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New Research Reveals Undisclosed Dangers of Chemical Abortion

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KEY POINTS:

- More than **1 in 10 women** who use the chemical abortion pill experience a serious adverse event.
- Medical claims data shows that the rate of serious adverse events of the chemical abortion pill is **22 times higher** than the rate stated by the Food and Drug Administration.
- Women are not being given true informed consent when taking the chemical abortion pill. **Policymakers should consider severely restricting the use of mifepristone to protect the safety of pregnant women.**

Background

Chemical abortion is the use of the medication mifepristone, most commonly followed by misoprostol, to end the life of a human fetus and cause the expulsion of the fetus from the uterus.[1,2] The Guttmacher Institute, a non-profit research organization dedicated to advancing abortion in the United States and worldwide, estimates that chemical abortion represented 63 percent of abortions in 2023, up from 53 percent in 2020 and 31 percent in 2014.[3] The growth in chemical abortion is likely driving the growth in total abortions in the United States, which increased 11 percent from 2020 to 2023.[4] Despite the United States Supreme Court's groundbreaking decision to overturn *Roe v. Wade* in June of 2022, abortions are increasing as abortion advocates encourage chemical abortion pill use, interstate abortion travel, and the shipping of dangerous abortion pills to circumvent pro-life state laws. As the abortion industry-aligned Guttmacher Institute stated in its review of the 2023 abortion data, "Medication abortion has proven to be a game changer in expanding abortion care in the United States."[5]

The FDA and the abortion industry acknowledge that there are risks to the chemical abortion pill but portray the risks as minor. The FDA label for mifepristone acknowledges that about 85 percent of users experience at least one non-serious adverse event including nausea, fever or chills, vomiting, headache, and diarrhea.[6] The label also acknowledges serious adverse events observed either in clinical trials or in post-approval reported cases, including sepsis, blood transfusion, hospitalization, infection, hemorrhage, uterine rupture, ruptured ectopic pregnancy, and death. However, the FDA's interpretation of the clinical trial data determined that overall fewer than 0.5 percent of women experienced a "serious adverse event."[7] Planned Parenthood reiterates that serious or life-threatening complications are "extremely rare" and claims that the chemical abortion pill is "safer than Tylenol."[8]

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A Review of the Data

This paper challenges the prevailing narrative that chemical abortion is safe for women. National insurance claims data obtained by the Restoration of America Foundation and reviewed by our clinical team of board-certified obstetrician-gynecologists reveals the significant risks of mifepristone to women's health. Our data shows that **chemical abortion poses greater risks to women in real-world clinical use than revealed in the clinical trials** of mifepristone and that the rate of serious adverse events from the chemical abortion regime continues to grow in recent years. The risks of the widespread use of the chemical abortion pill are dire, including a rate of serious adverse events among patients at 22 times the rate stated on the mifepristone label.

THE RATE OF SERIOUS ADVERSE EVENTS AMONG PATIENTS IS 22 TIMES THE RATE STATED ON THE MIFEPRISTONE LABEL

Our dataset of insurance claims for the years 2017 to 2023 identified 692,873 patients who obtained 865,727 chemical abortions (indicating repeat abortions among a significant portion of the dataset).[9] This represents 25% of the chemical abortions that occurred in the US according to Guttmacher Institute's chemical abortion estimates for the same time period.[10] The percentage of abortions that resulted in at least one serious adverse event was 10.9 percent over the seven-year study period.[11,12] The dataset further shows an upward trend in serious adverse event rates in recent years. In 2023 alone, 154,554 chemical abortions occurred with a serious adverse event rate of 11.2 percent.

Number of Chemical Abortions and Serious Adverse Event Rate

Year	Number of Chemical Abortions	Serious Adverse Event Rate
2017	92,391	9.6
2018	92,493	9.6
2019	114,919	11.0
2020	124,243	10.5
2021	134,903	11.4
2022	152,224	12.2
2023	154,554	11.2

Based on the dataset, California had the most chemical abortions and the highest rate per 1,000 in 2023. This state alone made up more than 50 percent of the total 154,554 chemical abortions for the year 2023. The next **largest state contributors of chemical abortion** nationally were (in order): **New York**, **Illinois**, **Washington State**, **New Jersey**, **Minnesota**, **Maryland**, and **Massachusetts**.

The states with the **lowest rates of identified chemical abortions** in 2023 were: **Mississippi**, **Alabama**, **Arkansas**, **Oklahoma**, **Kansas**, **Kentucky**, **Tennessee**, and **Louisiana**. This data shows that these state's pro-life laws have been effective in discouraging the use of any publicly funded insurance resources for abortion, though our team still found instances of women from these states obtaining chemical abortions and billing insurance.

Our findings contradict claims that the chemical abortion pill regime is safe. The finding from this dataset that more than 1 in 10 women who use mifepristone experience at least one serious health complication within 45 days is in stark contrast to past research, including the original clinical trials of mifepristone. This discrepancy is largely due to our use of post-market, real-world data which captures outcomes across larger, more diverse populations, over longer periods of time, and in everyday clinical settings. Unlike controlled trials, real-world evidence reflects how mifepristone performs in practice, offering a more accurate and comprehensive view of patient safety.

MORE THAN 1 IN 10 WOMEN
WHO USE MIFEPRISTONE EXPERIENCE AT LEAST ONE SERIOUS HEALTH COMPLICATION WITHIN 45 DAYS

Conclusion

Our review of insurance claims data for patients who used mifepristone reveals serious dangers posed by the use of the chemical abortion pill regime. We show that more than 1 in 10 US women experience a serious adverse event, 22 times the rate stated to patients by the FDA. This drastic difference between the disclosed risk and the actual risk to patients undermines informed consent and endangers the lives of pregnant women. Policymakers and regulatory bodies should review real-world evidence and act decisively to prevent serious harms to women and their health and safety.

Appendix A: Adverse Event Categorization

The list of adverse event codes was compiled using ICD-10 diagnosis codes and CPT/HCPCS procedure codes from various sources including:

- CDC's Severe Maternal Morbidity (SMM) list[13]
- CMS.gov DRG 770 and DRG769[14]
- FAERS mifepristone reported adverse events[15]
- Additional clinician suggested and verified adverse event codes

Adverse events were categorized by FDA definition[16] of Serious or Non-Serious and reviewed by a team of clinicians according to the FDA standard. Only Serious Adverse Events were included for consideration.

Serious Adverse Events were segmented into 2 categories:

1) Serious Adverse Events as reported on the Mifeprex label

2) Other Serious Adverse Events

1. **Serious Adverse Events** as reported on the Mifeprex label, which includes those used by the FDA for clinical trials of the medication abortion pill and reported on the Mifeprex (mifepristone) label[17] or in post-market reporting. Categories include Transfusion, Sepsis, ER Visit, Hospitalization Related to Medical Abortion, Infection without Sepsis, and Hemorrhage.

2. **Other Serious Adverse Events** include those which were not reported on the Mifeprex label but required intervention to avoid life threatening events or death. These include ectopic pregnancies or abortion-specific complications and surgeries. In addition, they include life-threatening events studied in the clinical trials but also disclosed on the Mifeprex label, including cardiac, pulmonary, anaphylaxis and thrombosis-related events; ectopic pregnancy complications; subsequent surgical abortions within 45 days of failed medication abortion; birth resulting from a failed abortion; or "other abortion specific complications," including retained products of conception.

Multiple Abortion Procedures: Procedures coded as surgical abortions occurring within 45 days of a previous abortion are not counted as a new and separate abortion since the likelihood of repeat pregnancy within that timeframe is infinitesimally small, but instead are categorized as evidence of the adverse event of retained tissue. Surgical abortions within 45 days of a medication abortion are considered Serious Adverse Events because they require intervention to prevent a life-threatening complication such as sepsis from retained tissue. Subsequent administration of misoprostol occurring within 45 days of a previous medication abortion are considered a non-Serious Adverse Event according to FDA definitions.

Subsequent abortions that occurred beyond 45 days are counted as a distinct and separate abortion event.

Study Disclaimer

The presence of a diagnosis or procedure code within the categories analyzed in this study does not establish a clinical diagnosis (e.g., sepsis, hemorrhage, transfusion reaction, infection), nor does it imply causation. Rather, these codes are associated with such conditions and may reflect cases where they were present, considered, or managed. Clinical confirmation and causal inference would require additional patient-level information—such as laboratory results, provider documentation, and treatment details—which are beyond the scope of this analysis.

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7. The exact quote from the Mifeprex label is "Serious adverse reactions were reported in <0.5% of women." See: Mifeprex Label, (p.7), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.
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12. We chose to align our definition of serious adverse event with the Food and Drug Administration's definitions and the Common Terminology Criteria for Adverse Events (CTCAE) in order to provide a close comparison to other studies. A team of clinicians reviewed all flagged events to determine that the serious adverse events identified could be realistically attributed to the use of mifepristone for the purpose of causing a chemical abortion. For more details on our methodology, please see Appendix A.
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