Science Unpacked

False serious adverse events claims with medication abortion

Drafted October 12, 2025

This series unpacks the science behind studies, theories, or narratives that have achieved prominence in public discourse, underscoring the expertise, humility, and rigor required for research to meet the threshold of sound science. Concurrently, this effort aims to elevate the importance of legitimate scientific exchange, demonstrate fidelity to evidence, and promote public trust in the scientific process.

The intended audience for the Science Unpacked series includes Society of Family Planning members, scholars and clinicians outside of the family planning field, partners, policymakers, and the broader public. The series is intended to be additive and in partnership with other trust-building efforts across the family planning and scientific communities.

In this Science Unpacked, the Society invited Mitch Creinin, MD and Dave Turok, MD, MPH to respond to an April 28, 2025, report from the Ethics and Public Policy Center claiming a nearly 11% rate of serious adverse events in patients having a medication abortion with mifepristone, several fold higher than the established body of research.

Key takeaways

- The discussed paper does not change the established consensus affirming the safety of mifepristone.
- The discussed paper's methods are inconsistent with strong scientific standards. They do not meet the rigor, integrity, or transparency necessary to contribute to the evidence base.
- The authors of the discussed paper are affiliated with an organization that puts anti-abortion ideology over evidence.
- The measurement of the key outcome, serious adverse events, is flawed and inconsistent with well-established research practices on this topic.
- The discussed paper does not produce empirical evidence and should not be considered in decisions about clinical practice, public policy, or health service delivery.

An April 28, 2025 report from the Ethics and Public Policy Center, a conservative Washington, DC–based think tank and advocacy group, claims a nearly 11% rate of serious adverse events (SAEs) in patients having a medication abortion with mifepristone,[1] several fold higher than large preceding evaluations, which show SAE rates of <0.5%.[2-4] To estimate the number of medication abortions, the authors of the report purchased a commercially available de-identified all-payer health insurance claims database and identified cases using medication abortion billing codes, mifepristone prescription, and a diagnosis code for abortion combined with other codes that suggested a medication abortion from 2017 to 2023. The authors used insurance claim databases and the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) to identify outcomes defined as SAEs over the same time period. The implication of the timing of the assessment (starting in 2017) is that the FDA changed the label in 2016 and then again in 2023, removing what the authors claim are safeguards for mifepristone. The 2016 label changes, based on the extremely large existing volume of efficacy and safety data reviewed by the FDA, broadened prescriber eligibility and aligned the label with evidence-based practice. These changes included extending the gestational age limit for mifepristone use to 70 days and adjustments to dosing and timing instructions for mifepristone and its adjunct medication, misoprostol.[5] The 2023 changes, again backed by extensive safety data, included permanently removing the in-person dispensing requirement and allowed pharmacies to dispense mifepristone directly to patients with a prescription while still requiring both clinicians and pharmacies to be certified for dispensing.[6]

This web-based report drew the attention of the US Secretary of Health and Human Services who, within a few weeks, publicly called for the FDA to review the regulations around mifepristone, calling the Ethics and Public Policy Center report "alarming."[7] The health secretary stated that such a review was necessary due to "new data." Shortly thereafter, a June 2, 2025, letter from FDA Commissioner Dr. Martin Makary documented his commitment "to conducting a review of mifepristone…"[8]

1. Understanding the source

Before addressing the flaws of the April 2025 report, it is worth acknowledging the nature of the source organization. The Ethics and Public Policy Center has a religious-based mission that includes "pushing back against the extreme progressive agenda while building a consensus for conservatives."[9] They do acknowledge the version of "the truth" they pursue and state that the Center works "closely with parents and other culturemakers to apply the truth in daily life." They have no stated commitment to medical or health outcomes or science as a source for determining the truth. While the authors of the report may have quantitative analysis skills, they have no apparent experience with or skills in health care claims data analyses. This is important and worth mentioning because it may directly explain some of the elementary errors in their analysis and their lack of acknowledging these weaknesses. This crucial gap informs the quality of their report and its potential impact on clinical care. We mention this point in our commentary to explain why our comments address both the analyses and the source.

2. What are the fatal flaws?

This report has fatal flaws; clinicians, scientists and government officials need to understand these issues before making comments that are based on invalid, unsubstantiated data.

Errors in estimating SAE events

The authors calculated their SAE rate by totaling their reported SAE events; however, these are event rates, not patients. A patient who is hospitalized and has a transfusion is one patient, not two. The authors state the rate is "adjusted for the fact that some women suffer from adverse events in multiple categories" without explaining any statistical adjustment. When a report that does not engage or falsely applies scientific principles states an outcome that substantially differs from all other prior studies with thousands of participants undergoing close prospective surveillance, the likelihood that these findings are real is very low.

Errors in calculating medication abortions (the denominator)

The exposures, mifepristone abortions, are identified by procedure code and prescriptions for mifepristone. This may appear reasonable, as 78% of abortion patients have healthcare insurance coverage.[10] However, a 2020 report identified that 58% of abortions in the US occur at independent clinics,[11] and a more recent study found that about half (53%) of all patients pay out of pocket for their abortion care.[10] Thus, this large proportion of medication abortion services will not be identified using procedure codes and prescriptions for mifepristone, meaning the denominator is considerably smaller than it should be. Insurance claims data use billing codes to indicate reasons for a visit and are limited in their definitions. Billing codes are layered by billing experts to list all reasons related to the visit to ensure insurance reimbursement and are likely to contain errors.[12,13] As an example, directly relevant to this report, a patient who presents to an emergency room (ER) with vaginal bleeding is coded as vaginal hemorrhage; there is no code delineating the degree of bleeding.[14] For this reason, simply using billing codes does not identify an actual SAE. If bleeding was truly serious, transfusion would be the appropriate indicator.

Errors in confirmation of outcomes

Prospective studies have the benefit of chart review to ensure if the event is related or not. Billing evaluations do not associate events in this manner. Scientific studies that use billing codes for uncommon or rare events (eg, thromboembolism with combined oral contraceptive use) will commonly review patient records to confirm the care (Was the patient truly taking a combined oral contraceptive?) and the outcome (Did the patient have a confirmed thromboembolism?).[2] The authors of this report did not review any records — not even a subset — which means the data is unconfirmed and, thus, unvalidated.

Errors in the definitions of SAEs

The report's authors state that a team of physicians used the National Institutes of Health Common Terminology Criteria for Adverse Events to categorize severity, which they could not assess for events based on billing codes. Additionally, the report claims to only include hospitalization and ER visits with abortion-related diagnosis and procedure codes, which again is not possible without direct chart review. For example, a patient hospitalized from a car accident eight days after a medication abortion could be coded by a biller as post-abortion even though the SAE is unrelated.

Even more important is that the designation for SAEs is used incorrectly. The FDA definition of a SAE requires the event first be classified as an adverse event (AE) and one of the following criteria to be met:[15]

- Death
- Life-threatening: at substantial risk of dying at the time of the AE
- Hospitalization (initial or prolonged). The FDA adds that ER visits without hospital admission are not included here but should be evaluated for one of the other serious outcomes.
- Caused disability or permanent damage
- Required intervention to prevent permanent impairment or damage
- Congenital anomaly/birth defect
- Other serious (important medical events): the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes, for example allergic bronchospasm requiring treatment in an ER.

The study critically mislabels SAEs, as the vast majority of events they report would be considered non-serious adverse events in any study. Of the ten categories listed in the report, the two most common are "ER visit (related to the abortion)" (4.73%) and "Other abortion-specific complications" (5.68%). The report lacks any detail on how these were assessed as serious, especially since ER visits, by themselves, are not SAEs.

Four categories fail to meet the FDA's SAE definition. First, "repeated (surgical) abortion" (2.84%) is a procedure to complete the abortion and, as such, is an outcome (the definition of medication abortion failure), not an AE. Since it is not an AE, it cannot be a SAE without meeting other FDA criteria for a SAE. Second, infection (1.34%) treated as an outpatient is not a SAE. Infections could also be inappropriately assigned as an abortion complication if, for example, the primary diagnosis was pneumonia, ear infection, or COVID-19. If a diagnosis of sepsis was included, this would generate double-counting including sepsis and the primary infection diagnosis in the same patient. Third, for hemorrhage (3.31%), to be a SAE, it would most commonly occur in a patient receiving a transfusion or hospitalization; cases in this category are also likely double counting from other categories. Lastly, ectopic pregnancy (0.35%) is not related to the study drug so would not be counted as a related SAE.

The events that meet the definition of a SAE occur at the frequency expected: sepsis (0.10%), transfusion (0.15%), other life-threatening events (0.22%), and hospitalization (0.66%), although the first three are likely double counted with hospitalization. Importantly, the authors fail to identify how they can claim the hospitalization is related to the abortion other than the timing being "within 45 days of a mifepristone abortion."

The authors do not describe how they ensured that the two methods used to identify AEs (billing codes and FAERS reports) did not overlap for a specific patient, implying further overcounting of potential AEs. Additionally, the authors do not acknowledge the inherent limitations of the FAERS public dashboard, as described by the FDA on the FAERS website.[16] These limitations include existence of duplicate and incomplete reports within the system, lack of cause and effect between product use and an adverse event, lack of verification of reports in the system, and, most importantly, that the information in these reports cannot determine rates of occurrences. Because of these severe limitations, analysis methodology for using regulatory databases most ideally is limited to using disproportionality analysis with standardized reporting according to the REporting of A Disproportionality analysis for drUg Safety signal detection using individual case safety reports in PharmacoVigilance (READUS-PV) statement.[17] Thus, the authors use the FAERS data beyond the scope of scientific validity.

Errors in translation of findings to recommendations
Based on their unsubstantiated findings, the authors state that their findings support that the "FDA should immediately reinstate its earlier, stronger patient safety protocols," referring to the pre-2016 label. To make such a claim, the authors would need to include data prior to 2017 to show changes over time. Additionally, the data would need to be presented on a year-by-year basis to show shifts over time.

3. Conclusions

This summary is not an exhaustive account of the errors in the report and the authors' conclusions; we only highlight some of the major errors. Most importantly, the event rates reported do not truly reflect SAEs and do not represent the proportion of individual patients with SAEs. The authors fail to meet numerous measures of scientific rigor for execution of a database study, especially one that uses regulatory data, and use inappropriate methodologies to derive their conclusions. The April 28, 2025 report from the Ethics and Public Policy Center report fits into the broader political and legal campaign to restrict all abortions, the majority of which are now completed with medication abortion pills.[18] In conclusion, the report is not a scientific study, does not represent any true scientific findings, and is simply propaganda that claims to be science.

Funding: None

References

1. Hall JB, Anderson RT. The abortion pill harms women: Insurance data reveals ane in ten patients experiences a serious adverse event. April 28, 2025. Accessed October 12, 2025. https://eppc.org/publication/stop-harming-women/
2. Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol*. 2015;125(1):175-183. doi: 10.1097/AOG.0000000000000603
3. Chen MJ, Creinin MD. Mifepristone with buccal misoprostol for medical abortion: A systematic review. *Obstet Gynecol*. 2015 Jul;126(1):12-21. doi: 10.1097/AOG.0000000000000897
4. Danco Laboratories. Mifeprex (mifepristone) [package insert]. US Food and Drug Administration website Revised January 2023. Accessed October 12, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf
5. NDA 020687 MIFEPREX® (mifepristone) Tablets, 200 mg, Risk Evaluation and Mitigation Strategy (REMS). Accessed October 12, 2025. https://www.fda.gov/media/164649/download?attachment
6. Information about mifepristone for medical termination of pregnancy through ten weeks gestation. Accessed October 12, 2025. https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation
7. Nava V. New York Post, May 15, 2025. Accessed October 12, 2025. https://nypost.com/2025/05/15/us-news/hhs-chief-rfk-jr-says-hes-ordered-a-complete-review-of-chemical-abortion-pill/
8. Hawley J. X. Accessed October 12, 2025. https://x.com/HawleyMO/status/1929696353010987013
9. Ethics & Public Policy Center. Accessed October 12, 2025. https://eppc.org/about/
10. Jones RK. Medicaid's role in alleviating some of the financial burden of abortion: Findings from the 2021-2022 Abortion Patient Survey. *Perspect Sex Reprod Health* 2024;56(3):244-4. doi: 10.1111/psrh.12250
11. Abortion Care Network. Communities need clinics. The essential role of independent abortion clinics in the United States. Accessed October 12, 2025. https://abortioncarenetwork.org/wp-content/uploads/2020/12/CommunitiesNeedClinics-2020.pdf
12. Kotecha D, Asselbergs FW, Achenbach S, Anker SD, Atar D, Baigent C, et al. CODE-EHR best-practice framework for the use of structured electronic health-care records in clinical research. *Lancet Digit Health*. 2022;4:e757–e764. doi: 10.1016/S2589-7500(22)00151-0
13. Saraswathula A, Merck SJ, Bai G, Weston CM, Skinner EA, Taylor A, et al. The volume and cost of quality metric reporting. *JAMA*. 2023;329:1840–47. doi: 10.1001/jama.2023.7271
14. US Centers for Disease Control and Prevention. International Classification of Diseases, Tenth revision, Clinical Modification (ICD-10-CM). Accessed October 14, 2025. https://www.cdc.gov/nchs/icd/icd-10-cm/index.html
15. US Food and Drug Administration. What is a serious adverse event? Accessed October 12, 2025. https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event
16. US Food and Drug Administration. FDA Adverse Event Reporting System (FAERS) public dashboard. Accessed October 12, 2025. https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard
17. Fusaroli M, Salvo F, Begaud B, AlShammari TM, Bate A, Battini V, et al. The REporting of A Disproportionality analysis for drUg Safety signal detection using individual case safety reports in PharmacoVigilance (READUS-PV): Explanation and elaboration. *Drug Saf*. 2024;47(6):585-99. doi: 10.1007/s40264-024-01423-7
18. Society of Family Planning. #WeCount Report April 2022 through December 2024. June 23, 2025. Accessed October 12, 2025. https://societyfp.org/wp-content/uploads/2025/06/WeCount-Report-9-December-2024-data.pdf