



## The FDA Safety Information and Adverse Event Reporting Program

### Selective Serotonin Reuptake Inhibitor (SSRI) Antidepressants: Drug Safety Communication - Use During Pregnancy and Potential Risk of Persistent Pulmonary Hypertension of the Newborn

[Posted 12/14/2011]

FDA 通知醫療人員和大眾，使用選擇性血清素再攝取抑制劑（selective serotonin reuptake inhibitor, SSRI）抗憂鬱藥的懷孕婦女，與新生兒持續性肺動脈高壓（Persistent Pulmonary Hypertension of the Newborn, PPHN）的潛在風險。這種潛在風險是在 2006 年 7 月一篇研究報告發表，之後有數篇研究繼續討論，但其相關性仍保持爭議。

FDA 已審閱了新的研究，鑑於不同的研究結果仍相互矛盾，因此對於「懷孕過程使用 SSRI 是否造成 PPHN」，目前仍無法做任何結論。FDA 將更新的 SSRI 類藥物標籤，標示新的研究數據和存有爭議的結果。

FDA 建議醫護專業人員，不用改變目前孕婦罹患憂鬱症的治療方式。

[Posted 12/14/2011]

**AUDIENCE:** Psychiatry, OB/GYN, Family Practice

**ISSUE:** FDA notified healthcare professionals and the public on the use of selective serotonin reuptake inhibitor (SSRI) antidepressants by women during pregnancy and the potential risk of a rare heart and lung condition known as Persistent Pulmonary Hypertension of the Newborn (PPHN). The initial Public Health Advisory in July 2006 on this potential risk was based on a single published study. Since then, there have been conflicting findings from new studies evaluating this potential risk, making it unclear whether use of SSRIs during pregnancy can cause PPHN.

FDA has reviewed the additional new study results and has concluded that, given the conflicting results from different studies, it is premature to reach any conclusion about a possible link between SSRI use in pregnancy and PPHN. FDA will update the SSRI drug labels to reflect the new data and the conflicting results.

**BACKGROUND:** SSRIs are marketed under various brand and generic drug names, and are used to treat depression and other psychiatric disorders. There are no adequate and well-controlled studies of SSRIs in pregnant women.

PPHN occurs when a newborn baby does not adapt to breathing outside the womb. Newborns with PPHN may require intensive care support including a mechanical ventilator to increase their oxygen level. If severe, PPHN can result in multiple organ damage, including brain damage, and even death.

**RECOMMENDATION:** FDA advises health care professionals not to alter their current clinical practice of treating depression during pregnancy.