



PRESS RELEASE

Pregnancy Registry Reports Drug Risk To Fetus

Washington, D.C., February 14, 2003 -- A report from a research team headed by the director of the Harvard-based Antiepileptic Drug (AED) Pregnancy Registry details for the first time the risk of birth defects in women taking a widely-used anticonvulsant drug.

The report described effects on babies of 125 women who took the anticonvulsant drug valproate (Depakote, Depakene, Epivil) as monotherapy during pregnancy and who had signed up with the [Antiepileptic Drug \(AED\) Pregnancy Registry](#). It found an 8.9% rate of major birth defects in those babies. Problems in the affected babies included spina bifida, cardiac abnormalities, extra fingers, kidney problems and clubfoot. The researchers compared these results to those in a group of women not exposed to any antiepileptic drug. The rate of birth defects in those women was 1.6 percent.

Valproate is an antiepileptic drug used by women with epilepsy to prevent seizures. Like some other anticonvulsant drugs, it is also used to treat other health problems, including mood disorders and migraine.

The report was presented by Lewis Holmes, M.D. at last week's Annual Meeting of the Society for Maternal and Fetal Medicine in San Francisco. An abstract of Dr. Holmes's report is published in the *American Journal of Obstetrics and Gynecology* (Vol. 187, No.6, abstract 286). The abstract is also posted on the website of the [Antiepileptic Drug Pregnancy Registry](#).

"This is important new information for women with epilepsy and their physicians to have," said Patricia Osborne Shafer, RN, MN, chair of the Epilepsy Foundation's professional advisory board, who herself has epilepsy. "We hope it will help women and their physicians make informed choices on treatment during pregnancy before or very soon after the pregnancy begins.

"At the same time, we urge women taking this drug not to stop it on their own. Suddenly stopping this medication can cause potentially dangerous seizures. Nor should they change their medication based on these results alone. For some women, valproate is the only drug that prevents seizures. Seizures during pregnancy also have the potential to harm the fetus, either from the mother's falls or deprivation of oxygen during the seizure, so it is important to maintain seizure control," Shafer said.

Most estimates of birth defects among the general population are between 2 and 3 percent. For many years, it has been recognized that women's use of anticonvulsant medications during pregnancy increases this risk of birth defects, although until now there have been no major studies to identify the level of risk with specific medications. An earlier report by Dr. Holmes, published in the journal *Teratology* (63:250, 2001), reported an elevated incidence of fetal malformations (cleft lip and palate and heart defects) in babies of women being treated with phenobarbital.

The AED Pregnancy Registry is based at the Massachusetts General Hospital, Genetics and Teratology Unit, Harvard Medical School. Its mission is to study and report on fetal risks associated with use of anticonvulsant medications during pregnancy. "We owe a big vote of thanks to the women who've signed up with the Registry and have allowed their experiences to produce information that will help others," said Eric Hargis, president and CEO of the Epilepsy Foundation. Currently about 3,000 women have signed up with the registry.

"It's very important that physicians and women have as much information as possible about these medications," said Hargis. "The Registry is really the only way at present to collect data on what meds women are taking, and what effects they may be having on their babies. We hope pregnant women taking anticonvulsants for any reason will continue to sign up."

The Epilepsy Foundation, with national offices in metropolitan Washington, D.C., and a network of affiliates throughout the nation, is the leading volunteer organization devoted to research, education, advocacy, and the provision of services in the community for people with seizure disorders and their families.

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