Diabetes Drug Avandia Associated With Liver Injury And Liver Failure, Again

July 2009 Medical Journal Article Follows 2008 Public Citizen's Petition For FDA To Ban Sales Of Avandia In U.S.

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 31, 2009; see http://bit.ly/c5rY8)

In October 2008 Public Citizen petitioned the FDA to ban the sale of the diabetes drug Avandia (rosiglitazone) in the U.S. because its risks, which include heart attack and heart failure in addition to liver toxicity, far outweigh its benefits and because much safer alternatives exist for treating Type 2 diabetes.

To our knowledge, there has been no word from the FDA, yet, about how long the agency will need to make a determination on the Avandia recall requested by Public Citizen.

In late July 2009, however, a new medical journal article about Avandia and liver failure was published in *Pharmacoepidemiology and Drug Safety*.

This article, "Case series of liver failure associated with rosiglitazone and pioglitazone."-- by James S. Floyd, MD, Elizabeth Barbehenn, PhD, Peter Lurie, MD, MPH, and Sidney M. Wolfe, MD, of Public Citizen's Health Research Group -- seemingly adds further support to the contention that Avandia can cause death from liver failure and should be banned immediately by the FDA.

In more detail, the study found 11 cases of severe liver toxicity, mostly fatal, related to using Avandia. Those cases were identified after careful analysis of MedWatch forms submitted between 1997 and 2006 to the FDA's Adverse Event Reporting System (AERS).

From a July 22, 2009 press release, "Rigorous Study Adds to Case That FDA Should Ban the Diabetes Drug" (cached version), which was issued by Public Citizen in connection with this new Avandia medical journal article, we get these points:

- "Because of low reporting rates to the AERS database, the 11 cases likely represent a small fraction of patients who developed liver failure because of the drug," said Dr. James Floyd, a Public Citizen health researcher and lead author of the study. "Our best estimate is that one case of liver failure occurs for every 44,000 patients who take Avandia."

- "The research is yet another indication that Avandia is too dangerous to remain on the market," said Dr. Sidney Wolfe, acting president of Public Citizen, director of Public Citizen's Health Research Group and co-author of the study. "The FDA's new leadership should demonstrate its commitment to public health by banning this drug, thereby preventing needless deaths and serious adverse events."

- In 2006, the number of prescriptions filled for the drug peaked at 13.2 million. That number dropped to 3.1 million in 2008. This means that about 8,500 prescriptions a day are still being filled for this dangerous drug.

To date, most of the drug injury litigation concerning Avandia has involved cardiovascular adverse reactions such as heart attacks and strokes.

Conversely, it is not widely known that Avandia can be "hepatotoxic", meaning that it can cause liver injury accompanied by hepatic encephalopathy or liver failure, and in some instances require liver transplantation.

We are currently investigating cases where there has been possible Avandia-induced liver damage as potential drug injury lawsuits.

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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