FDA Wants Merck To Change Januvia Label With Increased Warning About Pancreatitis Risk

Is Januvia Similar To Byetta In Terms Of The So-Called Class Effect And Drug Injury Lawsuits Being Filed?

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 29, 2009; see http://bit.ly/L9OUo)

On September 25, 2009 the FDA posted on its web site "Information for Healthcare Professionals - Acute pancreatitis and sitagliptin (marketed as Januvia and Janumet)".

From the Background and Data Summary part of that document:

> FDA has completed a review of 88 cases of acute pancreatitis in patients using sitagliptin or sitagliptin/metformin. The cases were reported to FDA's Adverse Event Reporting System (AERS) between October 2006 and February 2009. Hospitalization was reported in 58/88 (66%) of the patients, 4 of whom were admitted to the intensive care unit (ICU). Two cases of hemorrhagic or necrotizing pancreatitis were identified in the review and both required an extended stay in the hospital with medical management in the ICU. The most common adverse events reported in the 88 cases were abdominal pain, nausea and vomiting.
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> Additionally, the analysis found that 19 of the 88 reported cases (21%) of pancreatitis occurred within 30 days of starting sitagliptin or sitagliptin/metformin. Furthermore, 47 of the 88 cases (53%) resolved once sitagliptin was discontinued. It is important to note that 45 cases (51%) were associated with at least one other risk factor for developing pancreatitis, such as diabetes, obesity, high cholesterol and/or high triglycerides.
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> Based on the temporal relationship of initiating sitagliptin or sitagliptin/metformin and development of acute pancreatitis in the reviewed cases, FDA believes there may be an association between these events....

Also on September 25 Merck & Co., Inc. issued a statement saying its own analysis of the post-marketing adverse experience reports data did not confirm an excess risk for developing acute pancreatitis. From this "Merck Statement About JANUVIA™ (sitagliptin) and JANUMET™ (sitagliptin/metformin)" document:

> The safety profile of JANUVIA and JANUMET has been established through an extensive clinical development program. In addition, in the nearly three years of marketed use, more than 18 million total prescriptions have been dispensed for sitagliptin worldwide.

In the September 25 edition of *MedPage Today* there appears an article, "Sitagliptin Label to Reflect Pancreatitis Risk", which suggests that the increased risk of developing acute pancreatitis may be a so-called "class effect" for some of the newer diabetes drugs such as Januvia and Byetta:

> Acute pancreatitis is beginning to look like a class effect for the newer drugs against diabetes that act through the glucagon-like peptide-1 pathway.
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> Two years ago, the FDA demanded a similar label change for the incretin mimetic exenatide (Byetta), after 30 pancreatitis cases were reported. (See FDA Wants Pancreatitis Caution Added to Exenatide (Byetta) Label)
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> Both exenatide and sitagliptin act through receptors for GLP-1 -- exenatide is a synthetic mimic of the peptide, while sitagliptin inhibits the dipeptidyl peptidase-4 enzyme that degrades GLP-1 in vivo.

According to a September 25, 2009 *Wall Street Journal* Health Blog post, "Another Diabetes Drug is Linked to Pancreas Inflammation", by Jacob Goldstein:

> This is the second time in just over a year that a popular, new-ish diabetes drug has been linked to pancreatitis — the previous case was Byetta, which is co-marketed by Amylin and Eli Lilly. In that instance, several deaths were reported....

> Amylin and Lilly have been named as defendants in Byetta cases brought by 110 plaintiffs in cases primarily related to pancreatitis, Amylin said in its most recent quarterly report. Byetta sales fell slightly in the first half of this year, to $332.8 million from $336 million in the year-earlier period.

As we reported two years ago, the FDA first issued an alert to doctors informing them reports of acute pancreatitis in patients taking Byetta back in October 2007.

We will have to wait to see whether this increased warning about pancreatitis for Januvia results in any drug injury lawsuits being filed against Merck.

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