



Seizure Prevention Drug May Lead to Birth Defects

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A drug commonly used to prevent epileptic seizures may cause severe birth defects when taken by pregnant women, according to a study led by Harvard Medical School Professor of Pediatrics Lewis B. Holmes.

Of 123 pregnant women who took valproate—a widely-prescribed anti-convulsive drug—about 8.9 percent gave birth to babies with major deformations such as heart defects, spina bifida and kidney abnormalities, a figure more than five times greater than the birth-defect rate of women who did not take valproate.

Holmes, who runs the Harvard-based Antiepileptic Drug (AED) Pregnancy Registry, presented his findings at the annual meeting of the Society for Maternal and Fetal Medicine last month.

Holmes said this study—which he said is the largest of its kind to date—is “a heads up that valproate is more dangerous than people thought it was.”

He said he hopes that it will spur research into safer anti-epileptic drugs.

Like other anti-convulsants, the drug is also used to treat other disorders such as bipolar disorder and migraines.

Holmes directs the Harvard-based Anti-epileptic Drug Pregnancy Registry, a program started in 1997 that has recruited about 3,200 pregnant women in the United States and Canada as possible subjects for studies. Women from the registry were the subjects of this study.

Although the pregnancy registry is funded by six pharmaceutical companies, Holmes said that doctors make all the important scientific decisions, and that the registry is overseen by an independent scientific advisory committee.

Holmes said the pregnancy registry strives to represent a broad cross-section of the population of women who take anti-epileptic drugs.

Women themselves—not their doctors—must make the call to join the registry, he said. In addition, the registry does not admit women who have already had prenatal screenings for birth defects—which, he said, assures that the registry gets a random sample of women.

Patricia Osborne Shafer, RN, MN, who chairs the professional advisory board of the Epilepsy Foundation, praised the study, according to the trade periodical Drug Week.

Shafer says that she hopes the study will encourage “informed choices on treatment during pregnancy” for patients and students.

“This is important new information for women with epilepsy and their physicians to have,” Shafer said. But Shafer warned that pregnant women taking valproate should not immediately stop taking the drug, as they might suffer seizures, which can also harm a developing fetus.

Although there are alternatives to valproate—which is marketed under the brand names Depakote, Depakene, and Epivil—some patients say that it is the only effective drug for them, she said.