UCLA School of Law Center on Reproductive Health, Law, and Policy

ANSIRH ADVANCING NEW STANDARDS IN REPRODUCTIVE HEALTH

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5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

Supplemental Comment in Support of Citizen Petitions FDA-2025-P-0377-0001; FDA-2025-P-1576-0001; FDA-2025-P-2162-0001

The undersigned 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 ask FDA to refrain from imposing additional or increased restrictions on mifepristone. We are 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.[1] Additionally, we share a commitment to evidence-based reproductive health care and FDA decision-making based on sound and transparent science.

More specifically, we submit this comment to supplement a prior comment (FDA-2025-P-1576-0151) (Aug. 27, 2025), submitted on behalf of over 260 reproductive health researchers, which explains the flaws in reports on mifepristone, including by the Ethics and Public Policy Center (EPPC), that are not grounded in gold standard science. Among other issues, EPPC's self-published 2025 report and fact sheets offered sweeping conclusions and policy recommendations not supported by its own stated evidence. Relevant to the topic of this comment, EPPC argued for the reinstatement of the in-person dispensing requirement without providing any evidence that the rate of serious adverse events differs based on whether mifepristone is dispensed in person or remotely.

[1] 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.

In this comment, we address a new fact sheet issued by EPPC in March 2026. The new fact sheet claims that after the FDA eliminated the in-person dispensing requirement, there was a statistically significant increase in serious adverse events, which can be attributed to remote dispensing.[2] EPPC presumably relies on its undisclosed database and analysis from its prior report, which had substantial flaws related to transparency, reproducibility, and methodology, all set forth in detail in our prior comment. The new fact sheet does not address the previously identified flaws; it uses the same unknown data to make additional claims related to remote dispensing. But EPPC admits the dataset does not include the necessary information to support its headline causal claim—it has no patient-level record of who received mifepristone remotely versus in person. This comment contextualizes and explains why the March 2026 fact sheet does not reliably support EPPC's latest claims about the in-person dispensing requirement but merely replicates and compounds its previously flawed analysis.

The Fact Sheet Offers No New Data or Evidence Contrary to the Robust Body of Gold Standard Science Supporting the Safety and Effectiveness of Mifepristone, Including When Provided Through Telehealth

Substantial research illustrates that mifepristone is safe and effective, including via telehealth. As detailed in our August 27, 2025, regulatory comment, FDA's 2021 decision to allow for dispensing of mifepristone by mail and in pharmacies, which was formalized in a 2023 change to the REMS, was based on overwhelming scientific evidence that shows that in-person dispensing is not necessary to ensure that the use of mifepristone is safe and effective.[3]

[2] Hall, J.B. & Anderson, R.T. (2026). Fact Sheet: Data Reveals the FDA's Removal of In-Person Dispensing Requirement Increased the Dangers of the Abortion Pill. *Ethics & Public Policy Center*. https://media.eppc.org/2026/03/FACT-SHEET-Data-on-FDA-Removal-of-In-person-dispensing-requirement-2.pdf (hereinafter "Fact Sheet").

[3] UCLA Center on Reproductive Health, Law, and Policy and Advancing New Standards in Reproductive Health. (2025, August 27). Reproductive Health Researchers' Comment [Comment on Citizen Petition from Attorney General of Massachusetts, et al.], Docket No. FDA-2025-P-1576-0151, Food and Drug Administration. https://www.regulations.gov/comment/FDA-2025-P-1576-0151, at 1-6 (hereinafter "Reproductive Health Researchers' Comment") (summarizing the substantial body of scientific evidence considered by and supporting FDA's decision-making in April 2021 and December 2021, as well as additional rigorous studies published between December 2021 and the FDA's finalization of its decision to remove the in-person dispensing requirement in January 2023 demonstrating the safety and effectiveness of remote provision of mifepristone and very low rates of serious adverse events).

Additional studies published since FDA's 2023 REMS decision further demonstrate that mifepristone prescription via telehealth is safe and effective.[4] As the June 2025 rigorous and systemic Cochrane Review concluded, "the use of telemedicine for medical abortion in early pregnancy is generally safe, effective, and acceptable" and "serious adverse events are rare."[5] Also relevant is research showing that telehealth is not only safe and effective, but also provides critical care for individuals who face significant barriers to in-person care. This includes patients living in rural areas who may face unmanageable or unaffordable travel over long distances to a facility,[6] and those who are unable to get to clinics because of financial barriers, immigration status, job commitments, or childcare needs.[7]

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[4] See *id.* at 4-5 n. 5 (citing studies); see also Koenig, L. R., Raymond, E. G., Upadhyay, U. D., Frye, L. J., Kaneshiro, B., Boraas, C. M., Oldenburg, C. E., & Glidden, D. V. (2025). Effectiveness and safety of medication abortion with vs without screening ultrasonography or pelvic examination. *American Journal of Obstetrics and Gynecology*, *233*(5), 453.e1–453.e16. https://doi.org/10.1016/j.ajog.2025.06.013; Hunter, C., Burck, M., Chambers, C., Shawon, F., Lavergne, M. R., Whitten, A., & Wiedmeyer, M. L. (2025). Test or No-Test: Comparison of Medication Abortion Outcomes and Adverse Events When Forgoing Ultrasound, Laboratory Testing, and Physical Examination. *Journal of Obstetrics and Gynaecology Canada : JOGC = Journal d'obstetrique et Gynecologie du Canada : JOGC*, *47*(1), 102730. https://doi.org/10.1016/j.jogc.2024.102730; Raymond, E. G., Frye, L. J., Tocce, K., Gingras, S., Almquist, A., Firstenberg, A., Ortega, C., Blumenthal, P. D., Winikoff, B., & Boraas, C. (2024). Evaluation of a "smart" screening tool for asynchronous assessment of medication abortion eligibility: A pilot study. *Contraception*, *131*, 110340. https://doi.org/10.1016/j.contraception.2023.110340; see also Smith, M. K., Biderman, M., Frotten, E., Warden, S., Dunn, S., Dmytryshyn, R., & Thorne, J. G. (2024). The Safety and Efficacy of a "No Touch" Abortion Program Implemented in the Greater Toronto Area During the COVID-19 Pandemic. *Journal of Obstetrics and Gynaecology Canada : JOGC = Journal d'obstetrique et Gynecologie du Canada : JOGC*, *46*(6), 102429. https://doi.org/10.1016/j.jogc.2024.102429 (assessing results for a similar program in the Toronto area); Ralph, L. J., Baba, C. F., Biggs, M. A., McNicholas, C., Hagstrom, Miller A., Grossman, D. (2024). Comparison of No-Test Telehealth and In-Person Medication Abortion. *JAMA, 332*(11), 898–905. https://doi.org/10.1001/jama.2024.10680 (among 585 medication abortions received, where 228 patients received no-test telehealth and medication by mail, 119 received no-test medication and pickup in-person, and 238 received in-person care with ultrasonography, the study found that effectiveness of telehealth medication abortion was not inferior to in-person care (95.1% for no-test + mail group; 96.5% for no test + pickup group; and 94.1% for the in-person group) and the study found comparably low serious adverse event rates across the three groups (1.5%, 0%, and 1.4%, respectively)).

[5] 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.

[6] See 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*, e45671. https://doi.org/10.2196/45671.

[7] See Koenig, L. R., Ko, J., Valladares, E. S., Coeytaux, F. M., Wells, E., Lyles, C. R., & Upadhyay, U. D. (2024). Patient Acceptability of Telehealth Medication Abortion Care in the United States, 2021–2022: A Cohort Study. *American Journal of Public Health*, *114*(2), 241–250. https://doi.org/10.2105/AJPH.2023.307437; see also Becker, A., Doria, C., Koenig, L. R., Ko, J., & Upadhyay, U. (2026). "It Was So Easy in a Situation That's So Hard": Structural Stigma and Telehealth Abortion. *Journal of Health and Social Behavior*, *67*(1), 120–134. https://doi.org/10.1177/00221465241303873.

As discussed below, the fact sheet offers no new sources of data or research relevant, let alone contrary, to this body of evidence.

The Fact Sheet Relies on Past Data Analysis That Is Not Verifiable or Reproducible, Suffers Methodological Flaws, and Posits Only a Hypothetical

While EPPC is not explicit about the data it uses in the March 2026 fact sheet, it presumably draws on the data and methodology used in its 2025 report. Here, we briefly summarize the flaws that were identified and explained in our prior comment,[8] which render EPPC's new fact sheet similarly unreliable.

EPPC's Data and Analysis Are Not Transparent or Reproducible

Scientific gold standards require data and research methods to be transparent, the work to be reproducible by other scientists, and the work to be subject to rigorous, unbiased peer review.[9] EPPC's analysis adheres to none of these standards.

EPPC does not make the data underlying its analyses public and does not share the name of the database on which it relied.[10] Although EPPC has previously argued it need not disclose its database because substantially similar databases are widely available, gold standard science calls for reproducibility, which requires use of the same, not only similar, data and codes.[11] Additionally, EPPC's analysis has obstructed replicability by concealing the coding used to analyze the data.[12]

EPPC's failure to disclose its database makes it impossible to know if the experiences of patients in the dataset are adequately counted or representative of the general population of abortion patients. 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 limitations of some databases for analyzing abortion

[8] Reproductive Health Researchers' Comment, *supra* note 3, at 7-19.
[9] White House. (2025, May 23). *Executive Order: Restoring Gold Standard Science*., https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/.
[10] See Reproductive Health Researchers' Comment, *supra* note 3, at 8-11.
[11] *Id.* at 6.
[12] *Id.* at 8.

claims data, such as over- or under-representation of certain populations of regions of the country, or potential for claims misclassifications in particular datasets.[13]

The Fact Sheet Relies on EPPC's Prior Flawed Analysis and Reporting of an Inflated Rate of Serious Adverse Events

EPPC claims that its data shows "the rate of serious adverse events" from abortions with mifepristone was "significantly higher after the FDA's in-person dispensing requirement was removed."[14] But this claim of a significantly higher increase is premised on EPPC's unreliable and inflated "overall" serious adverse event rate of 10.93%. Because EPPC does not describe the data source or methodology for determining this overall rate, we assume it is from the same "commercially available all-payer health insurance claims database" that it relied on for its previous report.[15]

As explained in our prior comment letter, EPPC's analysis for determining the rate of serious adverse events suffers multiple flaws. In summary: first, EPPC did not adequately define "other serious abortion-specific complications," a vague catch-all category which is its largest category of serious adverse events. Second, EPPC did not sufficiently define hemorrhages, which accounted for a significant number of its claimed serious adverse events, making it likely EPPC misclassified cases of normal, expected bleeding as serious adverse events. Third, EPPC included emergency room visits in its characterization of serious adverse events, even though research consistently shows that emergency room

[13] 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. Medicaid claims data thus overrepresent abortions to prevent life-threatening health risk 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 health care – 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. See Reproductive Health Researchers' Comment, *supra* note 3, at 9-10. See also, e.g., Strasser, J., Gorak, T., Griffin, R., Luckenbill, S., Schenk, E., & Luo, Q. E. (2026). Mifepristone provision following policy shifts in 2022 & 2023. *Contraception*, *163*, 111545. https://doi.org/10.1016/j.contraception.2026.111545 (using the IQVIA dataset that includes mifepristone prescription rates in 2022 and 2023, and disclosing limitations, including that most patients self-pay for abortions and the IQVIA dataset captured some, but not all, self-pay abortions).

[14] Fact Sheet, s*upra* note 2.

[15] 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*. https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/ (hereinafter "EPPC Report on Serious Adverse Event").

visits following medication abortion do not often result in treatment[16] and FDA has determined that an emergency room visit in and of itself, is not a serious adverse event.[17] Fourth, EPPC counted circumstances where patients sought subsequent treatment to complete a medication abortion as a serious adverse event, even though it is known and expected that about 3-5% of patients will need additional medications or a procedure to complete an abortion.[18] Fifth, EPPC's methodology likely erroneously includes miscarriage and procedural abortion treatments within its dataset, thus artificially inflating the purported rate of serious adverse events. And sixth, EPPC provides no indication of whether its category of "other life-threatening adverse events" includes events that are related to abortion.[19]

The March 2026 fact sheet does not respond to, adjust for, or correct for any of these problems. It simply reasserts the prior overestimate of an overall serious adverse event rate associated with mifepristone of 10.93%. For all the reasons above, this is an inaccurate and unreliable starting point for further analysis related to any change in serious adverse events after a certain point in time.

EPPC Posits Only a Hypothesis, Not Data, to Support Its Claim That Removal of the In-Person Dispensing Requirement for Mifepristone Caused an Increase in Serious Adverse Events

In an attempt to show that the removal of the in-person dispensing requirement for mifepristone caused an increase in serious adverse events, EPPC sets out to compare the

[16] 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 Med, 16*(1), 88(. https://doi.org/10.1186/s12916-018-1072-0.
[17] See FDA. (2023). *What is a Serious Adverse Event?*, https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.
[18] 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.0000000000000897; 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; 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.0000000000000603.
[19] For a fuller explanation of each of these deficiencies, see Reproductive Health Researchers' Comment *supra* note 3, at 11-19.

rate of serious adverse events between two multi-year time periods on either side of July 2020, the earliest point at which remote dispensing of medication abortion began. [20]

But, after claiming that removal of the in-person dispensing requirement led to an increase in serious adverse events and prescriptions of mifepristone to women with ectopic pregnancies, EPPC also claims its undisclosed database does not include key patient-level information that would enable it to identify for whom mifepristone was dispensed in person or remotely. EPPC states: "[t]he estimated strength of the relationship between remote dispensing and mifepristone and the higher rate of serious adverse events depends on the percentage of mifepristone prescriptions in Period 2 that were dispensed remotely. *We do not have firm data on that percentage*."[21] Thus, EPPC's fact sheet is not providing any data or evidence showing the introduction of telehealth in Period 2 caused any overall increase in the rate of serious adverse events among insured patients prescribed mifepristone. Telehealth is likely not the cause of any such increase. In fact, because most telehealth providers did not accept insurance during this period, the vast majority of telehealth abortions would not even be captured in EPPC's dataset.[22]

Instead, EPPC bakes multiple assumptions into "two illustrative scenarios" to suggest there is a causal relationship. Below we explain why the hypothetical scenarios offer no relevant insights, let alone evidence, related to the removal of the in-person dispensing requirement.

To begin with, as EPPC acknowledges, remote dispensing was not legal or in fact available during the entirety of Period 2. The in-person dispensing requirement was back in effect for several months of Period 2, when a court order enjoined the FDA REMS permitting remote dispensing from January 12, 2021, to April 12, 2021. In reality, even after remote dispensing

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[20] EPPC does this by taking the inflated serious adverse event rate of 10.93% from its prior report and stratifying it into two time periods: Period 1, covering July 1, 2017 through July 13, 2020, and Period 2, covering July 13, 2020 through December 31, 2023.

[21] *Id.* at 1-2 (emphasis added). This vague reference to a lack of "firm data" is another example of EPPC's lack of transparency. Use of telehealth or telemedicine is recorded in some insurance claims databases. It is problematic that EPPC does not disclose more specifically the extent to which that information is, or is not, captured in the dataset it used.

[22] See Koenig, L. R., Ko, J., & Upadhyay, U. D. (2024). Virtual Clinic Telehealth Abortion Services in the United States One Year After Dobbs: Landscape Review. *Journal of Medical Internet Research*, *26*, e50749. https://doi.org/10.2196/50749 (of 20 virtual clinics providing telehealth abortion care in 27 states and Washington, D.C. in June 2023, only two accepted private insurance and one accepted Medicaid); Upadhyay, U. D., Schroeder, R., Kaller, S., Stewart, C., & Berglas, N. F. (2024). Pricing of medication abortion in the United States, 2021-2023. *Perspectives on Sexual and Reproductive Health*, *56*(3), 282–294. https://doi.org/10.1111/psrh.12280 ("Most virtual clinics did not accept Medicaid. In 2021, none of the 31 (0%) virtual clinics accepted Medicaid, increasing to 16 out of 226 (7%) in 2023.").

could legally resume, as a practical matter resuming or newly adopting a telehealth model of care was not immediate or uniform among providers.[23] Thus, EPPC is misattributing serious adverse events that occurred during at least three months—and likely more—of Period 2 to remote dispensing, even though only in-person dispensing was permitted during this time. This is just one of many potential confounding factors that would have impacted the actual availability and use of remote dispensing at different points of time or for different populations during Period 2.

Further, because EPPC does not have the individual level data necessary to calculate the share of mifepristone prescriptions that involved remote dispensing, it proposes its own rough high and low thresholds of a hypothetical percentage of remote dispensing in Period 2. To justify this, EPPC cites data reported by three different sources, which it asserts collectively "implies that the remote dispensing share of mifepristone abortions reached roughly 30% by the last quarter of 2023 but was likely substantially lower in earlier years."[24] It fails, however, to clarify that the three cited sources each report different types of data, none of which provide insight into what proportion of medication abortion patients in EPPC's dataset would have received telehealth services. Only one of the data sources includes specific statistics about the share of all abortions that were delivered via telehealth each month, but it does not include any information about the proportion of these patients served by providers that accepted insurance and thus would be included in EPPC's dataset. In fact, nearly half of the abortions provided via telehealth reported by this source were provided under shield laws, and thus definitely not covered by insurance or included in EPPC's dataset. A second source reports on the total number of abortion *clinics* (both virtual and brick-and-mortar) that offered medication abortion via remote dispensing from 2020 to 2022, but not the number of medication abortions provided via telehealth, nor the proportion of those facilities that accepted insurance at that time. And the third reported an overall percentage of medication abortions from 2000 to 2023 (dispensed both remotely and in person). EPPC does not explain how they combined estimates from these three sources, which report or compare different measures and use different time units (month vs. years), to choose the 10% and 25% hypothetical benchmarks.[25]

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[23] See Baker C. N. (2023). History and Politics of Medication Abortion in the United States and the Rise of Telemedicine and Self-Managed Abortion. *Journal of Health Politics, Policy and Law*, *48*(4), 485–510, 492-496. https://doi.org/10.1215/03616878-10449941 (describing how after the FDA's April 2021 action lifting the in-person dispensing requirement, some virtual abortion clinics opened and began operating several months later in the Fall of 2021).

[24] Fact Sheet, *supra* note 2, at 2.

[25] *Id*.

Finally, the fundamental problem with EPPC's scenarios is that they assume that the removal of the in-person dispensing requirement is the only relevant change that occurred around July 2020, without accounting for the many other potential variables that may be related to the outcomes of interest. The claimed change in serious adverse events from Period 1 to Period 2 could be attributed to other changes relevant to abortion provision that occurred around the same time (such as COVID, the *Dobbs* Supreme Court decision, and the expanded use of mifepristone for miscarriage treatment[26]), a combination of multiple factors, or limitations of EPPC's underlying data.

In the end, the fact sheet offers no more than a hypothetical scenario *designed* to show remote dispensing causes higher rates of serious adverse events. EPPC offers nothing to validate this theory or the underlying assumptions and data it relies upon.

EPPC's Conclusions Regarding Ectopic Pregnancies Are Similarly Unsound

EPPC's claim that the removal of the in-person dispensing requirement caused an increase in prescriptions to people with ectopic pregnancies—based *only* on an alleged increase in ectopic pregnancies during a period in which remote dispensing was permitted—is also plagued by fundamental analytical errors. EPPC's claim assumes incorrectly that eliminating the in-person dispensing requirement impacted the proportion of ectopic pregnancies among people who were prescribed medication abortion. EPPC has no data to back this up. The standard of care for *all* medication abortion, *including* by telehealth, includes evaluating a patient for their risk of ectopic pregnancy.[27] According to the standard of care, patients determined to be at risk of ectopic pregnancy are referred to in-person care. Telehealth abortion care is not associated with an increase in serious

[26] Mifepristone and misoprostol are also used for miscarriage management, which is associated with a slightly higher complication rate than for abortion. See Reproductive Health Researchers Comment, *supra* note 3, at 16-17 (citing studies). As discussed above and in our prior comment, EPPC's method of identifying abortions in its 2025 report could have captured use for miscarriage management, and thus artificially inflated the serious-adverse event rate. *Id*.

[27] Raymond, E. G., Grossman, D., Mark, A., Upadhyay, U. D., Dean, G., Creinin, M. D., Coplon, L., Perritt, J., Atrio, J. M., Taylor, D., & Gold, M. (2020). Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. *Contraception*, *101*(6), 361–366. https://doi.org/10.1016/j.contraception.2020.04.005.

adverse events related to ectopic pregnancy,[28] and in fact some evidence indicates it facilitates earlier detection and treatment of such pregnancies.[29]

Conclusion

EPPC's fact sheet offers only a theory, no data, and no rigorous scientific findings. It cannot be relied upon as demonstrating any type of causal relationship between remote dispensing of medication abortion and patient safety. In contrast, decades of scientific peer-reviewed research show clearly that mifepristone is safe and effective, including when dispensed remotely.

Sincerely,

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[28] Aiken A. R. 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 & Gynaecology*, *128*(9),1464-1474. https://doi.org/10.1111/1471-0528.16668.

[29] Biggs, M. A., Kaller, S., Grossman, D., Ko, J., Koenig, L., & Upadhyay, U. (2024). Experiences of Ectopic Pregnancy Among People Seeking Telehealth Abortion Care. *Contraception*, *134*, 110405. https://doi.org/10.1016/j.contraception.2024.110405.