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Reframing FDA guidance on SSRI use in pregnancy: a rights-centered perspective

Abstract

Perinatal mood and anxiety disorders affect up to one in four pregnant and postpartum individuals, representing one of the most common complications of the perinatal period. Untreated illness carries serious risks including preterm birth, impaired bonding, neurodevelopmental vulnerability, and suicide—a leading cause of maternal death in high-income countries. Conversely, selective serotonin reuptake inhibitors (SSRIs), when clinically indicated, have not been consistently associated with teratogenic or long-term neurodevelopmental risks. Large-scale studies such as Huybrechts et al. (2014), Furu et al. (2015), and Brown et al. (2017) confirm that most apparent associations disappear after accounting for confounding factors. Recent reviews (Wisner et al., 2020; Pawluski & Oberlander, 2025) highlight the importance of contextualizing these risks. Importantly, SSRIs may even confer developmental resilience in children of mothers with depression.

This viewpoint argues for reframing FDA guidance within a dual-risk, equity-oriented framework, grounded in international guidelines (ACOG, 2023; 2025; NICE, 2020; CANMAT, 2016) and regional perspectives such as the Latin American Perinatal Mental Health Network (2025). A rights-centered approach is advocated, one that respects women's autonomy, ensures equitable access to treatment, and promotes evidence-based decision-making globally. Ultimately, reframing FDA guidance through a dual-risk, rights-based lens is not only a matter of clinical nuance but also of public health significance, as regulatory messaging profoundly shapes treatment adherence, health equity, and maternal–infant outcomes worldwide.

Keywords: postpartum, selective serotonin reuptake inhibitors, perinatal mental health, pregnancy

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Introduction

Perinatal mental health has emerged as a critical determinant of maternal and child well-being. Globally, approximately one in four pregnant and postpartum women experiences a mood or anxiety disorder—a prevalence far higher than in the general population.[1] Untreated illness is associated with adverse obstetric outcomes, impaired infant development, and maternal mortality, with suicide recognized as one of the leading causes of death in the perinatal period.[2] Despite this, regulatory debates have historically emphasized the potential risks of SSRIs. In 2005, the FDA issued a warning about paroxetine and congenital cardiac malformations, triggering widespread alarm. Subsequent large cohort studies, however, such as Huybrechts et al.[3] and Furu et al.,[4] found no significant increase in congenital malformations once confounding was addressed. Similarly, Brown et al.[5] showed that the association with autism spectrum disorder disappeared after adjusting for familial confounding. Nevertheless, public discourse and regulatory messaging remain disproportionately risk-focused. The July 2025 FDA panel has been criticized for adopting alarmist narratives that undermine treatment adherence, particularly in Latin America, where access to perinatal mental health care is already limited.[6] This viewpoint proposes reframing FDA guidance within a balanced, rights-centered perspective that considers both the relatively low risks of SSRIs and the severe costs of untreated illness.

SSRI risk narratives in context

Initial reports linked SSRIs, particularly paroxetine, to congenital cardiac malformations. However, subsequent large-scale studies have provided critical context. Huybrechts et al.[3] demonstrated no increased risk once maternal illness severity and confounders were addressed. Nordic registry studies Furu et al.,[4] confirmed no significant increase in overall birth defects when comparing exposed children to unexposed siblings. Similarly, Brown et al.[5] showed that autism risk was not attributable to SSRIs after family-level confounders were considered. Wisner et al.[7] argued that we are still refining causal interpretations but emphasized the lack of consistent evidence of harm. Pawluski & Oberlander[8] further suggested SSRIs may buffer against developmental vulnerabilities. Overall, current evidence supports that SSRIs, when indicated, do not pose significant teratogenic or long-term risks.

The overlooked costs of untreated perinatal mental illness

By contrast, the risks of untreated perinatal mental illness are unequivocal. Perinatal depression and anxiety are associated with preterm birth, low birth weight, and preeclampsia, as well as impaired bonding and insecure attachment. Suicide remains one of the leading causes of maternal mortality.[2] Howard et al.[1] highlighted the substantial global burden of non-psychotic perinatal mental disorders. Reducing or discontinuing effective pharmacotherapy during pregnancy has not been shown to lower neonatal adaptation syndrome risk,[9] but is strongly linked to maternal relapse.[10] Therefore, undertreatment not only jeopardizes maternal well-being but also child health and survival.

Equity and patient rights in Latin America

The Latin American Perinatal Mental Health Network[6] stresses the need for rights-based, individualized care. Overemphasis on hypothetical fetal risks may disproportionately harm women in resource-limited settings, exacerbating stigma and reducing

adherence. The World Health Organization[11] underscores maternal mental health as a human rights and child development issue. Policies must ensure equitable access to treatment, recognizing cultural and systemic barriers. In low and middle-income countries, where perinatal mental health resources are scarce, alarmist regulatory messages may inadvertently widen existing inequities by deterring women from continuing effective antidepressant treatment, thereby reinforcing systemic barriers to care. Limited access to first-line SSRIs such as sertraline or escitalopram may further exacerbate these inequities, leaving vulnerable women without safe and effective treatment options.

Guideline-based clinical perspectives

The American College of Obstetricians and Gynecologists[12,13] reaffirmed that SSRIs are safe in pregnancy, and strongly advised against discontinuing effective medications solely due to pregnancy. Sertraline and escitalopram are considered reasonable first-line choices. Similarly, NICE[14] and CANMAT[15] guidelines recommend SSRIs as first-line therapy for moderate to severe perinatal depression. International consensus emphasizes individualized care, shared decision-making, and continuity of treatment.

Neonatal adaptation syndrome

Concerns about neonatal symptoms are often framed as withdrawal. However, evidence suggests this represents a self-limited adaptation process rather than withdrawal.[9,16] Symptoms such as irritability and jitteriness occur in up to 25% of exposed infants but also in 10% of unexposed newborns. Reducing or stopping SSRIs before birth has not shown consistent benefit, while significantly increasing the risk of maternal relapse.[10] Thus, continuing effective treatment is generally recommended, with neonatal monitoring as needed.

Importantly, most neonatal adaptation symptoms are mild, self-limited, and resolve within days. Management generally involves observation and reassurance, with pharmacological intervention rarely required. This clinical reality underscores the need to contextualize these findings and avoid premature discontinuation of effective maternal treatment.

Toward balanced, rights-based policy and practice

Reframing regulatory guidance requires moving beyond one-dimensional risk narratives toward an integrative framework that balances maternal, fetal, and infant outcomes within real-world contexts. Four guiding principles are essential:

1) **Adopt dual-risk framing**: Regulatory communications must present both sides of the risk equation, acknowledging the relatively low risks of SSRIs alongside the substantial dangers of untreated maternal mental illness.

2) **Center shared decision-making**: Clinical decisions should emerge from collaborative discussions that incorporate women's values, preferences, and circumstances, reflecting ACOG's[12,13] recommendations and Pawluski & Oberlander's[8] emphasis on nuance.

3) **Ensure equity-oriented messaging**: Particularly in resource-limited settings, balanced and culturally sensitive messaging is necessary to prevent disparities in treatment access and adherence.

4) **Strengthen inclusion in research**: Pregnant individuals remain systematically excluded from most randomized clinical trials. Expanding research participation is vital for building evidence equity and informing safer, more precise perinatal pharmacology.

Conclusion

The controversy surrounding SSRI use in pregnancy underscores the dangers of reductive, alarmist regulatory messaging. Current evidence supports the safety and clinical necessity of SSRIs for many pregnant individuals, while the harms of untreated perinatal mental illness are severe and well-documented. Medicine and policy must therefore embrace a balanced, equity-oriented, and rights-centered approach that empowers women to make informed decisions and ensures equitable access to effective treatment. Expanding evidence equity is essential to generate precise, context-specific data that can guide both safer pharmacotherapy and more balanced regulatory policies.

SSRIs, when used judiciously and in the context of shared decision-making, remain a critical, often life-saving option for perinatal mental health care. As global stakeholders, we bear responsibility to advocate for policies and practices that safeguard maternal and infant health, reduce stigma, and uphold women's autonomy. Ensuring that pregnant individuals are no longer excluded from clinical research is both a scientific necessity and an ethical imperative.

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Conflicts of interest

The author declares that there is no conflict of interest.

References

1. Howard LM, Molyneaux E, Dennis CL, et al. Non-psychotic mental disorders in the perinatal period. *Lancet*. 2014;384(9956):1775-1788.
2. Oates M. Suicide: the leading cause of maternal death. *BJP*. 2003;183(4):279-281.
3. Huybrechts KF, Palmsten K, Avorn J, et al. Antidepressant use in pregnancy and the risk of cardiac defects. *N Engl J Med*. 2014;370(25):2397-2407.
4. Furu K, Kieler H, Haglund B, et al. SSRIs and venlafaxine in early pregnancy and risk of birth defects. *BMJ*. 2015;350:h1798.
5. Brown HK, Ray JG, Wilton AS, et al. Association between serotonergic antidepressant use during pregnancy and autism spectrum disorder. *JAMA*. 2017;317(15):1544-1552.
6. Red Latinoamericana de Salud Mental Perinatal. Declaración sobre la FDA y el uso de ISRS en el embarazo. 2025.
7. Wisner KL, Oberlander TF, Huybrechts KF, et al. The association between antidepressant exposure and birth defects—are we there yet? *JAMA Psychiatry*. 2020;77(12):1215-1216.
8. Pawluski JL, Oberlander TF. Potential risks and benefits of prenatal selective serotonin reuptake inhibitor medications for maternal mental health and child development. *Nat Ment Health*. 2025.
9. Warburton W, Hertzman C, Oberlander TF, et al. Stopping third trimester SSRI exposure and neonatal health. *Acta Psychiatr Scand*. 2010;121(6):471-479.
10. Cohen LS, Altshuler LL, Harlow BL, et al. Relapse of major depression during pregnancy. *JAMA*. 2006;295(5):499-507.
11. World Health Organization. Improving early childhood development: WHO guideline. Geneva: WHO; 2022.

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12. American College of Obstetricians and Gynecologists. Treatment and management of mental health conditions during pregnancy and postpartum: Clinical Practice Guideline No. 5. *Obstet Gynecol*. 2023;141(6):1262-1288.

13. American College of Obstetricians and Gynecologists. Statement on the benefit of access to SSRIs during pregnancy. 2025.

14. NICE. Antenatal and postnatal mental health: CG192. 2020.

15. MacQueen GM, Frey BN, Ismail Z, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) 2016 clinical guidelines for the management of adults with major depressive disorder: section 6. Special populations: youth, women, and the elderly. *Can J Psychiatry*. 2016;61(9):588-603.

16. Suri R, Hellemann G, Stowe ZN, et al. A prospective, naturalistic, blinded study of early neurobehavioral outcomes following prenatal antidepressant exposure. *J Clin Psychiatry*. 2011;72(7):1002-1007.

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