September 2009 Update On Paxil Lawsuits Alleging Birth Defects

Reports About Paxil Cases In Boston, Philadelphia, And Mississippi

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 15, 2009; see http://bit.ly/Wp1dq)

To set the stage we start back in December 2005, when the FDA issued a News Release titled "FDA Advising of Risk of Birth Defects with Paxil", from which we take this excerpt:

> FDA has asked the manufacturer, Glaxo Smith Kline (GSK), to change the pregnancy category from C to D, a stronger warning. Category D means that studies in pregnant women (controlled or observational) have demonstrated a risk to the fetus. However, the benefits of therapy may outweigh the potential risks to the fetus.
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> Based on results of the preliminary data, GSK updated the drug's labeling in September 2005 to add data from one study. As additional data have become available, the label has now been changed to reflect the latest data from the two studies and to change the pregnancy category.

Since then, more than 600 lawsuits have been filed against Glaxo alleging its popular antidepressant drug Paxil causes birth defects. The general theme of these Paxil lawsuits is Glaxo failed to warn about the risks of Paxil until forced to do so by the FDA in late 2005, as seen above. Further, plaintiffs' lawyers assert that Glaxo documents show the drug company knew since 1980 that Paxil could raise the risk of birth defects.

From a September 11, 2009 *Bloomberg* article, "GlaxoSmithKline to Defend Paxil in Birth-Defect Case":

> Animal studies didn't show the drug was safe, company scientist John Baldwin wrote in a March 20, 1980, memo cited in court filings by [plaintiffs'] lawyers.
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> "There remains the possibility that this compound could be teratogenic at higher dose levels," he said. A teratogenic agent is one that causes malformations of an embryo or fetus.
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> "In the face of this warning from Baldwin, GSK chose not to perform any additional animal studies to explore the teratogenic effects of Paxil," the plaintiffs' lawyers wrote.

For our Paxil litigation September 2009 update we rely upon a second *Bloomberg* article, "Glaxo E-Mails Over Paxil Study Must Be Turned Over for Trial", by reporters Jef Feeley and Margaret Cronin Fisk, which was published on September 15, 2009.

First, we learn about a significant development in the Paxil litigation coming from the U.S. District Court, District of Massachusetts (Boston):

> U.S. District Judge Nancy Gertner in Boston [on September 14, 2009] refused to block William Seale's family from reviewing e-mails and other communications between Glaxo and Boston University researchers over Paxil's birth-defect risks. The 1-year-old Seale, whose pregnant mother took the antidepressant, died in 2004 after three surgeries to address heart defects, according to court filings.
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> Seale's family contends officials at London-based Glaxo, which funded the birth-defect research, sought to influence the study's results to help protect the company from lawsuits, Gertner said in her ruling. The study was done at the university's Slone Epidemiology Center.
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> "The plaintiffs are entitled to correspondence and documents between anyone at Slone and GSK about the study, its scope" and methodology, the judge concluded....
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> Gertner denied the family's request to access the study's raw data. The judge ordered Boston University researchers Allen Mitchell and Carol Louik to turn over other information about their contacts with the drugmaker.
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> Some of that information relates to communications Glaxo had with the researchers as they prepared to submit the study to the New England Journal of Medicine for publication, according to Gertner's order. The study was published in 2007.

This ruling by Judge Gartner is related to the case *Seale v. SmithKlineBeecham Corp.*, 07-cv-180-MPM, U.S. District Court, Northern District of Mississippi.

Coincidentally, on the day after this ruling was made in Boston, opening arguments were scheduled to begin in the first Paxil - birth defect case to go to trial: *Kilker v. SmithKline Beecham Corp.*, 2007- 001813, Court of Common Pleas, Philadelphia County, Pennsylvania.

From the September 15 *Bloomberg* article about this first Paxil trial:

> Michelle David, Lyam [Kilker]'s mother, contends Glaxo officials knew Paxil posed an increased risk of birth defects to pregnant users and hid the information to pump up sales.
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> Lyam was born with two holes in his heart as a result of the drug, his mother said in court papers. The infant underwent multiple surgeries within six months of his birth, she added.
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> Lawyers for the company countered at a Sept. 3 pretrial hearing that there is no evidence David was taking Paxil at the time Lyam was conceived and that the company acted responsibly in testing Paxil and updating safety information.

We will be watching for news reports about this Paxil trial in Philadelphia and let you know the outcome.

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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