Topamax During Pregnancy Increases Risk Of Cleft Lip And/Or Cleft Palate Birth Defects

Oral Clefts In Babies Are 20 Times More Likely With Women Who Used Topamax (topiramate) After Getting Pregnant

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 10, 2011; see http://bit.ly/h7ZFaJ

In early March 2011 the FDA announced that the prescribing information for Topamax and generic topiramate products would be changed to warn women and their doctors about an increased risk of oral cleft birth defects in children whose mothers used these epilepsy and migraine drugs during pregnancy.

Topamax is an Ortho-McNeil and Johnson & Johnson product. Generic versions of Topamax, known generally as topiramate, are sold by Teva Pharmaceuticals, Watson Pharmaceuticals, and Mylan as well as other generic drug companies.

From the March 4, 2011 "FDA Drug Safety Communication: Risk of oral clefts in children born to mothers taking Topamax (topiramate)":

Data Summary

Data from the North American Antiepileptic Drug (NAAED) Pregnancy Registry indicate an increased risk of oral clefts in infants exposed to topiramate monotherapy during the first trimester of pregnancy. The prevalence of oral clefts was 1.4% compared to a prevalence of 0.38% - 0.55% in infants exposed to other antiepileptic drugs (AEDs), and a prevalence of 0.07 % in infants of mothers without epilepsy or treatment with other AEDs. The relative risk of oral clefts in topiramate-exposed pregnancies in the NAAED Pregnancy Registry was 21.3 as compared to the risk in a background population of untreated women (95% Confidence Interval:7.9 – 57.1). The UK Epilepsy and Pregnancy Register reported a similarly increased prevalence of oral clefts (3.2 %) among infants exposed to topiramate monotherapy, a 16-fold increase in risk compared to the risk in their background population (0.2%).

For more concerning this new 2011 information about Topamax and oral birth defects, see these additional resources from the FDA:

1. "Questions and Answers: Risk of oral clefts (cleft lip and/or palate) in infants born to mothers taking Topamax (Topiramate)"

2. "Topamax (topiramate): Label Change - Risk For Development of Cleft Lip and/or Cleft Palate in Newborns"

We first learned about the possible link between birth defects and Topamax from the July 22, 2008 issue of the medical journal *Neurology*, specifically an article which reported that taking Topamax alone or along with other epilepsy drugs during pregnancy may increase the risk of birth defects.

More recently, the possibility that Topamax and generic topiramate increase the risk for cleft lip and cleft palate birth defects in babies born to women who used Topamax during pregnancy got our attention in January 2011 when the FDA wanted drug company Vivus to assess how feasible it would be to analyze available data to determine the risk of developing oral cleft birth defects due to Topamax use in connection with the new weight-loss drug Qnexa.

We are investigating possible legal compensation claims against Johnson & Johnson and Ortho-McNeil for birth defects in babies born to women who used Topamax or topiramate during their pregnancy.

We offer a free Topamax birth defect lawsuit case evaluation by an experienced drug injury attorney for a possible legal claim against Johnson & Johnson and Ortho-McNeil or the responsible generic drug company.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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