Case Report: Man Using Diabetes Medication Januvia Develops Elevated Hepatic Enzymes

Authors Suggest That Certain Patients Starting Januvia Should Have Their Liver Function Monitored

(Posted by Tom Lamb at www.DrugInjuryWatch.com on February 8, 2010; see http://bit.ly/d4MdGW)

In the recent past we <u>considered whether Januvia (sitagliptin) can cause pancreatitis in patients</u> using this relatively new diabetes medication.

Now, a new medical journal "To The Editor" letter suggests that Januvia may have a negative effect on the liver for certain patients, specifically "individuals with a history of nonalcoholic steatohepatitis or elevated hepatic enzymes".

From this letter titled <u>"Elevated Hepatic Enzymes Potentially Associated with Sitagliptin"</u>-- published online January 26, 2010 by *The Annals of Pharmacotherapy* -- we get the following case report concerning a patient who developed elevated hepatic enzyme levels after starting Januvia:

A 58-year-old male with a history of type 2 diabetes and nonalcoholic steatohepatitis (diagnosed in 2006) presented to the clinic for diabetes management. At the time, the patient's aspartate aminotransferase (AST) was 53 U/L (normal <40 U/L) and alanine aminotransferase (ALT) was 102 U/L (normal <40 U/L). The patient was started on rosuvastatin 10 mg once daily.... One month following therapy, AST and ALT had declined to 35 U/L and 64 U/L, respectively.

Two months after the initiation of rosuvastatin, the patient was started on sitagliptin 100 mg once daily due to elevated hemoglobin A1C of 8.2%. The patient's other medications included amlodipine 5 mg once daily, benazepril 20 mg once daily, aspirin 81 mg once daily, glucosamine 500 mg once daily, chondroitin 400 mg once daily, and indomethacin 25 mg once daily as needed. One month after initiation of sitagliptin, liver enzymes were monitored and revealed an AST and ALT of 71 U/L and 127 U/L, respectively. Four days later the AST and ALT levels were 70 U/L and 137 U/L, respectively. All other corresponding hepatic function results were within normal range for the patient. A full medication review was performed. Sitagliptin was discussed as a possible cause of increased liver enzyme levels and promptly discontinued. Reexamination of liver enzymes a month after discontinuing sitagliptin revealed a significant decrease in AST and ALT (48 U/L and 90 U/L, respectively). Most recently, 6 months after discontinuation, AST and ALT were 35 U/L and 62 U/L, respectively.

The authors of this letter about Januvia acknowledge that prior studies have not found any liver-related side effects associated with Januvia, and they list several articles concerning those earlier safety studies. They go on, however, to make this important point:

Although no significant elevation of hepatic enzymes has been reported in the literature, most of the trials involving the safety of sitagliptin were small and short in duration.

As such, in conclusion, they offer that certain patients starting Januvia should perhaps be monitored for possible liver side effects.

We will continue to monitor the safety profile of Januvia, and we welcome any information or insight you may have about this drug safety issue.

Attorney <u>Tom Lamb</u> 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. <u>http://www.DrugInjuryWatch.com</u>