JOSH HAWLEY
MISSOURI

115 RUSSELL SENATE OFFICE BUILDING
TELEPHONE: (202) 224–6154
FAX: (202) 228–0526

WWW.HAWLEY.SENATE.GOV

United States Senate

WASHINGTON, DC 20510–2509

COMMITTEES
JUDICIARY
HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS
HEALTH, EDUCATION, LABOR,
AND PENSIONS
SMALL BUSINESS
AND ENTREPRENEURSHIP

April 28, 2025

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

Commissioner Makary:

An alarming new study has revealed that the safety risks of the chemical abortion drug, mifepristone, are far greater than the FDA currently acknowledges. Just last week, you said that you had "no plans to take action" on mifepristone.[1] Yet during your confirmation hearing, you pledged to me that you would "review the totality of the data and ongoing data" to inform action on the drug. I urge you to follow this new data and take all appropriate action to restore critical safeguards on the use of mifepristone. The health and safety of American women depend on it.

The new study published today by the Ethics and Public Policy Center is the largest known study of mifepristone to date, with analysis of more than 865,000 prescribed mifepristone abortions. It finds that nearly 11% of women—more than *1 in 10 women*—who use mifepristone experience sepsis, infection, hemorrhaging, an emergency room visit, or another serious adverse event within 45 days.[2] This rate is at least 22 times greater than the less than 0.5% adverse event rate reported on the FDA-approved drug label for mifepristone.

As you well know, Democrat presidential administrations have stripped away basic safeguards regarding the use of mifepristone. In 2016, President Obama's FDA rolled back several safety measures: reducing the number of required in-person visits, removing the physician prescription requirement, and ending mandatory adverse event reporting. The Biden administration then ended in-person visits altogether, as well as the in-person dispensing requirement. Today, mifepristone can be delivered via mail and without any medical supervision whatsoever—jeopardizing the safety of women who use the drug.

You have stated publicly: "If the data suggests something or tells us that there's a real signal, we can't promise we're not going to act on that data."[3] The time to act is now. It is time to revisit and restore the FDA's longstanding safety measures governing mifepristone. And by May 15, 2025, please respond to the following questions:

1. Will the FDA now take action to restore longstanding, critical safeguards for mifepristone use? How quickly can we expect action?
2. What plans does the agency have to adjust the relevant drug safety label given this new information?
3. Going forward, how does the FDA plan to appropriately evaluate the real-world health effects of mifepristone on American women?

Sincerely,

Josh Hawley
United States Senator

[1] https://www.semafor.com/article/04/24/2025/fdas-marty-makary-no-plans-to-pull-abortion-pill-mifepristone
[2] https://eppc.org/wp-content/uploads/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf
[3] https://www.semafor.com/article/04/24/2025/fdas-marty-makary-no-plans-to-pull-abortion-pill-mifepristone