

## Introduction: A Methodologically Flawed Report

A recent, self-published report by Hall and Anderson attempts to muddy mifepristone's 25-year safety record, all while lacking scientific rigor and reliability. In their analysis, the authors used an unidentified all-payer insurance claims database from 2017-2023 to examine adverse events. This report was **not peer-reviewed**. They claim that nearly 11% of patients experience "a serious adverse event" after abortion, however, this number is seriously flawed for reasons outlined below. As a reminder, decades of scientific evidence amassed through more than 100 studies—based on hundreds of thousands of patient outcomes—have established the safety record for mifepristone use in medication abortion. **At several key points, the FDA reviewed this body of science in the past 25 years and confirmed, each time, the safety and effectiveness of mifepristone.**

## Addressing Unverified and Unreliable Data

### ER Visits in and of themselves are not serious adverse events.

In the report, abortion-related emergency room (ER) visits were counted as serious adverse events. However, this goes against FDA guidance, which states: "Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event)."<sup>1</sup> It is well-known that many people go to an emergency room after a medication abortion to get immediate care for symptoms, to ask questions, or to confirm they are no longer pregnant, without receiving any treatments.<sup>2-5</sup> This is more common when the patient lives far from the abortion provider.<sup>6</sup> ER visits are more common among people with Medicaid coverage, as they often do not have a primary healthcare provider.<sup>7</sup> Additionally, the analysis period overlaps with the height of the COVID pandemic, during which the implementation of social distancing policies created barriers to in-office primary care visits, which could have led to an increase in ER visits for routine follow-up care.<sup>8</sup> Thus, an ER visit alone does not constitute a serious adverse event. This category accounts for 40,960 of the 94,605 (nearly half of) "serious adverse events" documented in the analysis.

### Subsequent treatment to complete the abortion is not a serious adverse event.

The authors counted any subsequent procedure to complete the abortion as a serious adverse event. However, these are considered treatment failures and captured in effectiveness rates. It is known and expected that about 3-5% of patients will need additional medications or a procedure to complete the abortion.<sup>2,9</sup> This is not a serious or urgent complication, but an expected one. This category accounts for 24,563 (one-fourth) of the 94,605 "serious adverse events" in the report.

## **"Other abortion-specific complications" are not clearly defined.**

There is a need for greater transparency around the "other abortion-specific complications" category. This category is likely where the "[diagnosis and treatment] codes suggested by our doctors" landed, contributing to greater confusion and obscurity around the methods. No information about the doctors who did this coding or what they relied upon to designate abortion-specific complications for this category was offered, so we are unable to evaluate their expertise in abortion care. Relatedly, and deeply problematic, they included diagnosis codes for homicidal and suicidal ideation as two of the diagnosis codes qualifying as abortion-specific complications. However, rigorous published research overwhelmingly establishes that serious mental health crises are not a complication of abortion. This is the largest category of serious adverse events, accounting for 49,169 (about half) of the 94,605 serious adverse events in the analysis.

## **Conflation of abortion with miscarriage and other uses of mifepristone.**

One of the three ways they identified mifepristone abortions was "a prescription for mifepristone." However, mifepristone is used increasingly for other uses, including miscarriage management and labor induction, along with misoprostol; the prescription of mifepristone and misoprostol is not unique to abortion care.<sup>10–12</sup> Additionally, mifepristone is frequently used for cervical priming before procedural abortion in the 2nd trimester, and such uses would have been captured in this report. In general, miscarriage and treatment for miscarriage are associated with slightly higher complication rates than for abortion,<sup>13</sup> which would erroneously inflate the "serious adverse event" rate reported in the report.

While the methods are not clearly described, if the authors counted any emergency room visit that occurred on the day mifepristone was prescribed, any person who was miscarrying and received mifepristone as treatment at an emergency room would have been included as a serious adverse event.

## **Lack of a standardized definition of hemorrhage.**

The authors don't define hemorrhage. A successful medication abortion always induces some bleeding. When a patient presents with complaints of bleeding, it could be excessive bleeding or it could be the expected amount.<sup>14</sup> Without a standardized definition, they are likely capturing many cases of normal bleeding that occur with a medication abortion. In appropriately conducted studies, hemorrhage is considered a serious adverse event only when it requires a blood transfusion. This amorphous category accounts for 28,658 of the 94,605 "serious adverse events" in the report.

## **"Other life-threatening adverse events" and "infections" are not necessarily abortion-related.**

The analysis considers chronic issues including cardiac and pulmonary events, as "serious adverse events," but there is no indication that they are abortion-related. In fact, patients with these conditions may be more likely to have an abortion to avoid exacerbating their chronic condition, and thus the direction of causality is ambiguous. It is quite likely these types of cases are over-represented in the database because many public and private insurance plans cover abortions only if a pregnancy is causing or exacerbating serious health issues. This category accounts for 1,965 of the 94,605 "serious adverse events" in the report.

Similarly, the category for infections is inflated by inclusion of non-serious conditions that are unrelated to the abortion like yeast vaginitis and urinary tract infections, accounting for 11,707 of the 94,605 “serious adverse events” in the report.

### Over-reliance on diagnosis codes rather than treatment codes.

In standard studies of abortion safety, researchers use treatment codes to identify serious adverse events, given that diagnosis codes alone may not indicate the degree of seriousness of an event. A lack of treatment is an indicator of low severity.<sup>15</sup> For example, given the variety of presentations, a diagnosis of infection without any treatment should not be considered a serious adverse event. Thus, when classifying adverse events, it is critical to examine treatment/procedure codes.

### Policy implications not supported by the findings.

The policy implications stated do not follow from the authors’ own analyses, even if one were to take them at face value. For instance, they did not examine changes in serious adverse events after telehealth became available, nor did they find any evidence to support that a return to in-person dispensing of mifepristone for a medication abortion would reduce adverse events; the analysis does not stratify by the location of mifepristone dispensing so there is no evidence that adverse events would be different based on in-person versus remote dispensing of mifepristone. Similarly, they find no evidence to support that a return to three in-person office visits for a medication abortion would reduce adverse events. Thus, their statement of this as a first policy conclusion is unsupported. Similarly, their analysis does not examine adverse events by pregnancy duration, and thus, their claim that restricting medication abortion to the first 7 weeks is unsupported by the analysis conducted.

### Analyses cannot be verified or reproduced.

The authors did not disclose the source of the all-payer insurance claims database, and have refused subsequent requests to reveal it, precluding the ability to independently verify the results. There are known methodological limitations of some databases for analyzing abortion claims data. For example, some sources of Medicaid claims data are over representative of “Hyde exceptions.”<sup>16</sup> These are abortions that are covered by Medicaid only because they qualify for exceptions, allowable for pregnancies that endanger the life of the pregnant person or that result from rape or incest. These abortions are different than those for typical care because they can require a greater level of follow-up care. Additionally, the report does not disclose the diagnosis and treatment (ICD-10, CPT/HCPSCS, NDC) codes used in the analyses, as is standard practice in analyses of insurance claims data. In fact, it never identifies a single treatment code that was used as part of their methodology, let alone discloses all the treatment codes considered under each category it counts as a serious adverse event. Standard practices in epidemiology emphasize the importance of transparency in methodological approaches to ensure the reliability, reproducibility, and credibility of research findings.<sup>17</sup>

## Conclusion

This self-published report does not credibly cast doubt, nor outweigh the findings of a robust body of rigorous scientific studies that show that mifepristone is safe, including when provided through telehealth. In August 2025, the UCLA Law Center on Reproductive Health, Law, and Policy (CRHLP) and ANSIRH submitted [a letter on behalf of more than 260 researchers to the U.S. Food](#)

[and Drug Administration \(FDA\)](#). The letter further explains why this report lacks rigor and reliability, and urges the FDA to continue grounding any future decisions in scientific evidence.

## References

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