LIFE AND FAMILY INITIATIVE

Frequently Asked Questions About the Largest Study on Chemical Abortion

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The report we released last week is the largest-known study of the abortion pill, based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions from 2017 to 2023. We found that 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious adverse event within 45 days following a mifepristone abortion. This means that the real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of "less than 0.5 percent" in clinical trials reported on the drug label.

Some have raised questions about our data and methodology. We address some of those below. And will be updating this document with additional questions and answers and clarifications as needed.

1. How did you confirm solely from ICD-10 codes that the hospitalization or ER visits were related to the abortion? Isn't it possible that a person who had a medical abortion could end up at the ER within 45 days for something completely unrelated, such as a car accident or broken bone?

The emergency room visits included in the report are only those related to the chemical abortion, based on the diagnosis and procedure codes in the insurance records, and are counted only if treatment for a serious complication related to the chemical abortion took place. Thus, if a woman took the chemical abortion pill and then got into a car accident or broke a bone, that did not count. Likewise, if a woman took the chemical abortion pill and had mild cramping related to the chemical abortion, that also did not count. Only an ER visit when the woman was treated for a serious adverse event related to the chemical abortion was counted.

This led us to exclude 72% of emergency room visits that took place within 45 days of abortion from our analysis because they were either not serious enough or were unrelated to the chemical abortion. That is, 98,483 ER visits that occurred within 45 days of the chemical abortion involved diagnoses not clearly related to the chemical abortion or not medically serious, such as COVID-19 exposure, nicotine dependence, asthma, and anxiety disorder.

Moreover, our findings are consistent with existing FDA information: in the serious adverse event section, the Mifeprex label reports abortion-related ER visits of up to 4.6%, and this study identified a nearly identical rate of 4.7%.

The reason we reported on ER visits is because the FDA does so on the drug label for mifepristone.

2. What if one woman experienced multiple serious adverse events? Aren't you inflating the percentage of women who experience a serious adverse event?

Our reported 10.93% rate of serious adverse events means that women experienced at least one serious adverse event in 10.93% of pregnancies for which a mifepristone abortion was prescribed. We ensured that each pregnancy was counted only once, even if a woman experienced multiple serious adverse events within the same category or across different categories. 10.93% is simply the ratio of the sum of women who experienced one or more serious adverse events associated with the prescribed mifepristone abortion of a given pregnancy to the total number of pregnancies for which a mifepristone abortion was prescribed. It is not, as some have erroneously suggested, a rate of how many serious adverse events women experienced, on average, per pregnancy aborted with mifepristone.

3. Why have you included ectopic pregnancy as an adverse event associated with medical abortion? The pill can't cause a pregnancy to move from the uterus, so why include that as a condition that resulted from taking the medication?

We do not claim or suggest that mifepristone causes ectopic pregnancies. The warning on the first page of the FDA-approved drug label requires that ectopic pregnancy be ruled out as a condition prior to using mifepristone, precisely because the use of mifepristone by a woman with an ectopic pregnancy poses extraordinary, heightened risk to her health. As noted on page 5 of our report, only events occurring within 45 days *following* the abortion are included. The study reports 3,062 cases of ectopic pregnancy. These are cases in which a woman was diagnosed with this condition only after she had already taken mifepristone. This failure to properly diagnose the ectopic pregnancy before the abortion attempt placed each of these women's life at risk.

This reinforces why, at minimum, the safety protocols requiring an in-person doctor visit should be restored to protect women's health. Without a doctor visit, how can the FDA expect women with ectopic pregnancies to follow the FDA requirement that ectopic pregnancies be ruled out prior to a chemical abortion and thereby avoid the extreme risk of a chemical abortion for them? This data clearly shows that in over 3,000 cases in our data alone, the FDA, the manufacturer, and the prescriber of mifepristone failed these women who had pre-existing ectopic pregnancies and did not know it.

4. Could you be including miscarriage care as if it were an abortion? After all, isn't it accurate that you included patients who were only prescribed mifepristone and not also given misoprostol? Since the protocol for medical abortion is to take both medications, is it possible that your data includes some patients who were given mifepristone for other conditions, including miscarriage?

No, we were very careful to exclude miscarriage care in our report by requiring any mifepristone only prescription was accompanied by a Z332 code (encounter for elective termination of pregnancy) or Z640 (problems related to unwanted pregnancy).

5. Didn't you simply label everything a serious adverse event? How did you define it and then code for it?

We based our analysis on the official FDA definition of a serious adverse event and then identified treatment and diagnosis codes that matched that definition. For an event to be counted in our serious adverse event rate, it had to meet three criteria:

1. It aligned with the FDA's definition of a serious adverse event—for example, it was life-threatening, required hospitalization, or led to surgical intervention.
2. It occurred within 45 days of the medication abortion.
3. It was reasonably related to the abortion, as previously described.

The events we included covered hospitalizations for hemorrhage, sepsis, blood transfusions, surgical procedures after failed abortions, and complications from confirmed ectopic pregnancies. We limited our analysis to severe (Grade 3) and life-threatening (Grade 4) events as defined by the NIH's Common Terminology Criteria for Adverse Events (CTCAE). We were not yet able to include Grade 5 events (deaths).

Critics imply that the FDA definition of serious adverse event is simply whatever the FDA chose to count on the drug label. However, the drug label does not contain a definition of "serious adverse event," only an incomplete yet overlapping list of categories (three diagnoses, one treatment, and two places of service) *with* reported data, followed by a list of post-marketing categories *without* reported data (which includes "ruptured ectopic pregnancy"). We cited and followed the official FDA definition of the term (linked above); to then say that we use "a broader definition of 'serious adverse event' than the FDA" is highly misleading.

6. Can you explain what "other abortion-specific complications" includes in the paper's serious adverse events by category section? It accounts for around half of the serious adverse event rate but I don't see any more specifics about those 49,169 "other abortion-specific complications."

Other abortion-specific complications include problems like damage to the woman's internal organs from the abortion, fetal tissue remaining inside the woman's uterus after the abortion, kidney failure, as well as life-threatening mental health diagnoses occurring after the abortion.

These are overwhelmingly DRG 770 (Abortion with D&C, Aspiration Curettage, or Hysterotomy) and DRG 769 (Postpartum and Post Abortion Diagnoses with Operating Room Procedure) codes that were determined to be severe or life-threatening following CTCAE version 5. Furthermore, we limited mental health codes to only those that met the criteria for life-threatening in order to not overestimate that category. There were just a few diagnosis codes (representing a small share of the cases) that met our inclusion criteria, namely R45850 (Homicidal ideations) and R45851 (Suicidal ideations). Many women who were counted in the other categories in Figure 1 of our report also experienced an event that fell within this category.

7. Why wasn't this paper peer-reviewed?

The point is not peer review, but replicability. We have made our study fully replicable for anyone who wants to analyze the insurance claims data. The replicability crisis, well-documented in the press and denied by no responsible person, is the evidence that peer review guarantees little.

We stand behind our analysis of healthcare claims data which is why we are asking the FDA to conduct its own review of this data. Real world data in which money changed hands based on the treatment of patients and coding by doctors brings a higher level of confidence. The dataset is available for purchase and our methodology is public. This study is fully replicable, and we encourage others to replicate it.

The peer-review process is broken. It is terribly biased against conservatives, especially social conservatives, particularly pro-lifers. The paper would have been leaked, so as to prepare hostile responses, if it were ever published to begin with. Given the extensive pro-abortion bias in the peer-review process, there are, effectively, no opportunities to publish peer-reviewed analysis that offer major substantive critiques of the abortion pill or abortion.

8. Why should we trust insurance claims data?

Insurance claims data is a cornerstone of public health and safety monitoring. The FDA, CDC, NIH, CMS, and countless peer-reviewed journals rely on it precisely because it reflects real-world outcomes across massive populations. For example:

- The **FDA Sentinel Initiative** uses claims and electronic health record data to monitor post-market safety of medical products.
- The **CDC's Vaccine Safety Datalink (VSD)** uses claims data from millions of individuals to monitor vaccine safety.
- The **Centers for Medicare & Medicaid Services (CMS)** conduct quality assessments and cost analyses through large-scale claims-based research.

Peer-reviewed journals such as *JAMA*, *The New England Journal of Medicine*, and *Health Affairs* regularly publish studies based on administrative claims.

It is especially vital for medications like mifepristone, where:

- Controlled trials have small samples, carefully recruited healthy patients, physician oversight, and limited follow-up.
- Post-marketing surveillance (e.g., FAERS) is passive and incomplete.
- Reporting requirements were loosened in 2016, obscuring complications.

Our analysis examines hundreds of thousands of real-world chemical abortion events—across settings, payors, and demographics—and identifies follow-up care patterns at scale. This is real-world data, in real-world clinical settings, in which real money changed hands from public and private payors as a result of real serious harm faced by real women. These women, and hundreds of thousands like them, were seriously harmed, not carefully protected in idealized clinical studies.