FDA Seeks Information About Topamax-Related Oral Cleft Birth Defect Cases

Request For Historical Incidence Data Made In Connection With NDA For New Obesity Drug

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 1, 2011; see http://bit.ly/huRARC)

In mid-January 2011 the biopharmaceutical company Vivus, Inc. -- while providing a regulatory update on its New Drug Application (NDA) for QNEXA -- announced that the FDA had asked the company to look into the possibility that the drug Topamax (topiramate) is associated with a certain type of birth defect, oral cleft.

According to a January 21, 2011 news report, "FDA Requests Vivus For Birth-defect Data For QNEXA; Shares Down 11 Percent":

> ... the U.S. Food and Drug Administration has requested Vivus to assess the feasibility of analyzing existing healthcare databases to determine the historical incidence of oral cleft in offspring of women treated with topiramate for migraine prophylaxis (100 mg)....
>
> The FDA made [this] request based on two published reports which cited two oral clefts in the UK Epilepsy and Pregnancy Register and four, including two isolated cleft lips, from the North American AED Pregnancy Registry.

As background, from the same January 21 news report:

> QNEXA is an investigational drug for the treatment of obesity. Qnexa is a controlled-release formulation of two drugs - Phentermine and Topiramate.
>
> Phentermine, approved in 1959, is the most widely prescribed weight loss therapy in the U.S. Topiramate was first approved in 1996 as a treatment for epilepsy and more recently as a prophylactic for migraine.

We will continue to monitor this emerging drug safety issue concerning Topamax and oral cleft birth defects.

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.
http://www.DrugInjuryWatch.com