
[19] RFK Jr. Finance Committee September Hearing, *supra* note 17.
[20] Letter to Attorneys General, *supra* note 4, at 1.

Solutions' ANDA for its mifepristone generic drug (ANDA 216616) was received by FDA on October 1, 2021, and was not approved until September 30, 2025—well beyond 180 days after receipt of the application.

a. Did FDA have any agreements with Evita Solutions to extend the period by which FDA could review its mifepristone generic ANDA? If so, please provide complete and unredacted copies of these agreements.

b. Why did FDA decide to approve Evita Solutions' mifepristone generic ANDA before completing its review of mifepristone's safety data and determining whether the Mifepristone REMS Program should be modified?

Thank you for your prompt attention to this important matter.

Sincerely,

Bill Cassidy, M.D.
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions

Tommy Tuberville
United States Senator

Rand Paul, M.D.
United States Senator

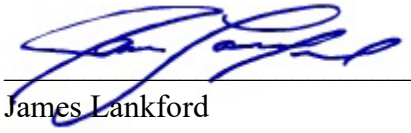
Josh Hawley
United States Senator

Pete Ricketts
United States Senator

Mike Lee
United States Senator

James E. Risch
United States Senator

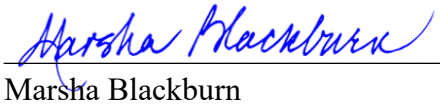
John Cornyn
United States Senator



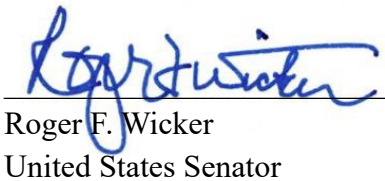
James Lankford
United States Senator

Lindsey O. Graham
United States Senator

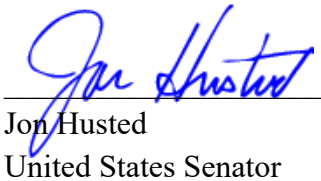
Ted Budd
United States Senator



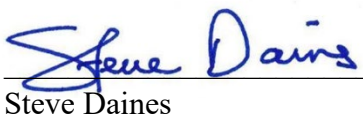
Marsha Blackburn
United States Senator



Roger F. Wicker
United States Senator



Jon Husted
United States Senator



Steve Daines
United States Senator

Tim Scott
United States Senator

M. Michael Rounds
United States Senator