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## Analysis: SSRIs' risk to infants

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WASHINGTON, Feb. 6 (UPI) -- The class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs) is facing more bad news this week with the release of a study indicating that pregnant women's use of the drugs may be dangerous to their newborn infants.

The study, which appears in the February issue of *Archives of Pediatrics and Adolescent Medicine*, found that nearly one-third of newborn infants whose mothers took SSRIs during pregnancy experienced withdrawal symptoms that included high-pitched crying, tremors and disturbed sleep.

Natalie Taylor, an analyst with Decision Resources, said the finding could affect the SSRI market but noted that the field is already leveling off due to another danger previously linked to the drug class, an increased risk of suicidal behavior and thoughts in children and adolescents.

The suicidal risk, first publicized in late 2004, prompted the Food and Drug Administration to add a black-box warning to top-selling SSRIs like GlaxoSmithKline's Paxil and Pfizer's Zoloft.

Aside from the bold new warnings on SSRI labels, Taylor added, many of the medications have gone off patent or will soon.

"This might have an impact, but I think in any case the bottom line ... is that you need to weigh the benefits with the risks," she told United Press International.

The symptoms of major depression are severe enough that it may warrant putting a pregnant woman on an SSRI even if that does increase the risk of withdrawal symptoms in her infant, Taylor said. But if the patient has a milder case of depression, it might be worth reconsidering whether to put her on the medications, she said.

Overall, "the market (of SSRIs) ... is plateauing," Taylor said.

In the study, a team of researchers led by Gil Klinger of Tel Aviv University assessed withdrawal symptoms in 60 newborn infants who had prolonged exposure in the womb to SSRIs, including GlaxoSmithKline's Paxil, Lilly's Prozac, Forest's Celexa, Pfizer's Zoloft and Wyeth's Effexor.

Eighteen of the infants had symptoms of withdrawal, including eight with severe symptoms and 10 with milder symptoms.

"The high prevalence of neonatal abstinence syndrome in infants exposed to SSRIs in utero should be brought to the attention of family physicians, psychiatrists, gynecologists, pediatricians and mothers," Klinger and colleagues wrote in the journal.

"Because maternal depression during pregnancy also entails a risk to the newborn, the risk-benefit ratio of continuing SSRI treatment should be assessed," the researchers said.

They also recommended that infants of mothers taking SSRIs should be monitored closely after birth for a minimum of 48 hours and that "follow-up of exposed infants, particularly those who develop severe symptoms, is needed to assess the long-term effects of prolonged exposure to SSRIs."

Neonatal safety is an issue that apparently neither the FDA nor most SSRI manufacturers want to discuss. UPI contacted the FDA and several manufacturers, including Forest Laboratories, Pfizer and GlaxoSmithKline, but only Eli Lilly, which makes Prozac, responded.

"Lilly does not and has never promoted the use of Prozac in pregnant or nursing mothers," Lilly spokeswoman Heather Lusk told UPI.

Nevertheless, Lusk said, "Decisions regarding the use of anti-depressants during pregnancy should be made after considering an appropriate benefit-risk assessment by the attending physician. Absent such a determination, conclusions resulting in discontinuation of Prozac or any other anti-depressant treatment may result in serious health consequences from untreated maternal depression."

SSRIs came under fire in 2004 when British researchers obtained unpublished studies from manufacturers and concluded the medications (except for Prozac) appeared to increase the risk of suicide and suicide attempts in children.

The FDA is currently reviewing studies to determine if the same risk is present in adults. The agency said last July that it could take more than a year to complete its review.