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October 3, 2025

Dr. Marty Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Commissioner Makary:

I write with grave concern regarding your agency's surprise approval of a new generic abortion drug. This decision appears to ignore the science while advancing a highly questionable ideological agenda. And I fear this decision may render moot your promise to conduct a safety review of mifepristone. I request your immediate assistance in explaining your agency's decision.

As you know, recent data shows that nearly 11% of women who use the chemical abortion drug, mifepristone, experience a serious adverse health event—like sepsis or hemorrhaging—within 45 days. That is an adverse-event rate at least 22 times greater than currently disclosed on the FDA-approved drug label.[1] In light of this data, your agency has committed to a thorough safety review of mifepristone and existing regulations. In your letter to me of June 2, 2025, you stated that you were "committed to conducting a review of mifepristone."

But this week, before any such review has been completed, your Food and Drug Administration approved a *new* generic abortion drug developed by Evita Solutions, LLC. This is a company with highly ideological, even extreme, views on gender and abortion. The company's website declares its mission is to "normalize abortion." The company decries regulations protecting life and maternal safety as "unnecessary restrictions." Moreover, the company appears not to recognize distinctions between men and women. Its website states: "Evita Solutions believes ***all people*** should have access to . . . abortion care, regardless of their race, ***sex***, ***gender***, age, sexuality, income, or where they live" (emphasis added). The company conspicuously refuses to use the word "woman" on its website. This is a woke corporation that clearly seeks to promote a woke ideological agenda.

The timing of your agency's approval raises further questions. FDA is supposed to be conducting a review of the safety regulations around mifepristone. But because this new generic has been approved before any changes to those safety protocols, this drug may be exempted from any new safety standards imposed on mifepristone in the future. That would render your safety review toothless and irrelevant.

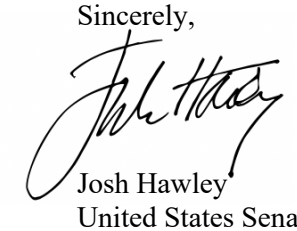
I invite you to explain your decision. Please answer the following questions by no later than October 10, 2025:

1. Were you personally involved in the approval process of ANDA 216616? What was the nature of your involvement?
2. Please describe the timeline of ANDA 216616 submission and approval.

[1] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf

3. Please describe the scope and nature of the FDA's therapeutic equivalence evaluation for ANDA 216616, including whether your bioequivalence review evaluated the risk of increased adverse events.
4. Please explain how the FDA considered the aforementioned new data on mifepristone safety in its approval.
5. Did your agency consider Evita Solutions's stated goals and mission in its approval?
6. Because this approval preceded the safety review and any updated Mifepristone Risk Evaluation and Mitigation Strategy (REMS), will the new generic now be allowed to remain on the market without immediately complying with any new safety standards?

Sincerely,



Josh Hawley
United States Senator