

# Child Injury Laws *Blog*

## More Evidence That Topamax Manufacturer Is Responsible For Birth Defects

Posted by **Jonathan Rosenfeld** on April 28, 2011

I've written a lot about the serious problems associated with use of Topamax during pregnancy. After all, the FDA ordered Topamax to be re-labelled and re-classified in March, 2011 in response to data suggesting a conclusive correlation between Topamax usage by pregnant woman and birth defects such as: cleft lip, cleft palate, Spina Bifida, facial defects and pediatric heart problems.

The swift decision to change the classification / labelling of Topamax is mainly due to the data collected by the FDA. The FDA collects information about problems associated with all drugs in an Adverse Event Database. According to the FDA's adverse Event Report database:

- There are 244 safety reports concerning Topamax users who believe their child was adversely affected by the drug
- 114 of the 244 safety reports (approximately 47%) are related to birth defects
- 12% of adverse complaints are related to cleft lip / cleft palate
  - 12% of the adverse complaints relate to limb malformation such as: cleft hand foot defects
  - 11% of adverse complaints are heart related
  - 10% of adverse complaints relate to facial defects
  - 6% of adverse complaints relate to spinal defects

Jonathan Rosenfeld offers legal services relating to: birth injuries, medical malpractice, day care abuse, foster care abuse, swimming pool injuries, automobile accidents, school bus accidents, dog bites, food poisoning, product liability, amusement park accidents and clergy abuse. For more information please visit Child Injury Laws Blog (<http://www.childinjurylaws.com/>) or call Jonathan directly at (888) 424-5757. ([www.rosenfeldinjurylawyers.com](http://www.rosenfeldinjurylawyers.com).)

## Off Label Uses Of Topamax

Topamax was originally approved by the FDA as a drug to treat epilepsy in 1996. In 2004, the FDA approved Topamax to treat migraine headaches.

Despite its limited approved uses, Ortho-McNeil was illegally promoting Topamax to treat conditions such as bipolar mood disorder, alcohol dependence and weight loss for several years.

In May, 2010 Ortho-McNeil plead guilty and and paid fines of more than \$81.5 million for their off-label promotion of Topamax to broad range of people for which the drugs safety was never approved.

Certainly, the more information that comes to light regarding Topamax birth defects and marketing, it is becoming more apparent that scope of potential pharmaceutical claims against Ortho-McNeil and various generic manufacturer are indeed quite strong. As we learn more about this troubling situation, I encourage you to give [my law office](#) a call or email us a contact form and allow us to begin an evaluation of your case.

Related:

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

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

[May 21, 2010: Ortho-McNeil Pharmaceutical, LLC Pleads Guilty to Illegal Promotion of Topamax and is Sentenced to Criminal Fine of \\$6.14 Million FDA](#)

[FDA Drug Safety Communication: Risk of oral clefts in children born to mothers taking Topamax \(topiramate\)](#)

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