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FDA To Finally Study Possible Increased Heart Risks Caused By Attention Deficit Medications

POSTED: Tuesday, September 18, 2007

The Safety Profile Of Adderall, Concerta, Ritalin, Dexedrine And All Other ADHD / ADD Drugs Will Be Reviewed

(Posted by Tom Lamb at DrugInjuryWatch.com)

In a September 17, 2007 *FDA News* article titled "[AHRO and FDA to Collaborate in Largest Study Ever of Possible Heart Risks With ADHD Medications](#)" we learned that the safety of Adderall, Concerta, Ritalin, and Dexedrine -- as well as all other attention deficit hyperactivity disorder (ADHD) and attention deficit disorder (ADD) drugs -- will be finally be reviewed.

In more detail, the FDA will collaborate with the Agency for Healthcare Research and Quality (AHRQ) to examine clinical data regarding 500,000 children and adults who have used ADHD / ADD drugs in the past to determine these drugs cause an increased [risk of heart attacks](#), strokes, or other serious cardiovascular problems. The study is expected to take about two years to complete.

As stated in the September 17 *FDA News* item:

"Case reports have described adverse cardiovascular events in adult and pediatric patients with certain underlying risk factors who receive drug treatment for ADHD, but it is unknown whether or not these events are causally related to treatment," said Gerald Dal Pan, M.D., director of FDA's Office of Surveillance and Epidemiology. "The goal of this study is to develop better

Drug Injury Watch



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information on this question."

We get the impressions of [Steven Nissen, a prominent cardiologist who has been involved previously with the ADHD / ADD safety debate](#) about this new FDA study announcement from the September 17, 2007 post "[Feds Studying Risks of ADHD Drugs](#)" by Jacob Goldstein at *The Wall Street Journal (WSJ) Health Blog*:

... told the Health Blog that the study could be "potentially very helpful," because it will look at seven years' worth of data, while earlier studies have looked at shorter periods of time....

Nissen... pointed out both that ADD and ADHD drugs tend to raise blood pressure (which raises cardiovascular risks) and that 10% of those treated for the disorders are over 55 years old — an age group where the risk of heart attack and stroke tends to be higher to begin with.

"We really don't know what the long-term impact of the drugs is going to be on cardiovascular health," said Nissen, who is not involved in the federal project. "This would obviously be unique data and potentially very helpful because it's long-term."

[In August 2006 the FDA approved label changes they had requested from the drug companies that make ADHD / ADD medications](#) -- such as Novartis AG's Ritalin and Shire Plc's Adderall -- to add information about the emerging heart-related issues. Later, in February 2007, [the FDA](#) asked those same drug companies to develop patient guides that explained the possible cardiovascular risks associated with ADHD / ADD drugs.

We will monitor and report the results of this seemingly long overdue ADHD / ADD drug safety study by the FDA and AHRQ.

| [Read more from this blogger](#)

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