

SSRI Use in Pregnancy Linked to Risk for Pulmonary Hypertension in Newborns

Yael Waknine

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July 20, 2006 — The US Food and Drug Administration (FDA) has warned healthcare professionals of new findings regarding the potential risks associated with both discontinuation and continuation of anti-depressant therapy during pregnancy.

The warning was based on two studies performed in women receiving selective serotonin reuptake inhibitors (SSRIs) or other drugs (in a few cases), according to an alert sent yesterday from MedWatch, the FDA's safety information and adverse event reporting program.

Data from the first study revealed that women who discontinued anti-depressant therapy were 5 times more likely to have a relapse during pregnancy compared with those who continued treatment.

Results of the second study suggested that there may be a rare risk associated with SSRIs during pregnancy; continued use of anti-depressants past the 20th week of pregnancy was linked to a six-fold increase in the risk for persistent pulmonary hypertension (PPHN) in newborns.

PPHN, which typically occurs in 1 or 2 per 1000 births, often involves severe respiratory failure that requires immediate treatment.

Although the study was too small to compare individual drugs and the risk has thus far not been investigated by other studies, the FDA notes that the potential risk adds to growing concerns regarding use of SSRIs during pregnancy.

Newborn adverse events previously reported in association with continued use include irritability, difficulty feeding, and rare cases of difficulty breathing. In addition, use of paroxetine HCl (*Paxil*, made by GlaxoSmithKline) during the first trimester has been epidemiologically linked to an increased risk for cardiac birth defects.

The FDA advises that women receiving anti-depressant therapy who are pregnant or thinking about becoming pregnant consult with their healthcare professional prior to discontinuing or continuing anti-depressant therapy; such a decision should only be made after careful individualised consideration of the risks and benefits associated with treatment. Patients who elect to discontinue therapy should be closely monitored for depression relapse.

Additional studies are being conducted regarding the potential risk for PPHN associated with use of SSRIs during pregnancy. As findings become available, corresponding safety labelling revisions will be made for citalopram HBr (*Celexa*, made by Forest Laboratories, Inc); fluvoxamine (previously marketed as *Luvox* by Solvay Pharmaceuticals, Inc, and now available in generic formulations); escitalopram oxalate (*Lexapro*, made by Forest Laboratories, Inc); paroxetine HCl (*Paxil*, made by GlaxoSmithKline), fluoxetine HCl (*Prozac*, made by Eli Lilly and Company); olanzapine/fluoxetine (*Symbyax*, made by Eli Lilly); and sertraline HCl (*Zoloft*, made by Pfizer, Inc).

Reviewed by Gary D Vogin, MD