

## Child Injury Laws *Blog*

# Topamax Injuries: Drug's Impact On Effectiveness Of Birth Control May Have Contributed To Outburst Of Birth Injuries

Posted by **Jonathan Rosenfeld** on April 08, 2011

Just last month, the FDA issued some fairly impressive warnings regarding women's use of Topamax during pregnancy. In fact, the FDA re-categorized the drug from a Category C- Pregnancy Drug to Category D-- an important reclassification due to the scientific evidence linking Topamax usage with birth defects.

Like other drugs categorized as a Class D, the FDA has conclusively established the use of Topamax with "human fetal risk based on adverse reaction data from investigations or marketing experience or studies in humans." However the FDA's Class D warning goes on to say that even with the known risks, the use of the drug may be acceptable if the pregnant woman has a medical condition that threatens her life.

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In particular, Topamax has been associated with birth defects such as:

- Cleft lip
- Cleft palate
- Heart defects
- Facial deformities
- Deformed limbs

While some of these Topamax birth defects, appear to have been known by the medical community years before the stern warnings, I find it particularly troubling that an added side-effect of Topamax usage is the ineffectiveness of oral contraceptives taken by woman to avoid becoming pregnant.

A study published in 1996, the same year the FDA approved Topamax for treatment for partial onset seizures, indicates that seizure medications-- such as Topamax may substantially increase the likelihood of a woman becoming pregnant while she is on birth control.

The net result of this important information is that many woman were likely taking Topamax before they knew they were pregnant in the first

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place. Given the nature of fetal development, it is likely that many of the facial malformations and cleft palates are due to the mother taking Topamax during the vital first trimester when many of these features form.

As we begin the process of learning just how much Ortho-McNeil and other generic manufacturer had about this drug, I believe the drug's impact on the effectiveness of women's birth control medication will prove to be important as women begin to disclose the fact that they may never have intended to give birth to a child with birth defects.

**Rosenfeld Injury Lawyers** is in the process of evaluating Topamax (and generic equivalents) cases. Please use our **contact form** or call us and we will return you call promptly.

Related:

**Effect of Topiramate on the Pharmacokinetics of an Oral Contraceptive Containing Norethindrone and Ethinyl Estradiol in Patients with Epilepsy (PDF)** By William E. Rosenfeld, Dennis R. Doose, Sally A. Walker, and R. K. Nay *Epilepsia*, 38(3):3 17-323, 1997

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## New FDA Warnings Suggest Correlation Between Topomax And Birth Defects Including: Cleft Lip & Cleft Palate

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