



August 27, 2025

#### **Submitted Electronically**

Division of Dockets Management
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#### **Reproductive Health Researchers' Comment**

The UCLA Law Center for Reproductive Health, Law, and Policy and UCSF Advancing New Standards in Reproductive Health submit this comment on behalf of the below signed 263 reproductive health researchers trained and experienced in conducting or evaluating clinical and social science studies on reproductive health issues, including studies on the safety and effectiveness of mifepristone. Signatories share a commitment to evidence-based reproductive health care and FDA decision-making based on sound and transparent science. Signatories submit this comment in support of pending citizen petitions (FDA-2025-P-0377-0001; FDA-2025-P-1576-0001; FDA-2025-P-2162-0001) that, among other steps to ensure medication abortion remains accessible, ask the FDA to refrain from imposing additional or increased restrictions on mifepristone. Specifically, signatories submit this comment to contextualize the relevant research and to explain the flaws in recent reports on mifepristone that are not grounded in gold standard science or transparent and reliable data and analysis.

### I. Decades of Voluminous Gold Standard Science Support the Safety and Effectiveness of Mifepristone, Including Through Telehealth

Decades of conclusive scientific evidence amassed through more than one hundred rigorous studies based on hundreds of thousands of patient outcomes have overwhelmingly established the safety and effectiveness of mifepristone for medication abortion and management of early pregnancy loss. The FDA has reviewed that large and sound body of science at many junctures over the past 25 years and, at each moment,

<sup>&</sup>lt;sup>1</sup> The institutional affiliations of signatories are for identification purposes only and the views expressed in this letter do not necessarily reflect the views of signatories' affiliated institutions.

confirmed the safety and effectiveness of mifepristone generally<sup>2</sup> and, time and time again, the FDA has found complications and serious adverse events associated with mifepristone extremely rare.<sup>3</sup> Based on this body of evidence, the FDA has modified mifepristone labeling, and eased specific REMS restrictions when science proved they were unnecessary to protect patient safety and unduly restricted access.<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> See American College of Obstetricians and Gynecologists, Society of Family Planning, and Society for Maternal Fetal-Medicine. (2025, Jan. 31). Citizen Petition, Document FDA-2025-P-0377, at pp. 3-11. FDA. https://www.regulations.gov/document/FDA-2025-P-0377-0001 (hereinafter "ACOG Petition"); Commonwealth of Massachusetts, California, New Jersey, and New York. (2025, June 5). Citizen Petition, Document FDA-2025-P-1576, at pp. 2-3, 10-11, 12-15. FDA. https://www.regulations.gov/document/FDA-2025-P-1576-0001; GenBioPro. (2025, Jul. 3). Citizen Petition, Document FDA-2025-P-2162-0001, at pp. 4-14. FDA. https://www.regulations.gov/document/FDA-2025-P-2162-0001 (hereinafter "GenBioPro Petition"); see also Kulier, R., Kapp, N., Gülmezoglu, A. M., Hofmeyr, G. J., Cheng, L., & Campana, A. (2011). Medical methods for first trimester abortion. The Cochrane Database of Systematic Reviews, 2011(11), CD002855. https://doi.org/10.1002/14651858.CD002855.pub4 (systematic review); The Safety and Quality of Abortion Care in the United States (with Committee on Reproductive Health Services: Assessing the Safety and Quality of Abortion Care in the U.S., Board on Population Health and Public Health Practice, Board on Health Care Services, Health and Medicine Division, & National Academies of Sciences, Engineering, and Medicine). (2018). National Academies Press. https://doi.org/10.17226/24950 (systematic review); Chen, M. J., & Creinin, M. D. (2015). Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review. Obstetrics and Gynecology, 126(1), 12-21. https://doi.org/10.1097/AOG.00000000000897 (systematic review); Raymond, E. G., Shannon, C., Weaver, M. A., & Winikoff, B. (2013). First-trimester medical abortion with mifepristone 200 mg and misoprostol: A systematic review. Contraception, 87(1), 26-37. https://doi.org/10.1016/j.contraception.2012.06.011 (systematic review).

<sup>&</sup>lt;sup>3</sup> U.S. Food and Drug Administration/Center for Drug Evaluation and Research ("FDA/CDER"). (2016, Mar. 29) *Application No. 020687Orig1s020 Medical Review(s)*, at p. 12. <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/nda/2016/020687Orig1s020MedR.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/nda/2016/020687Orig1s020MedR.pdf</a> (hereinafter "FDA/CDER 2016") (concluding medication abortion's "efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare"); *id.* at p. 47 (serious adverse events "exceedingly rare"): U.S. Food and Drug Administration ("FDA"). (2024). *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024*, at p. 1. <a href="https://www.fda.gov/media/185245/download">https://www.fda.gov/media/185245/download</a> (discussing rarity of serious adverse events, that there is no established causal relationship between those events and medication abortion and that, rather, the "critical risk factor" is pregnancy itself); *see also* Kulier et al., 2011, *supra* note 2 (systematic review finding "serious adverse events are rare"); GenBioPro Petition, *supra* note 2, at pp. 12-14 (summarizing evidence on serious adverse events).

<sup>&</sup>lt;sup>4</sup> See, e.g. FDA/CDER 2016, supra note 3, at p. 47; Letter from Janet Woodcock, Acting Commissioner of Food & Drugs, to Maureen Phipps, Chief Executive Official, American College of Obstetricians & Gynecologists, and William Grobman, President, Society for Maternal Fetal Medicine, (Apr. 12, 2021).

https://www.aclu.org/sites/default/files/field\_document/fda\_acting\_commissioner\_letter\_to\_acog

The evidence supporting the safety and effectiveness of telehealth provision of medication abortion is part of this body of sound, gold standard science. The FDA has reviewed the safety of telehealth provision of mifepristone multiple times, each time reaffirming the safety and effectiveness. In April 2021, the FDA reviewed clinical outcome data for over 50,000 instances of medication abortion provision in rigorous studies that evaluated the safety and effectiveness of care delivered in-person, via telehealth, with pharmacist dispensing of mifepristone, and through hybrid options both before and during the COVID-19 public health emergency. In that review, the FDA concluded that studies of telehealth provision and real world postmarketing adverse event data did not show increases in safety concerns. Again in December 2021, the FDA further reviewed some of the studies it

<sup>&</sup>lt;u>april\_12\_2021.pdf</u>; FDA. (2021, Dec. 16). *REMS Modification Rationale Review, NDA 020687 & 91178*, at p. 39.

https://www.accessdata.fda.gov/drugsatfda\_docs/summary\_review/2023/020687Orig1s025SumR.pdf#page=41; FDA. (2025). Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (detailing mifepristone REMS reviews and modifications in 2021 and 2023). https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

<sup>&</sup>lt;sup>5</sup> ACOG Petition, supra note 2, at pp. 6-11; GenBioPro Petition, supra note 2 at pp. 10-12.

<sup>&</sup>lt;sup>6</sup> See supra note 4 (citing multiple FDA reviews from 2016 to 2023); see also Chong, E., Shochet, T., Raymond, E., Platais, I., Anger, H. A., Raidoo, S., Soon, R., Grant, M. S., Haskell, S., Tocce, K., Baldwin, M. K., Boraas, C. M., Bednarek, P. H., Banks, J., Coplon, L., Thompson, F., Priegue, E., & Winikoff, B. (2021). Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. *Contraception*, 104(1), 43–48. https://doi.org/10.1016/j.contraception.2021.03.019 (study of 1157 patients, finding 95% effectiveness and only 0.9% serious adverse events); Kerestes, C., Murayama, S., Tyson, J., Natavio, M., Seamon, E., Raidoo, S., Lacar, L., Bowen, E., Soon, R., Platais, I., Kaneshiro, B., & Stowers, P. (2021). Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models. *Contraception*, 104(1), 49–53.

https://doi.org/10.1016/j.contraception.2021.03.025 (study of 334 patients finding effectiveness and "low rates of adverse events" consistent between in-person, fully telemedicine, and hybrid provision methods, with fully remote having the highest effectiveness); Aiken, A., Lohr, P. A., Lord, J., Ghosh, N., & Starling, J. (2021). Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: A national cohort study. *BJOG: An International Journal of Obstetrics and Gynecology*, 128(9), 1464–1474.

https://doi.org/10.1111/1471-0528.16668 (study of 29,984 medication abortions performed after the introduction of telehealth services (with 18,435 provided using telehealth) compared to 22,150 in-person medication abortions, finding very high effectiveness (over 98%) and extremely low rates of serious adverse events across all care models (0.04% or less across all models)); Reynolds-Wright, J. J., Johnstone, A., McCabe, K., Evans, E., & Cameron, S. (2021). Telemedicine medical abortion at home under 12 weeks' gestation: A prospective observational cohort study during the COVID-19 pandemic. *BMJ Sexual & Reproductive Health*, *47*(4), 246–251.

https://doi.org/10.1136/bmjsrh-2020-200976 (study of 663 patients receiving telemedicine

examined in its April 2021 determination plus additional studies that looked at hundreds of additional patient experiences and postmarketing adverse event data, all of which found comparable effectiveness rates to models of care with in-clinic dispensing of mifepristone and very low rates of serious adverse events. Between December 2021 and January 2023 when the FDA ultimately announced its decision to formally remove the in-person dispensing requirement, additional rigorous studies involving thousands more patient abortion outcomes confirmed the safety and effectiveness of telehealth provision of mifepristone and very low rates of serious adverse events. Unsurprisingly, a June 2025

provision, finding effectiveness (98%) and very low rates of serious adverse events, with only two patients (0.3% being admitted to the hospital)).

https://doi.org/10.1016/j.contraception.2021.09.008 (among 224 patients whose eligibility was assessed in an in-person visit but received medication through a mail-order pharmacy rather than in-clinic, finding 96.9% effectiveness and only two serious adverse events (0.9%)); Upadhyay, U. D., Koenig, L. R., & Meckstroth, K. R. (2021). Safety and efficacy of telehealth medication abortions in the US during the COVID-19 pandemic. *JAMA Network Open*, 4(8), e2122320.

https://doi.org/10.1001/jamanetworkopen.2021.22320 (among 110 patients receiving medication abortion delivered by a mail-order pharmacy after online evaluation, finding 95% effectiveness and no serious adverse events were reported); Grossman, D., Baba, C. F., Kaller, S., Biggs, M. A., Raifman, S., Gurazada, T., Rafie, S., Averbach, S., Meckstroth, K. R., Micks, E. A., Berry, E., Raine-Bennett, T. R., & Creinin, M. D. (2021).). Medication Abortion With Pharmacist Dispensing of Mifepristone. *Obstetrics and Gynecology*, *137*(4), 613–622.

https://doi.org/10.1097/AOG.0000000000004312 (among 260 patients provided mifepristone through retail pharmacies after in-clinic evaluation, finding 93.5% effectiveness and no serious adverse events).

<sup>&</sup>lt;sup>7</sup> See supra note 4 (citing multiple FDA reviews from 2016 to 2023); see also Chong et al., 2021, supra note 6; Kerestes et al., 2021, supra note 6; Raymond, E., Chong, E., Winikoff, B., Platais, I., Mary, M., Lotarevich, T., Castillo, P. W., Kaneshiro, B., Tschann, M., Fontanilla, T., Baldwin, M., Schnyer, A., Coplon, L., Mathieu, N., Bednarek, P., Keady, M., & Priegue, E. (2019). TelAbortion: Evaluation of a direct to patient telemedicine abortion service in the United States. Contraception, 100(3), 173–177. https://doi.org/10.1016/j.contraception.2019.05.013 (among 190 patients, finding 93% effectiveness and only two serious adverse events (1%)); Grossman, D., Raifman, S., Morris, N., Arena, A., Bachrach, L., Beaman, J., Biggs, M. A., Hannum, C., Ho, S., Schwarz, E. B., & Gold, M. (2022). Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment. Contraception, 107, 36–41.

<sup>&</sup>lt;sup>8</sup> See Upadhyay, U. D., Raymond, E. G., Koenig, L. R., Coplon, L., Gold, M., Kaneshiro, B., Boraas, C. M., & Winikoff, B. (2022). Outcomes and Safety of History-Based Screening for Medication Abortion. *JAMA Internal Medicine*, *182*(5), 482–491. https://doi.org/10.1001/jamainternmed.2022.0217 (among 3,779 patients receiving medication abortion with history-based screening for eligibility in different settings, finding similar effectiveness and rare serious adverse events when medications dispensed via mail and in-person); Peña, M., Figueroa Flores, K., Muñoz Ponce, M., Facio Serafín, D., Camarillo Zavala, A. M., Ruiz Cruz, C., Ortiz Salgado, I. G., Ochoa Rosado, Y., Socarras, T., Pacheco López, A., & Bousiéguez, M. (2022). Telemedicine for medical abortion service provision in Mexico: A safety, feasibility, and acceptability study. *Contraception*, *114*, 67–73.

rigorous systematic Cochrane Review concluded that "the use of telemedicine for medical abortion in early pregnancy is generally safe, effective, and acceptable," that the review's findings were "consistent with the conclusions of previous work on the topic, including

https://doi.org/10.1016/j.contraception.2022.06.009 (among 330 patients finding 93% effectiveness with only one serious adverse event (0.3%)); Schummers, L., Darling, E. K., Dunn, S., McGrail, K., Gayowsky, A., Law, M. R., Laba, T.-L., Kaczorowski, J., & Norman, W. V. (2022). Abortion Safety and Use with Normally Prescribed Mifepristone in Canada. The New England Journal of Medicine, 386(1), 57–67. https://doi.org/10.1056/NEJMsa2109779 (study of nearly 280,000 abortions before and after Canada eliminated its REMS-like restrictions on mifepristone and made it available with normal prescriptions, finding no material changes in incidence of serious adverse events). Since then, even more studies have confirmed the safety of telehealth provision of mifepristone and that serious adverse events are rare. See, e.g., Koenig, L. R., Becker, A., Ko, J., & Upadhyay, U. D. (2023). The Role of Telehealth in Promoting Equitable Abortion Access in the United States: Spatial Analysis. JMIR Public Health and Surveillance, 9(1), e45671. https://doi.org/10.2196/45671 (finding virtual care particularly beneficial for younger patients, those living in rural areas, those experiencing food insecurity, and those living far from the nearest abortion facility); Koenig, L. R., Raymond, E. G., Gold, M., Boraas, C. M., Kaneshiro, B., Winikoff, B., Coplon, L., & Upadhyay, U. D. (2023). Mailing abortion pills does not delay care: A cohort study comparing mailed to in-person dispensing of abortion medications in the United States. Contraception, 121, 109962. https://doi.org/10.1016/j.contraception.2023.109962 (dispensing mifepristone via mail does not delay care); Pearlman Shapiro, M., Dethier, D., Kahili-Heede, M., & Kaneshiro, B. (2023). No-Test Medication Abortion: A Systematic Review. Obstetrics and Gynecology, 141(1), 23–34. https://doi.org/10.1097/AOG.00000000005016 (medication abortion performed without prior pelvic examination or ultrasonogram is a safe and effective); Upadhyay, U. D., Koenig, L. R., Meckstroth, K., Ko, J., Valladares, E. S., & Biggs, M. A. (2024). Effectiveness and safety of telehealth medication abortion in the USA. Nature Medicine, 30(4), 1191–1198. https://doi.org/10.1038/s41591-024-02834-w (study of over 6,000 patients receiving medication abortion via asynchronous telemedicine, finding 97.7% effectiveness and only 0.25% with serious adverse events, with no significant differences between synchronous and asynchronous models of care); Srinivasulu, S., Nyandak, D., Fiastro, A. E., MacNaughton, H., Tressan, A., & Godfrey, E. M. (2024). Telehealth Medication Abortion in Primary Care: A Comparison to Usual in-Clinic Care. Journal of the American Board of Family Medicine: JABFM, 37(2), 295–302. https://doi.org/10.3122/jabfm.2023.230178R1 (among 184 patients comparing in-clinic care to telehealth care with medication mailing, finding telehealth was "as effective, timelier, and potentially more accessible than in-clinic" care); Grossman, D., Raifman, S., Morris, N., Arena, A., Bachrach, L., Beaman, J., Biggs, M. A., Collins, A., Hannum, C., Ho, S., Seibold-Simpson, S. M., Sobota, M., Tocce, K., Schwarz, E. B., & Gold, M. (2024). Mail-Order Pharmacy Dispensing of Mifepristone for Medication Abortion After In-Person Screening. JAMA Internal Medicine, 184(8), 873-881. https://doi.org/10.1001/jamainternmed.2024.1476 (among 510 medication abortions where eligibility was assessed in an in-person visit but patients received medication through a mailorder pharmacy rather than in-clinic, finding 97.8% effectiveness and only three serious adverse events (0.6%)).

more recent non-comparative studies," and that "serious adverse events are rare." Telehealth for medication abortion is an accepted, standard method of abortion provision in the United States and around the world. <sup>10</sup>

The White House has recently directed that agencies must produce and act upon sound, gold standard science. A recent Executive Order defines gold standard science as science with data and methods that are, among other criteria, "reproducible," "transparent," "communicative of error and uncertainty," "skeptical of its findings and assumptions," and "subject to unbiased peer review," so that federal decisions can be "informed by the most credible, reliable, and impartial scientific evidence available. <sup>11</sup> An Office of Science and Technology Policy Memorandum further directs agencies to use gold standard science as defined by nine tenets that include reproducibility, transparency, and unbiased peer review. <sup>12</sup> Moreover, when federal agencies use scientific information to inform agency decision-making, federal employees are directed to apply a "weight of scientific evidence' approach." <sup>13</sup> FDA Commissioner Makary recently declared his pride in the FDA taking action grounded in "transparency [and] gold-standard science." <sup>14</sup>

<sup>&</sup>lt;sup>9</sup> Cleeve, A., Lavelanet, A., Gemzell-Danielsson, K., & Endler, M. (2025). The use of telemedicine services for medical abortion. *The Cochrane Database of Systematic Reviews*, *2025*(6), CD013764. https://doi.org/10.1002/14651858.CD013764.pub2.

<sup>&</sup>lt;sup>10</sup> American College of Obstetricians and Gynecologists. (2020). Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. *Obstet Gynecol* 2020;136:e31–47. https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation ("Medication abortion can be provided safely and effectively by telemedicine with a high level of patient satisfaction"); World Health Organization. (2022). *Abortion Care Guideline*, at p. 95. https://www.who.int/publications/i/item/9789240039483 (recommending the option of telemedicine to deliver medical abortion services); National Abortion Federation. (2024). *Clinical Policy Guidelines for Abortion Care*, at p. 1 ("[t]elemedicine can be safely used to provide abortion care, including medication abortion provision, informed consent, and follow-up").

<sup>&</sup>lt;sup>11</sup> White House. (2025, May 23). *Executive Order: Restoring Gold Standard Science.*, at Sections 1; 3(i)(ii) & (vii). <a href="https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/">https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/</a>.

<sup>&</sup>lt;sup>12</sup> White House, Office of Science and Technology Policy. (2025, June 23). *Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities.*, at pp. 2-5. <a href="https://www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf">https://www.whitehouse.gov/wp-content/uploads/2025/03/OSTP-Guidance-for-GSS-June-2025.pdf</a>.

<sup>&</sup>lt;sup>13</sup> White House, 2025, supra note 11, at Sections 2(e) &4(f).

<sup>&</sup>lt;sup>14</sup> See FDA. (2025, July 10). A Statement from FDA Commissioner Marty Makary, M.D., M.P.H: 100 Days of Embracing Gold-Standard Science, Transparency and Common Sense.

We strongly believe that the lynchpin of sound science is whether the data and methods are transparent, the work is reproducible by other scientists, and the work has been subject to the rigors of unbiased peer review. We are extremely concerned that the FDA may be considering significant action to reverse previous mifepristone REMS and label updates based on unverified and unreliable reports and studies that do not satisfy gold science standards. For the reasons discussed below, significant federal action based on these recent reports, or others that similarly lack scientific rigor and reliability, would be inappropriate and unsound federal agency decision-making.

- II. New Research That is Not Reproducible, is Methodologically Flawed, or Both, Does Not Outweigh the Overwhelming Body of Rigorous Evidence on Mifepristone's Safety and Effectiveness
  - A. The Self-Published Analysis of Unknown Data by the Ethics and Public Policy Center is Not Verifiable or Reproducible and Suffers Multiple Methodological Flaws

In support of its recommendation that the FDA reinstate a regulatory protocol from when mifepristone was first approved over 20 years ago, the Ethics and Public Policy Center (EPPC)<sup>15</sup> has self-published two position papers on medication abortion – one on occurrences of serious adverse events<sup>16</sup> and one on the occurrence of failure.<sup>17</sup> In these papers, EPPC presents its findings and conclusions as the product of the "largest-known study of the abortion pill" derived from its "analysis of data from an all-payer insurance

https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-100-days-embracing-gold-standard-science-transparency.

<sup>&</sup>lt;sup>15</sup> According to EPPC, its mission is "to apply the riches of the Jewish and Christian traditions to contemporary questions of law, culture, and politics" in America. See Ethics & Public Policy Center (n.d.). *Our Mission*. Retrieved August 25, 2025, from <a href="https://eppc.org/about/">https://eppc.org/about/</a>. EPPC's "The Life and Family Initiative," which produced the recent reports on mifepristone, is "committed both to ensuring the equal protection of unborn children in law and to providing concrete support to families by advancing a pro-life, pro-family agenda that takes our duties in justice to the unborn and to families seriously." See Ethics & Public Policy Center (n.d.). *Life and Family Initiative*. Retrieved August 25, 2025, from <a href="https://eppc.org/program/life-and-family-initiative/">https://eppc.org/program/life-and-family-initiative/</a>.

<sup>&</sup>lt;sup>16</sup> Hall, J. B., & Anderson, R. T. (2025). The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event. *Ethics & Public Policy Center*. <a href="https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/">https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/</a> (hereinafter "EPPC Report on Serious Adverse Event").

<sup>&</sup>lt;sup>17</sup> Hall, J. B., & Anderson, R. T. (2025). The Abortion Pill Harms Women: Insurance Data Reveals Repeated Abortion Attempts Due to High Failure Rate. *Ethics & Public Policy Center*. https://eppc.org/publication/the-abortion-pill-harms-womeninsurance-data-reveals-repeated-abortionattempts-due-to-high-failure-rate/ (hereinafter "EPPC Report on Failure Rate").

claims database." <sup>18</sup> However, as discussed below, these reports lack basic information and disclosures that reputable studies provide for transparency and reproducibility. Moreover, several claimed findings and conclusions appear to be based on errors and/or flawed assumptions drawn from the undisclosed data source and guided by an unnamed research team. Given these serious deficiencies, EPPCs position papers do not credibly call into question, let alone outweigh, the consistent findings from an overwhelming body of rigorous scientific studies and methodologically transparent data demonstrating that mifepristone, including when provided through telehealth, is safe and effective.

Below we summarize some of the most serious concerns and questions about the underlying data and analysis from which these position papers draw their conclusions and upon which they base sweeping recommendations to more heavily regulate mifepristone.

### The Data and Analyses Used by EPPC are Not Disclosed and Cannot be Verified or Reproduced

In its first self-published report of insurance data for medication abortion prescriptions, EPPC claims that its analysis shows 10.93% of patients experienced "a serious adverse event" after a mifepristone abortion. <sup>19</sup> This purported finding is the foundation of their claim that the "real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as reported on the drug label." <sup>20</sup> But the report does not provide reliable evidence to support this claim, nor does any published literature.

In describing their data and methodology, the authors assert the data came from an "all-payer insurance claims database," from which they analyzed data of 865,727 "prescribed mifepristone abortions from 2017-2023," and that their analysis was "conducted and validated" by a research team of "data scientists, analysts, and engineers, with assistance from our clinical team of board-certified obstetricians and gynecologists." However, the EPPC report authors do not identify the name of the database or the researchers and their affiliations, nor do they share the coding they used to generate the study cohort and analyze the data. Likewise, two follow-on explainers<sup>22</sup> and the second report on emergency

<sup>&</sup>lt;sup>18</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at p. 1.

<sup>&</sup>lt;sup>19</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at p. 1.

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>21</sup> *Id.* at pp. 1, 6.

<sup>&</sup>lt;sup>22</sup> Hall, J. B., & Anderson, R. T. (2025). Fact Sheet: Excluded Adverse Events in Real-World Study of Mifepristone. *Ethics & Public Policy Center*. <a href="https://eppc.org/publication/fact-sheet-excluded-adverse-events-in-real-world-study-of-mifepristone/">https://eppc.org/publication/fact-sheet-excluded-adverse-events-in-real-world-study-of-mifepristone/</a> (hereinafter "EPPC Fact Sheet"); Hall, J. B., & Anderson, R. T. (2025). Frequently Asked Questions About the Largest Study on Chemical Abortion.

visits following failed medication abortion<sup>23</sup> do not share any of this information and thus offer no greater transparency or ability to verify and reproduce the data and analysis.

One of the most problematic aspects of representing their analysis as a scientifically validated large-scale study is that they do not provide the source of the all-payer insurance claims database, precluding the ability of other researchers and scientists to independently verify their analysis and results. Despite a statement in the Frequently Asked Questions ("FAQ") release that: "We have made our study fully replicable for anyone who wants to analyze the insurance claims data" and the "dataset is available for purchase and our methodology is public,"<sup>24</sup> the information simply is not provided in any of these reports and explainers. Additionally, EPPC has stated publicly that it will not reveal the dataset used to identify patient outcomes.<sup>25</sup>

And while EPPC suggests this singular database is readily identifiable, to the best of our knowledge that is not the case. Signatories to this letter, which includes numerous researchers who regularly analyze insurance and medical claims data in their work, do not know of a single "commercially available all-payer health insurance claims database" that includes both private and public health insurance "data for all U.S. patients" as described by EPPC.

Assuming the EPPC research team did acquire data from a commercial compilation of Medicaid and several private insurance claim datasets or databases, it is crucial to know which ones were relied upon and included in the study. There are known methodological

Ethics & Public Policy Center. <a href="https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/">https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/</a> (hereinafter "EPPC FAQ").

https://www.theatlantic.com/health/archive/2025/05/mifepristone-abortion-rfk-fda/682939/ ("In an email, Hunter Estes, EPPC's communications director, told [the Atlantic] that the center's contract with their data vendor prevents EPPC from sharing the name of the database or even of the vendor."). And at least one signatory to this comment directly contacted the authors asking for information on the database but received no answer.

<sup>&</sup>lt;sup>23</sup> EPPC Report on Failure Rate, *supra* note 17.

<sup>&</sup>lt;sup>24</sup> EPPC FAQ, supra note 22, at pp. 3-4.

<sup>&</sup>lt;sup>25</sup> EPPC repeatedly told journalists it could not reveal the dataset or even its source. See, e.g., Glenn Kessler, Digging Into the Math of a Study Attacking the Safety of the Abortion Pill, WASH. POST (May 12, 2025), <a href="https://www.washingtonpost.com/politics/2025/05/12/abortion-pill-medication-abortion-study-mifepristone">https://www.washingtonpost.com/politics/2025/05/12/abortion-pill-medication-abortion-study-mifepristone</a> ("[EPPC's spokesperson] cited a confidentiality agreement with the vendor. . . . 'we do not view the confidentiality of our specific dataset as a barrier for others interested in obtaining similar data and replicating or extending this research.'"); Keren Landman, A Convenient Piece of Junk Science, ATLANTIC, (May 24, 2025),

<sup>&</sup>lt;sup>26</sup> EPPC Serious Adverse Event, *supra* note 16, at p. 5.

limitations of some databases for analyzing abortion claims data. For example, some commercially available sources of Medicaid claims data are over-representative of "Hyde exceptions" because many states only provide Medicaid coverage for abortions in situations of rape, incest, or life endangerment. Pedicaid claims data thus overrepresent abortions to prevent life-threatening health risks and are not representative of abortion cases overall. Likewise, patients covered by Medicaid often present with more complex needs and additional health conditions that can contribute to a higher risk of complications as compared to the general population. Thus, for patients with Medicaid coverage, abortions – like any healthcare – can result in a greater need for follow-up care. Accordingly, in a retrospective review of insurance or medical claims, it is standard to disclose the different payer and billing sources and to identify and address any inherent limitations in the data such as over- or under-representation of certain populations or regions of the country, or potential for claims misclassifications in particular datasets.

Additionally, it is highly problematic that EPPC does not disclose the full list of diagnosis and procedure codes used in its analyses, nor many other standard disclosures like the coding they used to analyze data, information about their study cohort (such as comorbidities), or how that cohort was created. Full disclosure of methods for creating the study cohort and lists of the diagnoses and procedure codes for measuring both exposures and outcomes is standard practice in analyses of insurance claims data. But EPPC simply states that it "identified relevant ICD-10 diagnoses codes and CPT/HCPCS procedures codes from multiple sources," (including from CDC, CMS, FDA and "codes suggested by our doctors")<sup>28</sup> without listing each diagnosis and procedure code used or saying more about its study cohort.

In standard studies of medication 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.<sup>29</sup> A lack of treatment indicates the encounter did not

<sup>&</sup>lt;sup>27</sup> Frederiksen, B., Dennis, E., Liu, G., Leslie, D., Salganicoff, A., & Roberts, S. (2025). The limitations of using Medicaid administrative data in abortion research. *Contraception*, *142*, 110704. https://doi.org/10.1016/j.contraception.2024.110704.

<sup>&</sup>lt;sup>28</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at p. 5.

<sup>&</sup>lt;sup>29</sup> Taylor, D., Upadhyay, U. D., Fjerstad, M., Battistelli, M. F., Weitz, T. A., & Paul, M. E. (2017). Standardizing the classification of abortion incidents: The Procedural Abortion Incident Reporting and Surveillance (PAIRS) Framework. *Contraception*, 96(1), 1–13. <a href="https://doi.org/10.1016/j.contraception.2017.05.004">https://doi.org/10.1016/j.contraception.2017.05.004</a>. The full list of diagnosis and procedure codes is also important to verify if the medications or procedures provided to a patient were in fact related to an abortion. Some medications and procedures commonly used in abortion are also commonly

involve a serious adverse event. For example, given the variety of definitions of hemorrhage, it would be inaccurate to consider a hemorrhage diagnosis a serious adverse event if it did not require any treatment. Thus, when classifying adverse events, it is critical to examine treatment/procedure codes, not only diagnosis codes. While EPPC's subsequent FAQ claims its analysis was based on "diagnosis and procedure codes" and only counted "treatment for a serious complication," it never identifies a single treatment code that was used as part of that methodology, let alone discloses all the treatment codes considered under each category it counts as a serious adverse event.

Finally, contrary to standards for transparency in scientific studies, the EPPC report has no discussion of the limitations of its analysis. For example, EPPC does not address how the serious adverse event rate they report is impacted by exclusion of certain populations from an insurance claims database, such as patients who pay out of pocket.<sup>31</sup> Some public and private insurance plans cover abortions only in limited circumstances, such as when continuing the pregnancy poses a serious health risk. Pregnant people who do not qualify will be among those who pay out of pocket for abortion. Thus, people more likely to have pregnancy complications or require more complex abortion treatment are overrepresented in insurance claims data.

### 2. EPPC's Findings and Conclusions, to the Extent Explained, are Inconsistent and Unsound

To the extent possible given the summary description of the data purchased, and the piecemeal explanations of the methodology used, we outline several additional concerns related to specific unexplained variables, assumptions, findings, and conclusions made by EPPC in its reports:

**Lack of definitions and methodology to identify hemorrhage**: The authors do not sufficiently define hemorrhage. This category accounts for 28,658 of the 94,605 "serious adverse events," which is one of the three largest categories of serious adverse events in their report.<sup>32</sup>

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used for other indications unrelated to pregnancy. For example, a uterine aspiration may be performed to evaluate and treat heavy menstrual bleeding when a patient is not pregnant.

<sup>&</sup>lt;sup>30</sup> EPPC FAQ, supra note 22, at p. 1.

<sup>&</sup>lt;sup>31</sup> The authors state that the data excludes "cash pay transactions (which are disproportionately common for abortion)." EPPC Report on Serious Adverse Event, *supra* note 16, at p. 5. But there is no discussion of how that, or other excluded populations, impacts their findings.

<sup>&</sup>lt;sup>32</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at Fig. 1.

A successful medication abortion always involves some bleeding. When a patient presents with complaints of bleeding, it could be excessive bleeding or it could be the expected amount. 33 Without a standardized definition, 34 EPPC is likely misclassifying many cases of normal bleeding that occur with a medication abortion. Indeed, the FDA has previously addressed the problem of mischaracterizing or misclassifying treatment for heavy bleeding after medication abortion as a serious adverse event: "Heavy bleeding or hemorrhage after medical abortion is a small subset of bleeding and can require a surgical procedure due to ongoing pregnancy or incomplete expulsion; these are considered failed treatment rather than adverse events and are not characterized using the [Council for International Organizations of Medical Sciences'] definitions. Even if heavy, bleeding after medical abortion may not be considered a serious adverse event unless clinically diagnosed as hemorrhage or requiring a transfusion." 35

EPPC's Fact Sheet claims that they "excluded non-serious bleeding" such as "typical expected bleeding," <sup>36</sup> but does not confirm how their methodology ensured this was done reliably. For example, relying only on diagnostic codes – as they seem to have done – could erroneously elevate the hemorrhage category numbers. For example, a patient could present after an episode of heavy bleeding after using medication abortion. A clinician may use the diagnosis code of "hemorrhage" to justify checking the patient's blood count. But if the patient is clinically stable, bleeding resolves, blood count is normal, and no treatment for hemorrhage is provided, this would not be a serious adverse event. Again, this is why it

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<sup>&</sup>lt;sup>33</sup> Arey, W., Lerma, K., & White, K. (2024). Self-diagnosing the end of pregnancy after medication abortion. *Culture, Health & Sexuality*, *26*(3), 405–420. https://doi.org/10.1080/13691058.2023.2212298.

<sup>&</sup>lt;sup>34</sup> See, e.g., Taylor et al., 2017, *supra* note 29; Kerns, J. L., Brown, K., Nippita, S., & Steinauer, J. (2024). Society of Family Planning Clinical Recommendation: Management of hemorrhage at the time of abortion. *Contraception*, *129*, 110292. https://doi.org/10.1016/j.contraception.2023.110292.

<sup>&</sup>lt;sup>35</sup> Letter from Patrizia A. Cavazzoni, M.D., Director Center for Drug Evaluation and Research to Donna J. Harrison, M.D., Executive Director American Association of Pro-Life Obstetricians and Gynecologists, (Dec. 16, 2021), at pp. 36-37. <a href="https://downloads.regulations.gov/FDA-2019-P-1534-0016/attachment\_1.pdf">https://downloads.regulations.gov/FDA-2019-P-1534-0016/attachment\_1.pdf</a> (hereinafter "FDA Letter 2021").

<sup>&</sup>lt;sup>36</sup> EPPC Fact Sheet, *supra* note 22, at p. 2. Nor does their statement that they only used codes "related to hemorrhage or serious bleeding (according to the FDA definition)" help clarify what definition they are using. *Id.* They do not describe or cite to any FDA definition of "hemorrhage or serious bleeding" and the FDA guidance on serious adverse events that they cite to elsewhere does not include such a definition. *See* FDA. (2023). *What is a Serious Adverse Event?* https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

is imperative to look at diagnosis and treatment codes together to ensure proper classification.

#### Likely inclusion of emergency room visits unrelated to serious adverse events:

Abortion-related emergency room (ER) visits were counted as serious adverse events. At a count of 40,960, this is the second largest category included in their report.<sup>37</sup>

While the FDA collects, reviews, and includes on the mifepristone labeling information about ER visits related to medication abortion, when evaluating real-world safety and effectiveness it considers whether those visits are accompanied by other serious adverse events.<sup>38</sup> FDA guidance 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)."

Research shows that many people go to an emergency room after a medication abortion to get immediate care for symptoms, or to ask questions, or to confirm they are no longer pregnant, without receiving any treatment.<sup>40</sup> This is more common when the patient lives far from the abortion provider.<sup>41</sup> ER visits are more common among people with Medicaid coverage, as many do not have a primary healthcare provider.<sup>42</sup> Additionally, the time period of the data analyzed, 2017-2023, overlaps with the height of the COVID pandemic,

<sup>&</sup>lt;sup>37</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at Fig. 1.

<sup>&</sup>lt;sup>38</sup> See, e.g., FDA Letter 2021, *supra* note 35, at pp. 26-34, 35 (explaining recent review of safety and effectiveness of dispensing mifepristone by mail and finding, "[a]lthough the literature suggests there may be more frequent ED/urgent care visits related to the use of mifepristone when dispensed by mail from the clinic, there are no apparent increases in other serious adverse events related to mifepristone use").

<sup>&</sup>lt;sup>39</sup> FDA 2023, *supra* note 36.

<sup>&</sup>lt;sup>40</sup> Upadhyay, U. D., Desai, S., Zlidar, V., Weitz, T. A., Grossman, D., Anderson, P., & Taylor, D. (2015). Incidence of emergency department visits and complications after abortion. *Obstetrics and Gynecology*, *125*(1), 175–183. https://doi.org/10.1097/AOG.00000000000000603; Upadhyay, U. D., Johns, N. E., Barron, R., Cartwright, A. F., Tapé, C., Mierjeski, A., & McGregor, A. J. (2018). Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample. *BMC Medicine*, *16*(1), 88. https://doi.org/10.1186/s12916-018-1072-0.

<sup>&</sup>lt;sup>41</sup> Upadhyay, U. D., Johns, N. E., Meckstroth, K. R., & Kerns, J. L. (2017). Distance Traveled for an Abortion and Source of Care After Abortion. *Obstetrics and Gynecology*, *130*(3), 616–624. https://doi.org/10.1097/AOG.000000000002188.

<sup>&</sup>lt;sup>42</sup> Mortensen, K., & Song, P. H. (2008). Minding the gap: A decomposition of emergency department use by Medicaid enrollees and the uninsured. *Medical Care*, *46*(10), 1099–1107. https://doi.org/10.1097/MLR.0b013e318185c92d.

during which the implementation of social distancing policies created barriers for in-office primary care visits,<sup>43</sup> which could have led to an increase in ER visits for routine follow-up care.

While EPPC later states in its Fact Sheet that it excluded ER visits that did not include serious adverse events, <sup>44</sup> for reasons addressed above, it is impossible to verify how this was done. For example, as already explained, their definition of hemorrhage remains unclear and unreliable. Thus, it is possible that billing for an ER visit with an initial diagnosis of hemorrhage, but which self-resolved and did not require treatment, was included. Likewise, infection is another category that requires more explanation to determine the extent to which the EPPC reporting of a 1.34% rate of infection might be inflated by inclusion of non-serious conditions like yeast vaginitis and urinary tract infections. <sup>45</sup> Further, their decision to rely on NIH's Common Terminology Criteria for Adverse Events raises further questions about the reliability of their coding analysis. Those codes originated in connection with cancer treatment and research and are not commonly used in connection with ER care.

"Other abortion-specific complications" are not clearly defined: There is a need for greater transparency around this "other" category. This is likely where EPPC included the unidentified "codes suggested by our doctors," contributing to greater confusion and obscurity around the methods used. This is the largest category of serious adverse events, accounting for 49,169 of the 94,605 serious adverse events counted by EPPC. 46

Because no information about the researchers or doctors who did this coding was offered, we are unable to evaluate their expertise in abortion care or what they relied upon to designate abortion-specific complications for this category. Relatedly, and deeply problematic, they included diagnosis codes for homicidal and suicidal ideation as two of

<sup>&</sup>lt;sup>43</sup> Alexander, G. C., Tajanlangit, M., Heyward, J., Mansour, O., Qato, D. M., & Stafford, R. S. (2020). Use and Content of Primary Care Office-Based vs Telemedicine Care Visits During the COVID-19 Pandemic in the US. *JAMA Network Open*, *3*(10), e2021476. https://doi.org/10.1001/jamanetworkopen.2020.21476.

<sup>&</sup>lt;sup>44</sup> See EPPC Fact Sheet, supra note 22, at p. 1.

<sup>&</sup>lt;sup>45</sup> See EPPC Report on Serious Adverse Event, *supra* note 16, at Fig. 1. While neither the initial EPPC report, the EPPC Fact Sheet, nor the EPPC FAQ say anything about what types of infections were excluded, an EPPC spokesperson answering questions about the possible inclusion of yeast or urinary tract infections identified only one such diagnosis – vaginitis – that was excluded. *See* Kessler, *supra* note 25.

<sup>&</sup>lt;sup>46</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at Fig. 1.

the diagnosis codes qualifying as abortion-specific complications.<sup>47</sup> By including these codes, the EPPC team either misrepresents, or misunderstands, the evidence on abortion and the types of serious adverse events that relate to abortion. Rigorous published research overwhelmingly establishes that serious mental health crises are not a complication of abortion.<sup>48</sup> Thus, there is no basis for suggesting such events are related to an abortion because it was diagnosed within 45 days of an abortion, and it is irresponsible and misleading to suggest it does.<sup>49</sup>

Mischaracterizing subsequent treatment to complete a medication abortion as a serious adverse event and/or "repeated abortion": EPPC alternately counts any procedural abortion within 45 days following a medication abortion as a serious adverse event or as evidence that an initial medication abortion failed. But characterizing follow-up treatment for an incomplete or failed medication abortion as a serious adverse event is inconsistent with published literature and FDA guidance.

In their first report, EPPC counted "Repeated (surgical) abortion" after a medication abortion as a serious adverse event. Specifically, they assert procedural abortions account for 24,563 of the 94,605 serious adverse events in their findings. <sup>50</sup> Subsequently, in their second report claiming to identify the "real-world failure rate," of mifepristone abortion, they present this number differently. In the second report, EPPC claims "5.26 percent of women undergo a second abortion attempt within 45 days of the first," (this includes a

<sup>&</sup>lt;sup>47</sup> EPPC FAQ *supra* note 22, at p.3.

<sup>&</sup>lt;sup>48</sup> See, e.g., Biggs, M. A., Upadhyay, U. D., McCulloch, C. E., & Foster, D. G. (2017). Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study. *JAMA Psychiatry*, *74*(2), 169–178.

https://doi.org/10.1001/jamapsychiatry.2016.3478; Steinberg, J. R., Laursen, T. M., Lidegaard, Ø., & Munk-Olsen, T. (2024). Medication and procedural abortions before 13 weeks gestation and risk of psychiatric disorders. *American Journal of Obstetrics and Gynecology*, *231*(4), 437.e1-437.e18. https://doi.org/10.1016/j.ajog.2024.05.025; Steinberg, J. R., Laursen, T. M., Adler, N. E., Gasse, C., Agerbo, E., & Munk-Olsen, T. (2019). The association between first abortion and first-time non-fatal suicide attempt: A longitudinal cohort study of Danish population registries. *The Lancet. Psychiatry*, 6(12), 1031–1038. https://doi.org/10.1016/S2215-0366(19)30400-6; Biggs, M. A., Rowland, B., McCulloch, C. E., & Foster, D. G. (2016). Does abortion increase women's risk for post-traumatic stress? Findings from a prospective longitudinal cohort study. *BMJ Open*, 6(2), e009698. https://doi.org/10.1136/bmjopen-2015-009698.

<sup>&</sup>lt;sup>49</sup> Notably, a spokesperson for the authors admitted "there were zero instances of patients with those two SAE mental health diagnosis codes" within their data analysis. Kessler, *supra* note 25. This, however, does not minimize the harm of suggesting it is a risk related to medication abortion.

<sup>&</sup>lt;sup>50</sup> EPPC Report on Serious Adverse Event, supra note 16, Fig. 1.

second abortion by either mifepristone and/or surgical procedure). <sup>51</sup> They then conclude 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." <sup>52</sup> While this new presentation of the data seems to acknowledge not all treatments to complete an abortion are serious adverse events, in their conclusion they once again assert, as they do in their first report, that the "real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as reported on the drug label."

It is known and expected that about 3-5% of patients will need additional medications or a procedure to complete the abortion.<sup>53</sup> And while EPPC's report of a five percent real-world failure rate is within the range of some prior clinical studies on effectiveness, it cannot be evaluated or verified for the reasons already explained regarding the unknown dataset and methodologies for data analysis.

Whether wrongly counting treatment for completing a medication abortion as a "serious adverse event," using that data to suggest mifepristone is not effective, or combining and presenting the data in a conflicting and inconsistent way, the EPPC's interpretation of insurance claims regarding treatment for incomplete abortions and ongoing pregnancy is misleading.

**Problems identifying miscarriage treatment and other uses of mifepristone**: One of the three ways EPPC says they identified medication abortions was a prescription for mifepristone with or without misoprostol within the next 3 days. <sup>54</sup> But mifepristone is used for other indications, including for miscarriage management and induction termination, along with misoprostol. <sup>55</sup> Additionally, mifepristone is frequently used for cervical priming

<sup>&</sup>lt;sup>51</sup> EPPC Report on Failure Rate, *supra* note 17, at p. 2 and Table 1.

<sup>&</sup>lt;sup>52</sup> *Id.* at p. 2.

<sup>&</sup>lt;sup>53</sup> Chen & Creinin, 2015, *supra* note 2; Raymond et al., 2013, *supra* note 2; Upadhyay et al., 2015, *supra* note 40.

<sup>&</sup>lt;sup>54</sup> EPPC Report on Serious Adverse Event, *supra* note 16, at p. 4.

<sup>&</sup>lt;sup>55</sup> See, e.g., Boos, E. W., Horta, M., Thompson, I., Dusetzina, S. B., & Leech, A. A. (2023). Trends in the Use of Mifepristone for Medical Management of Early Pregnancy Loss From 2016 to 2020. *JAMA*, 330(8), 766–763. https://doi.org/10.1001/jama.2023.13628; Tarleton, J. L., Benson, L. S., Moayedi, G., Trevino, J., & with the assistance of Leah Coplon, Anitra Beasley, and Elise Boos on behalf of the Society of Family Planning Clinical Affairs Committee. (2025). Society of Family Planning Clinical Recommendation: Medication management for early pregnancy loss. *Contraception*, 144, 110805. https://doi.org/10.1016/j.contraception.2024.110805; Nobles, J., Hwang, S., Bennett, E., & Jacques, L. (2024). Abortion Restrictions Threaten Miscarriage Management In The United States. *Health Affairs (Project Hope)*, 43(9), 1219–1224. https://doi.org/10.1377/hlthaff.2023.00982;

before procedural abortion in the second trimester.<sup>56</sup> Any of these uses could have been captured in this study. In general, miscarriage and treatment for miscarriage are associated with slightly higher complication rates than for abortion,<sup>57</sup> which would erroneously inflate the "serious adverse event" rate reported by the study.

EPPCs follow-up explanations only add to the confusion and further highlight potential problems in their analysis. In the subsequent FAQ, EPPC states it "was 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)." But mifepristone along with misoprostol is a recommended standard of care for miscarriage management, high which means patients experiencing a miscarriage will commonly be prescribed both medications. Yet, EPPC does not say it ensured there was an accompanying Z332 or Z640 code when a patient was prescribed both medications. Thus, it seems, EPPC has not excluded cases of standard

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Schreiber, C. A., Creinin, M. D., Atrio, J., Sonalkar, S., Ratcliffe, S. J., & Barnhart, K. T. (2018). Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss. *The New England Journal of Medicine*, *378*(23), 2161–2170. https://doi.org/10.1056/NEJMoa1715726; Chu, J. J., Devall, A. J., Beeson, L. E., Hardy, P., Cheed, V., Sun, Y., Roberts, T. E., Ogwulu, C. O., Williams, E., Jones, L. L., La Fontaine Papadopoulos, J. H., Bender-Atik, R., Brewin, J., Hinshaw, K., Choudhary, M., Ahmed, A., Naftalin, J., Nunes, N., Oliver, A., ... Coomarasamy, A. (2020). Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): A randomised, double-blind, placebo-controlled trial. *Lancet (London, England)*, *396*(10253), 770–778. https://doi.org/10.1016/S0140-6736(20)31788-8; Zwerling, B., Edelman, A., Jackson, A., Burke, A., & Prabhu, M. (2023). Society of Family Planning Clinical Recommendation: Medication abortion between 14 0/7 and 27 6/7 weeks of gestation: Jointly developed with the Society for Maternal-Fetal Medicine. *American Journal of Obstetrics and Gynecology*.

https://doi.org/10.1016/j.ajog.2023.09.097; American College of Obstetricians and Gynecologists. (2013). Second-Trimester Abortion. ACOG Practice Bulletin No. 135. *Obstet Gynecol* 2013;121(6):1394-1406.

<sup>&</sup>lt;sup>56</sup> Diedrich, J. T., Drey, E. A., & Newmann, S. J. (2020). Society of Family Planning clinical recommendations: Cervical preparation for dilation and evacuation at 20-24 weeks' gestation. *Contraception*, *101*(5), 286–292. https://doi.org/10.1016/j.contraception.2020.01.002.

<sup>&</sup>lt;sup>57</sup> Roberts, S. C. M., Beam, N., Liu, G., Upadhyay, U. D., Leslie, D. L., Ba, D., & Kerns, J. L. (2020). Miscarriage Treatment–Related Morbidities and Adverse Events in Hospitals, Ambulatory Surgery Centers, and Office-Based Settings. *Journal of Patient Safety*, *16*(4), e317–e323. https://doi.org/10.1097/PTS.000000000000553.

<sup>&</sup>lt;sup>58</sup> EPPC FAQ, supra note 22, at p. 2.

<sup>&</sup>lt;sup>59</sup> Chu et al., 2020, *supra* note 55; Schreiber et al., 2018, *supra* note 54; Neilson, J. P., Hickey, M., & Vazquez, J. (2006). Medical treatment for early fetal death (less than 24 weeks). *The Cochrane Database of Systematic Reviews*, 2006(3), CD002253. https://doi.org/10.1002/14651858.CD002253.pub3 (meta-analysis).

miscarriage treatment, or the corresponding problem of an erroneously inflated rate of serious adverse events.

"Other life-threatening adverse events" are not necessarily abortion related: This category accounts for 1,956 of the 94,605 "serious adverse events" in the report. 60 The analysis captures 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 between the abortion experience and the serious adverse event is ambiguous. As explained above, 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. Again, without a clear list of each specific diagnosis and the corresponding treatment for claims included in this category, or description of the study cohort's characteristics, including existing comorbidities, it is impossible to determine if these are appropriately categorized as abortion-related complications simply by virtue of occurring within 45 days of an abortion.

**EPPC** makes sweeping conclusions and recommendations not supported by their stated evidence: The policy implications stated do not follow from the authors' own analyses, even if one were to take the reported findings at face value.

For instance, they find no 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. Likewise, they do not report serious adverse events by year, so there is no support for their conclusion that removing restrictions on mifepristone has resulted in increased adverse event rates. They also have no findings to support the recommendation that only physicians should provide mifepristone. The analysis does not look at or address whether a medication abortion was provided by a physician or an advanced practice clinician. Similarly, their analysis does not examine adverse events by pregnancy duration, and thus, their recommendation that medication abortion be restricted to the first seven weeks is unsupported by the analysis conducted.

<sup>&</sup>lt;sup>60</sup> EPPC Report on Serious Adverse Event, supra note 16, at Fig. 1.

Finally, as EPPC itself acknowledges, ectopic pregnancy is not caused by or a complication of medication abortion, <sup>61</sup> and evidence establishes that abortion medications do not create harm if taken by someone with an ectopic pregnancy. <sup>62</sup> Yet EPPC makes the baseless claim that "use of mifepristone by a woman with an ectopic pregnancy poses extraordinary, heightened risk to her health." <sup>63</sup>

# B. One New Study that Evaluates Emergency Department Visits Related to Abortion is Deeply Flawed

We are also aware of one new study published this year which sought to identify the prevalence and severity of emergency department ("ED") visits by patients who have taken mifepristone for medication abortion: *Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortions: An Analytical Observational Prospective Cohort Study.* <sup>64</sup> In this paper, lead author James Studnicki and co-authors, all affiliated with the Charlotte Lozier Institute (the research and education institute of Susan B. Anthony Pro-Life America), conclude that ED visits following induced abortion have high severity, and that rates of such outcomes are being deflated and concealed due to high rates of miscoding and misattributing these visits as related to a spontaneous abortion (miscarriage). But the authors' interpretation of the data and findings rest on serious methodological flaws and

<sup>&</sup>lt;sup>61</sup> See EPPC FAO, supra note 22, at p. 2.

<sup>&</sup>lt;sup>62</sup> Shannon, C., Brothers, L. P., Philip, N. M., & Winikoff, B. (2004). Ectopic pregnancy and medical abortion. *Obstetrics and Gynecology*, *104*(1), 161–167. https://doi.org/10.1097/01.AOG.0000130839.61098.12.

<sup>63</sup> EPPC FAQ, supra note 22, at p. 2.

<sup>&</sup>lt;sup>64</sup> Studnicki, J., Fisher, J. W., Cox, T. L., Cirucci, C. A., Reardon, D. C., Skop, I., Louttit, C., Harrison, D. J., & Craver, C. (2025). Determining the Period Prevalence and Acuity of Emergency Department Visits Following Induced Abortion Mistakenly Identified as Spontaneous Abortion: An Analytic Observational Prospective Cohort Study. Family Medicine and Primary Care: Open Access, 9(282). https://doi.org/10.29011/2688-7460.100282. The authors of this study are largely the same authors of prior studies attempting to show a higher rate of emergency department visits related to medication abortion that were retracted because of fundamental problems with the study design and methodology. Retraction Notice. (2024). Health Services Research and Managerial Epidemiology, 11, 23333928231216699. https://doi.org/10.1177/23333928231216699. Moreover, in this newest study, they again use the same methods as used in one of the studies that was retracted. Studnicki, J., Longbons, T., Harrison, D. J., Skop, I., Cirucci, C., Reardon, D. C., Craver, C., Fisher, J. W., & Tsulukidze, M. (2022). A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization. Health Services Research and Managerial Epidemiology, 9, 23333928221103107. https://doi.org/10.1177/23333928221103107 (Retraction published 2024, Health Services Research and Managerial Epidemiology, 11).

unreliable data that undermine their conclusions. As a result, the study does not credibly support their conclusion that use of mifepristone for induced abortion represents a "serious risk factor," and does not undermine the overwhelming body of scientific evidence demonstrating the safety of medication abortion with mifepristone.

# 1. The Methodology Used by the Authors to Code for Acuity of Emergency Department Visits is Gravely Inaccurate

The authors of this study are misclassifying acuity of patient outcomes and interventions to draw sweeping conclusions. Core to the conclusions of the paper are its determinations of acuity, or severity level, of patient emergency department visits following an induced abortion (as determined by the study authors, although this categorization is also flawed, see below). However, the study methodology misclassifies acuity based on use of Current Procedural Terminology (CPT) codes that do not support their determinations.

The study methodology classifies CPT codes 99284 and 99285 as "severe" or "critical" and thus labels any visit with one of these acuity codes as having high acuity. 65 However, these codes do not always support such categorization. CPT codes are used to describe emergency department visits for the evaluation and treatment of a patient, and the specific code is primarily determined on initial presentation of the patient and reflects the amount of cognitive work required for the ED clinician to evaluate the patient and make a diagnosis, not the severity of the overall visit once treatment is provided. These CPT codes have nothing to do with the seriousness of the final diagnosis and treatment. For example, an ED visit where detailed history, examination, urine and blood testing, and moderately complex medical decision making is required can push the CPT code to 99284 or 99285, but it does not necessarily indicate a serious adverse event or severe medical condition experienced by the patient. Additionally, the study does not disaggregate among all visits it categorizes as "high acuity," to show how many were put in that category because of CPT code 99284 versus CPT code 99285.

More generally, it is imprecise to use any single CPT code to determine the severity or acuity of an emergency department visit. It is critical to look at all treatment codes that patients receive in an emergency department to determine severity and acuity as accurately as possible. Comprehensively looking at multiple codes is also important to

<sup>&</sup>lt;sup>65</sup> Studnicki et al., 2025, supra note 64, at p. 3.

mitigate the possibility that some higher acuity codes are inaccurate. Research shows that there is a growing trend of providers and hospitals using higher acuity codes. <sup>66</sup>

Despite the ability to conduct a comprehensive review of all treatment codes, the authors of this study did not. The authors pulled data from the Centers for Medicare and Medicaid Services (CMS),<sup>67</sup> which is a data source that includes access to all billing information for included visits. Thus, the researchers could and should have used this data source to determine the nature of each adverse event, rather than relying on CPT codes that do not accurately or sufficiently describe acuity level. The failure to do so, in combination with the authors' misclassification of at least some CPT codes, render the authors' findings that most emergency department visits after abortion were high acuity unsupported by the study itself and inconsistent with methodology and conclusions in previous research.

# 2. The Determination of What Counts as a "Miscode," Relies on Flawed Methodology and Bad Faith Assumptions About Patients and Providers

The authors' methodology for classifying a "miscode" is flawed and undermines the credibility and reliability of the authors' staggering claim that 18% of all ED visits following medication abortion were miscoded. 68 The study authors identify a cohort of patients who had a medication abortion using a single Healthcare Common Procedure Coding System (HCPCS) code (HCPCS code S0190, which is the code for mifepristone). 69 However, mifepristone is not exclusively used to induce abortion, it is also increasingly used to treat miscarriages. 70 As a result, many of the uses of that code may in fact be actual miscarriages. But the authors only make the miscoding assumption in one direction – a direction that necessarily inflates the prevalence of ED visits related to induced abortion.

One major error is the authors' failure to account for the complexity of billing data and coding. Billing data for a single emergency department visit contains multiple claims, sometimes even hundreds of rows of claims for different tests, medications, IV fluids, etc., each of which will have a different claim and diagnosis or treatment code. In practice, this means that there may be some discrepancy between each claim for an emergency

<sup>&</sup>lt;sup>66</sup> See e.g., Ruxin, T., Feldmeier, M., Addo, N., & Hsia, R. Y. (2023). Trends by Acuity for Emergency Department Visits and Hospital Admissions in California, 2012 to 2022. *JAMA Network Open*, 6(12), e2348053. https://doi.org/10.1001/jamanetworkopen.2023.48053.

<sup>&</sup>lt;sup>67</sup> Studnicki et al., 2025, supra note 64, at p. 2.

<sup>&</sup>lt;sup>68</sup> *Id.* at p. 3.

<sup>&</sup>lt;sup>69</sup> *Id.* at p. 2.

<sup>&</sup>lt;sup>70</sup> See supra note 59 (citing multiple studies documenting increased use of mifepristone for miscarriage care).

department visit due to the number of claims related to each visit. For example, if a patient's urine goes to the emergency department lab for pregnancy testing, it is possible that the wrong diagnosis code could be used in that single claim, but that does not mean that the entire visit was miscoded. Nonetheless, in this study, the presence of a single code for miscarriage alongside a single code for induced abortion led authors to classify the entire visit as a "miscode." This methodological error undergirds a misunderstanding of the fundamental coding processes as used in the emergency department context.

The presence of codes for both induced abortion and miscarriage does not mean that the entire visit was miscoded, particularly in the emergency department context. Emergency department visits with severe acuity – which can include miscarriages – will have many, many claims, and thus an even greater likelihood of at least one claim being attributed to an induced abortion rather than a miscarriage, particularly given that the two conditions present very similarly. For the same reason, visits the authors consider to have been "miscoded" are also likely to be ones that present with higher acuity codes and have more claims associated with them.

Additionally unfounded, and especially concerning, is the authors' underlying assumption and premise that miscodes result from intentional deception for "concealment of the abortion." Foundational to the study's results and recommendations is the authors' postulation that these miscodes result from patients lying to the emergency department doctors and/or health care workers lying in their coding in order to attribute visits to miscarriages rather than induced abortions. The authors inappropriately assume bad faith of patients and providers and fail to adequately consider the likelihood of human error, given how easy it is to code incorrectly in one of the many claims associated with an ED visit (as described above). By way of example, even if ten codes are used and nine signal miscarriage, if one signals induced abortion, it appears as if the study authors consider the entire visit as purposeful lying or attempts to hide an abortion.

<sup>&</sup>lt;sup>71</sup> Studnicki et al., 2025, *supra* note 64, at p. 6. Relatedly, the authors assert that miscoding has created a problem for reliably researching prevalence rates of abortion complications, stating: "miscoded abortion complications remain invisible to research scientists resulting in large underestimation of actual abortion complications." *Id.* But, as described above, many researchers have used more rigorous methods to assess abortion complications. These researchers have examined actual treatment codes and reviewed comprehensive claims data to see whether an ED visit led to a hospital admission in order to accurately determine complications. *See, e.g.*, FDA/CDER 2016, *supra* note 3; FDA 2024, *supra* note 3; Kulier et al., 2011, *supra* note 2; GenBioPro Petition, *supra* note 2, at pp. 12-14.

<sup>&</sup>lt;sup>72</sup> Studnicki et al., 2025, supra note 64, at p. 6.

#### 3. The Study Lacks Reliable Data to Reproduce or Verify its Results

In addition to the above ways in which the study methodology is obscure and flawed, the study's reliance only on Medicaid administrative data for abortion is unreliable. The study draws data from the CMS Transformed Medicaid Statistical Information System Analytical Files (TAF) for 2016-2021 and from the discontinued Medicaid Analytic eXtract (MAX) files for 2004-2015.73 However, the use of Medicaid administrative data for abortion rates has been shown to be inaccurate. Research has shown that this dataset is unreliable for abortion-related studies.<sup>74</sup> In a recent study, researchers compared the number of abortions counted in the MAX and TAF datasets to the number of expected abortions covered by Medicaid nationwide and by state. The study found that MAX identified only 11% of expected Medicaid-covered abortions in 2009 and 13% in 2010, while TAF identified 25% of expected Medicaid-covered abortions in 2020, which constituted only 7% of total abortions in the United States for that year. 75 Thus the study authors concluded that these databases significantly undercount abortion covered by Medicaid and cautioned against use of MAX or TAF data for abortion-related research. Given that the Studnicki study relies solely on these databases, both the numerator and denominator used for their article are likely wrong.

#### CONCLUSION

Standard practices in epidemiology emphasize the importance of transparency in methodological approaches to ensure the reliability, reproducibility, and credibility of research findings.<sup>76</sup>

The issues discussed above reflect just some of the most serious transparency, reproducibility, and methodology problems that make any reliance on the recent EPPC papers, Studnicki study, or other research with similar flaws wholly inconsistent with FDA standards and obligation to rely on sound, gold standard science in its decision-making.

These shortcomings are even more problematic where, as here, claimed findings contradict consistent and overwhelming findings of decades of rigorous, transparent, and

<sup>&</sup>lt;sup>73</sup> Studnicki et al., 2025, supra note 64, at p. 2.

<sup>&</sup>lt;sup>74</sup> Frederiksen et al., 2025, supra note 27.

<sup>&</sup>lt;sup>75</sup> *Id.* at p. 3.

<sup>&</sup>lt;sup>76</sup> See, e.g., S. V., & Pottegård, A. (2024). Building transparency and reproducibility into the practice of pharmacoepidemiology and outcomes research. *American Journal of Epidemiology*, 193(11), 1625–1631. https://doi.org/10.1093/aje/kwae087.

reproducible research on the safety and effectiveness of medication abortion with mifepristone.

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