Acute Pancreatitis Case Associated With Victoza Use, Similar To Byetta And Januvia Case Reports

Drug Safety Issue Controversy Continues: True Serious Side Effect, Or Attributable To Type 2 Diabetes Condition

(Posted by Tom Lamb at <u>www.DrugInjuryWatch.com</u> on June 6, 2011; see <u>http://bit.ly/k9cCyO</u>)

Novo Nordisk has a relatively new diabetes drug, Victoza (liraglutide), approved by FDA in 2010, which has been linked to pancreatitis recently. From the Abstract for this medical journal article, <u>"Acute Pancreatitis Associated with Liraglutide"</u>, *The Annals of Pharmacotherapy*, April 2011, we get these basic facts:

OBJECTIVE: To report what is, to our knowledge, the first postmarketing case of acute pancreatitis associated with [Victoza (liraglutide)].

CASE SUMMARY: A 60-year-old female with type 2 diabetes presented with a 16-hour history of mid-epigastric pain 3 weeks after treatment was changed from exenatide 10 µg twice daily, which she had taken for 4 years, to liraglutide 1.8 mg daily. Her serum lipase level was elevated (478 units/L) at admission, and other laboratory values were within normal limits. Liraglutide was discontinued at admission. Standard therapy for pancreatitis resulted in symptom resolution and a significant decrease in serum lipase (131 units/L) by hospital day 4; she was discharged on hospital day 5.

DISCUSSION: Based on the Naranjo scale, this case represents a probable adverse drug reaction. Eight cases of pancreatitis were observed in liraglutide-treated patients in premarketing clinical trials. Extensive literature describing exenatide-related pancreatitis and premarketing reports of liraglutide-related pancreatitis, along with the temporal relationship between the initiation of liraglutide and the onset of this patient's symptoms, suggest that the episode of pancreatitis was induced by liraglutide.

CONCLUSIONS: Liraglutide should be used cautiously in patients with a history of pancreatitis, and clinicians should have a high index of suspicion for this rare, but potentially serious, adverse effect.

Victoza is in the same class of drugs as Byetta (marketed by Amylin Pharmaceuticals and Eli Lilly) and Januvia (marketed by Merck).

As regards the possible link between Byetta and pancreatitis, our first articles were written back in 2008:

- More Information About Reports Of Byetta Use Being Linked To Acute Pancreatitis
- August 2008: Byetta Associated With Hemorrhagic Pancreatitis And Necrotizing
 Pancreatitis

We have been monitoring the pancreatitis drug safety issue for Januvia since 2009, when we wrote these two articles:

- FDA Wants Merck To Change Januvia Label With Increased Warning About Pancreatitis Risk
- A Review Of Recent Research On Issue Of Whether Januvia Can Cause Pancreatitis

This June 1, 2011 news report headline, <u>"Diabetics show higher risk of pancreas disease"</u>, states succinctly why the apparent association between pancreatitis and Victoza -- as well as Byetta and Januvia -- has been questioned by some. From that *Reuters Health* report:

People with type 2 diabetes may have a heightened risk of a painful condition known as acute pancreatitis, but those odds are curbed in people on diabetes drugs, a new study suggests....

The findings back up earlier studies that have linked type 2 diabetes to acute pancreatitis, according to senior researcher Dr. Pei-Chun Chen, of China Medical University College of Public Health in Taiwan.

But they also add something new, Chen told Reuters Health in an email.

Among people with diabetes, the study found, those on diabetes medications had a lower risk of acute pancreatitis. And the more medications they were using, the lower the risk.

The potential benefit was seen with a range of diabetes drugs -- including metformin (Glucophage); sulfonylureas, which include drugs like glimepiride (Amaryl) and glipizide (Glucotrol); thiazolidinediones, including rosiglitazone (Avandia) and pioglitazone (Actos); and alpha-glucosidase inhibitors, like miglitol (Glyset) and acarbose (Precose).

In recent years, certain other diabetes drugs -- including the brand names Januvia and Byetta -- have been linked to cases of pancreatitis, and warnings are included in the drugs' prescribing information.

However, it has not been clear whether the drugs themselves cause the pancreas inflammation. The medications were not specifically analyzed in the current study.

Chen said that these latest findings cannot prove that any diabetes medication protects against acute pancreatitis. Nor do they prove that diabetes, itself, causes pancreatitis in some people, the researcher said.

This latest study about the development of pancreatitis in patients with type 2 diabetes -- which seems to raise more questions than it does to provide answers -- is <u>"Risk of Acute Pancreatitis in</u> <u>Type 2 Diabetes and Risk Reduction on Anti-Diabetic Drugs: A Population-Based Cohort Study in</u> <u>Taiwan</u>", published online May 17, 2011 by *The American Journal of Gastroenterology*.

We will continue to monitor this (still) emerging safety issue concerning pancreatitis and Victoza (as well as Byetta and Januvia).

If you have any knowledge about a case of pancreatitis in a patient using Victoza, Byetta, or Januvia, you may want to share what you know with others by leaving a Comment, below.

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>