LIFE AND FAMILY INITIATIVE

The Abortion Pill Harms Women: Insurance Data Reveals Repeated Abortion Attempts Due to High Failure Rate

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Summary

- The real-world failure rate of mifepristone abortion—at least 5.26 percent, or about one in 19 cases—is double the failure rate from the U.S. clinical trials and roughly two-thirds higher than the combined failure rate from all clinical trials reported on the FDA-approved drug label.
- Combined with our prior finding that 10.93 percent of women experience a serious adverse event and adjusting to avoid double-counting, we find that 13.51 percent of women—roughly one in seven—experience at least one serious adverse event or repeated abortion attempt within 45 days of first attempting a mifepristone abortion.
- This largest-known study of the abortion pill is based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions from 2017 to 2023.
- The FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects.
- The FDA should further investigate the harm this drug causes to women and, based on objective safety and effectiveness criteria, reconsider its approval altogether.

Danco Laboratories markets Mifeprex as "the safe and effective abortion pill," but our research shows that mifepristone abortion, as currently practiced in the U.S., is not safe or effective.[1] The manufacturer and the FDA rely on the results of clinical trials in which less than 0.5 percent of participants reportedly experienced serious adverse reactions and all but 2.6-3.8 percent obtained a complete abortion by taking mifepristone plus misoprostol.[2] In contrast, we analyzed real-world insurance claims data for 865,727 prescribed mifepristone abortions, broadly representative of women who obtain mifepristone abortions in the U.S. today, and we find a serious adverse event rate of 10.93 percent and a failure rate of at least 5.26 percent. In light of this research, we urge the FDA to reinstate earlier, stronger patient safety protocols and reconsider its approval of mifepristone altogether. Women deserve better than the abortion pill.

1 Danco Laboratories, "The Safe and Effective Abortion Pill | Mifeprex (mifepristone)," https://www.earlyoptionpill.com (accessed April 14, 2025)
2 Page 7 of the drug label states, "Serious adverse reactions were reported in <0.5% of women." Effectiveness data are reported in Table 3 on page 13. See Mifeprex (mifepristone) drug label, January 2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf

Repeated Abortion Attempts Following Failure of Mifepristone Abortion Regimen

According to the insurance data, 5.26 percent of women undergo a second abortion attempt within 45 days of the first, indicating that the first mifepristone abortion attempt failed.[3] Curiously, although the drug label does not appear to contemplate the possibility of a second abortion attempt using mifepristone for the same pregnancy, we regularly observe this in the insurance claims database. *See Table 1.*

The real-world failure rate of mifepristone abortion—at least 5.26 percent, [4] or about one in 19 cases—is double the failure rate of 2.6 percent from the U.S. clinical trials and roughly two-thirds higher than the combined failure rate of 3.2 percent from all clinical trials reported on the FDA-approved drug label.[5]

Safety and Effectiveness

As we previously reported, 10.93 percent of women—roughly one in ten—experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion.[6] Combined with the 5.26 percent of women who undergo a second abortion attempt following the failure of the mifepristone abortion regimen and adjusting to avoid double-counting, we find that 13.51 percent of women—roughly one in seven—experience at least one serious adverse event or repeated abortion attempt within 45 days of first attempting a mifepristone abortion. *See Table 2.*

Table 1

Repeated Abortion Attempts After Failed Mifepristone Abortion Attempts

Type	Number of pregnancies with repeated abortion attempts	Rate of occurrence
Repeated mifepristone abortion attempt after failed mifepristone abortion attempt	27,896	3.22%
Surgical abortion procedure after failed mifepristone abortion attempt	24,563	2.84%
Both	6,961	0.80%
Either	45,498	5.26%

Note: The insurance claims database includes 865,727 pregnancies with prescribed mifepristone abortion. These rates of occurrence are per pregnancy. The repeated abortion attempts in this table are subsequent attempts to abort the baby after the first attempt failed. Some patients had multiple pregnancies with abortion attempts in the database; this is *not* what is being measured in this table.

3 We also observe that 1.58 percent of women are prescribed a second dose of misoprostol but not a second dose of mifepristone, a possibility suggested on the drug label for cases in which the woman is no longer pregnant but fetal remains have not been fully expelled from her body. These are not counted as repeated abortion attempts, but repeated use of misoprostol has side effects that pose further harm to women.

4 We do not consider here those cases in which a woman gave birth following a mifepristone abortion attempt, which in a technical sense also indicate that the regimen failed to perform as intended. If these cases were also included, the failure rate would be slightly higher.

5 Table 3 on page 13 of the drug label reports surgical intervention in 2.6 percent of 16,794 cases in U.S. trials and 3.8 percent of 18,425 cases in non-U.S. trials. This averages to 3.2 percent of 35,219 cases overall. See Mifeprex (mifepristone) drug label, January 2023, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf.

6 Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics and Public Policy Center, April 28, 2025.

Table 2

Safety and Effectiveness of Mifepristone Abortion

Type of event	Number of pregnancies	Rate of occurrence
Serious adverse event following mifepristone abortion attempt	94,605	10.93%
Repeated abortion attempt following failed mifepristone abortion attempt	45,498	5.26%
Both	23,165	2.68%
Either	116,938	13.51%

Note: The insurance claims database includes 865,727 pregnancies with prescribed mifepristone abortion. These rates of occurrence are per pregnancy.

Conclusion

Mifepristone abortion as currently practiced in the U.S. is not safe or effective. As our previous paper showed, the real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as reported on the drug label. Now we also find that its failure rate is significantly higher than reported on the drug label. Altogether, roughly one in seven women who are prescribed a mifepristone abortion experiences a severe adverse event or undergoes a repeated abortion attempt soon afterwards due to the failure of the mifepristone abortion regimen.

In light of these findings, the FDA should immediately reinstate its earlier, stronger patient safety protocols to ensure physician responsibility for women who take mifepristone under their care, as well as mandate full reporting of its side effects. The FDA should further investigate the harm this drug causes to women and, based on objective safety and effectiveness criteria, reconsider its approval altogether. Women deserve to know the truth. Women deserve better than the abortion pill.

This paper is the second in a series investigating women's health and abortion using real-world data. It is based on the same data and follows the same methodology as described in "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Women Experiences a Serious Adverse Event" and its accompanying documentation.

You can read the first paper and accompanying documentation at eppc.org/stop-harming-women.

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