Congress of the United States

Washington, DC 20515

July 24, 2025

The Honorable Pamela Bondi
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Attorney General Bondi:

We write to you regarding a serious public-health failure that endangers countless American women. In light of new data, we request an investigation into whether drug manufacturers have misrepresented mifepristone's safety and efficacy—placing hundreds of thousands of women at risk.

The Ethics and Public Policy Center ("EPPC") recently completed the largest study ever performed on chemical abortion, focusing on mifepristone.[1] Mifepristone was first approved by the FDA in 2000 based on sparse clinical trials of only 859 U.S. participants.[2] The evidence shows that the current drug label is based on trials of fewer than 31,000 participants.[3] But EPPC has now analyzed insurance claims data from over 865,000 mifepristone abortions billed to public and private payors, along with the serious adverse events related to actual use of mifepristone between 2017 and 2023. Based on that real-world analysis, it has become clear that women who take mifepristone suffer serious adverse events at levels *22 times greater* than what is represented on the FDA-approved (19-page) drug label.[4]

Chemical abortions are more prevalent than ever in the post-*Dobbs* era. Roughly 2/3 of abortions today are chemical abortions.[5] These abortions are administered through a combination of mifepristone and misoprostol.[6] A person's opinion about abortion is irrelevant. This is a women's health and safety issue.

Upon initial FDA approval in 2000, modest and commonsense safeguards known as Risk Evaluation and Mitigation Strategies (REMS) were required for chemically induced abortions. For example:

- A woman would have to make at least three in-person doctor visits.
- Mifepristone could be prescribed only by a physician.

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[1] Jamie Bryan Hall, Ryan T. Anderson, Ethics and Public Policy Center, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event* 1 (April 28, 2025) (hereafter *One in Ten Patients*).
[2] Stop Harming Women, *FDA Regulation of Mifepristone: Timeline of Changes (2000–2023)* (April 27, 2025), https://perma.cc/Q8P7-JVEY (hereafter *FDA History*).
[3] *One in Ten Patients*, supra note 1, at 4.
[4] *Id.* at 1.
[5] Guttmacher Institute, *Medication Abortions Accounted for 63% of All US Abortions in 2023, an Increase from 53% in 2020* (March 19, 2024), https://perma.cc/JWQ4-F9H2 (hereafter *63% of Abortions*).
[6] *One in Ten Patients*, supra note 1, at 4.

- The drug could be administered only in a clinic, medical office, or hospital, under doctor supervision.
- Adverse events were required to be reported.[7]

But in 2016 and 2023, the FDA under Presidents Obama and Biden whittled these already-meager safeguards down to almost nothing.[8] Whereas the original approval permitted administering mifepristone up to the seventh week of pregnancy, the drugs may now be administered at a gestational age of 10 weeks (with no requirement for verification through a physical exam).[9] Further, a mifepristone abortion requires only a single telehealth visit.[10] No exam is required to rule out an ectopic pregnancy.[11] And it need not even be guided by a physician; any "approved healthcare provider" suffices.[12] A patient may receive the drugs through the mail and self-administer them. And, shockingly, under the revised REMs, the prescriber does not even need to report an adverse event unless the woman dies.[13]

Loosened requirements might have made sense for a noninvasive drug. But, as it happens, these lax requirements only simplified access to a drug that quite often causes great harm to the mother, as the latest data shows.

The real risk of serious adverse events to American women is also unconscionably downplayed on the label, which reports an adverse-effect rate of just 0.5%.[14] The label is appallingly wrong. Between 2017 and 2023, women were administered over 865,000 mifepristone abortions that were charged to a public or private payor. Of those, almost a full 5% of women—nearly 41,000—required serious to severe level emergency room (ER) visits related to mifepristone. Over 28,000 experienced hemorrhaging. More than 11,000 reported infection. At least 824 women had life-threatening sepsis. And well over 24,000 went on to need surgery to complete what the pill could not.[15] All told, a full *10.93%* of patients—more than one out of every ten women—endured some kind of serious adverse event after taking mifepristone.[16] In other words, women suffer from complications at a rate about 22 times higher than the drastically underreported 0.5% rate conveyed by the label.[17]

For every woman that the mifepristone label admits it could potentially harm, over 20 additional women suffer serious adverse events. Quite frankly, this is outrageous. And the American people deserve better.

The above data does not even include mifepristone failure rates. Outdated clinical trials suggest that between 2.6% and 3.8% of the time a woman takes mifepristone, it fails to result in an

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[7] *Id.* at 3.
[8] *Id.*; *FDA History*, supra note 2.
[9] *One in Ten Patients*, supra note 1, at 3.
[10] *Id.*
[11] *See id.* at 2–3.
[12] *Id.* at 3.
[13] *Id.*
[14] *Id.* at 1.
[15] Stop Harming Women, *Harms to Women From Mifepristone Abortion* (April 26, 2025), https://perma.cc/6VK2-VKUH (hereafter *Serious Adverse Effects*).
[16] *Id.*; Jamie Bryan Hall, Ryan T. Anderson, Ethics and Public Policy Center, *Frequently Asked Questions About the Largest Study on Chemical Abortion* 1 (May 7, 2025) (hereafter *FAQs*).
[17] *Serious Adverse Effects*, supra note 15; *One in Ten Patients*, supra note 1, at 1; *FAQs*, supra note 16, at 1.

abortion.[18] But the real-world healthcare-claims data shows that the number is actually higher. The reason: on 45,498 occasions, women whose chemical abortions failed either pursued a second chemical abortion or a surgical abortion. Thus, a whopping 5.26% of women who charged a mifepristone script to insurance, or one of every 19, sought additional abortions after their attempts to terminate their pregnancies after mifepristone failed.[19] All told, over 13.5% of women—nearly one in seven—either suffer serious adverse events or require subsequent chemical or surgical abortion attempts after taking mifepristone.[20]

Equally alarming, the numbers above represent only about one-quarter of the women experiencing such serious events. Consider the numbers from 2023. As the Guttmacher Institute, which has long-standing ties to Planned Parenthood, details, out of the 1,037,000 abortions that took place in 2023,[21] more than 60% of those—approximately 642,700—were medication abortions.[22] But the amount of medication abortions that appear in the data for 2023 is 154,554—or about 24% of the total number of chemical abortions in 2023. The remaining 76% are cash pay abortions. That means that all the numbers above regarding the number of women suffering serious ER visits, hemorrhaging, infections, etc., should be increased by a factor of four.

The EPPC's recent study has several advantages over the small and outdated clinical trials on which mifepristone's drug label is based. First, the scope of the study is far more robust than the clinical trials. The current FDA-approved drug label is based on clinical trials involving 30,966 healthy participants under supervised conditions.[23] The recent real-world study dwarfs that sample size with a dataset comprising 865,727 prescribed mifepristone abortions. Second, this study is more recent. FDA's approval of mifepristone is based on data more than a decade old.[24] The EPPC's study, however, draws from data collected between 2017 and 2023.[25] As such, in addition to being more recent, the EPPC's study captures the time period after the FDA began loosening safety regulations and waiving reporting requirements. Third, this study provides a snapshot of the real-life medical experience of actual American women, as opposed to tightly controlled clinical trials amongst only healthy women administered by physicians and sponsored by pharmaceutical companies.[26] Fourth, unlike the original trials, this data is safeguarded from outcome-bias. All of these reasons make the recent report more reliable than any other study of mifepristone ever performed.

There is a fifth advantage that the EPPC's study has over the current basis for the FDA's mifepristone label, and it is relevant for what follows in this letter: the study is designed to be replicable by anyone.[27] It is objective, repeatable, verifiable, and thus actionable.

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[18] Jamie Bryan Hall, Ryan T. Anderson, Ethics and Public Policy Center, *The Abortion Pill Harms Women: Insurance Data Reveals Repeated Abortion Attempts Due to High Failure Rate* 1 (May 12, 2025) (hereafter *High Failure Rate*).
[19] *Id.* at 2.
[20] *Id.*
[21] Guttmacher Institute, *Despite Bans, Number of Abortions in the United States Increased in 2023* (March 19, 2024), https://perma.cc/QC5L-Q7RF.
[22] *63% of Abortions*, supra note 5.
[23] *One in Ten Patients*, supra note 1, at 4.
[24] *Id.* at 2.
[25] *Id.* at 2, 4.
[26] *Id.* at 2.
[27] *FAQs*, supra note 16, at 3–4.

If it were any other issue, Democrats would be up in arms. But this issue relates to abortion, so the Democrats will do nothing. You, however, can. A key question is whether appropriate procedures were followed when safety regulations were lifted in 2016 and again in 2023. It is unclear what processes, if any, the FDA under Presidents Obama and Biden followed when loosening—and then waiving—the safety regulations originally put in place to protect women. It is also unclear if the FDA worked with the manufacturer of Mifeprex, Danco Laboratories, in considering new data, new clinical trials, or real-world market analysis that justified doing away with safety standards. What is clear is that not a single study cited publicly by the Obama or Biden FDA actually supported loosening mifepristone's safety regulations. This suggests blatant negligence by the Biden FDA at best and potentially politically motivated machinations within the Biden Administration to pressure FDA to loosen their safety standards to satisfy their pharmaceutical industry and political allies. The Biden FDA made additional moves to loosen regulations soon after the U.S. Supreme Court's Dobbs decision allowing abortion restrictions by the states, emasculating that ruling by changing regulations to allow one provider in one state to provide chemical abortions in all fifty states, regardless of their laws. The thousands of women being harmed by these moves are just unrecognized collateral damage.

In our experience, health insurance companies do not pay for procedures that were not done, so this recently released EPPC study showing real world data raises very concerning questions not only about the Biden FDA, but also about the actions of the chemical abortion manufacturers, including Danco Laboratories and GenBioPro. As you know, the Federal Food Drug and Cosmetic Act clearly states that knowingly providing false statements about a drug's effectiveness or safety, or failing to report a drug's adverse side effects, could constitute criminal or civil violations. Yet the EPPC healthcare claims data shows these high levels of serious adverse events over a 7-year period starting in January, 2017, well before and indeed during the Biden FDA loosening of the safety standards and reporting requirements on mifepristone. What did these manufacturers know and when did they know it? What did they report or say to the FDA and when? It is telling that even since the EPPC health care claims data has been released showing safety and efficacy failure rates at much higher levels than the FDA claims on the mifepristone label, a Danco spokesperson has asserted their previous "safe and effective" claims[28] while their business partners, including Planned Parenthood, assert the ludicrous lie to American women that "mifepristone is as safe as Tylenol."[29] This is unconscionable and must not be allowed to continue.

The waiver of the reporting requirements also needs to be investigated. American families rely upon the FDA to protect them from harmful drugs and are, at the very least, entitled to know the real risks of the drugs they take. There is no reason the FDA should waive reporting requirements when serious adverse events occur. Such conduct keeps our citizens in the dark and actively works against their being able to provide informed consent. And it is especially perilous when such waivers are issued in parallel with loosening the safety standards.

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[28] Fox News, July 8th, 2025: https://www.foxnews.com/politics/medical-groups-urge-kennedy-fda-reexamine-broad-approval-abortion-drugs

[29] Planned Parenthood: "Medication abortion is **safer than other common medicines like penicillin, Tylenol, and Viagra**." What You Need to Know About the Latest Attack on Abortion Care: the Mifepristone Abortion Pill

The FDA is responsible for ensuring safety, efficacy, and transparency around the drugs Americans take. By failing to hold to these standards, the FDA has permitted mifepristone to harm hundreds of thousands of women over the last decade. There is no reason to believe the dangers will stop without action. The extent of the harm has not been clear until now. And hundreds of thousands of women are at risk of serious harm to their bodies by the FDA's continued recklessness around this drug.

This is an urgent matter of public safety. Hundreds of women are being harmed every day. We encourage the Department of Justice to initiate a federal investigation into the potential criminal and civil misconduct of chemical abortion manufacturers. Given the breadth of the data and the implications for public health, we respectfully urge swift action to determine whether federal law was violated that compromised the safety of American women. Thank you for your continued work to uphold federal law, protect women's health, and ensure that government agencies and pharmaceutical companies are held accountable to the American people.

Sincerely,

Steve Daines
United States Senator

Jim Banks
United States Senator

Marsha Blackburn
United States Senator