

[A Review Of Recent Research On Issue Of Whether Januvia Can Cause Pancreatitis](#)

Is Pancreatitis A Januvia Side Effect Or Is There An Increased Risk Of This Medical Condition Among Type 2 Diabetics Across All Treatments

(Posted by Tom Lamb at www.DrugInjuryWatch.com on October 12, 2009; see <http://bit.ly/1dA3es>)

A few weeks back we reported that [the FDA wants Merck to change the package insert, or label, for the diabetes drug Januvia \(sitagliptin\)](#) so as to show an increased warning about the risk of developing pancreatitis.

Since then we have found some reports about relatively recent research about this issue of whether or not there is, in fact, any link between Januvia and pancreatitis.

We start with the early online publication of "[Beneficial Endocrine but adverse Exocrine effects of Sitagliptin in the HIP rat model of Type 2 Diabetes, interactions with Metformin](#)" in the medical journal Diabetes back in late April 2009.

From a press release which was issued by UCLA in connection that online publication, "[Popular diabetes treatment could trigger pancreatitis, pancreatic cancer](#)", we get these points:

- [R]esearchers from the Larry L. Hillblom Islet Research Center at UCLA found that sitagliptin, sold in pill form as Januvia, caused abnormalities in the pancreas that are recognized as risk factors for pancreatitis and, with time, pancreatic cancer in humans.
- Sitagliptin [*i.e.*, Januvia] is a member of a new class of drugs that enhance the actions of the gut hormone known as glucagon-like peptide 1 (GLP-1), which has been shown to be effective in lowering blood sugar in people with Type 2 diabetes.
- The UCLA study suggests that there may indeed be a link between drugs that enhance the actions of GLP-1 and pancreatitis — by increasing the rate of formation of cells that line the pancreatic ducts.

Moving on, we turn next to an October 1, 2009 article, "[EASD: No Extra Risk of Acute Pancreatitis Seen with Exenatide](#)", published online by *MedPage Today*. While this article is principally about a presentation on a large study concerning the diabetes drug Byetta (exenatide), it contains some discussion that is relevant to the Januvia - pancreatitis issue.

To start, the underlying study is "Incidence of acute pancreatitis in exenatide initiators compared to other antidiabetic drug initiators: a retrospective, cohort study", by Gary Bloomgren, of Amylin Pharmaceuticals, et al, which can be found in the medical journal *Diabetologia* (2009; 52: S9).

From the October 1 *MedPage Today* article we set these items for thought:

- Two years ago, after reports of 30 cases of acute pancreatitis in patients taking exenatide, the FDA forced Amylin and its marketing partner, Eli Lilly, to add a caution to the drug's prescribing information. [See: "[FDA Alerts Doctors About Diabetes Drug Byetta And Acute Pancreatitis Reports](#)"]
- The issue of acute pancreatitis and drugs acting on the glucagon-like peptide-1 pathway gained new prominence last week when the FDA requested a caution on the drug sitagliptin (Januvia), after 88 cases were reported to the agency.
- However, the agency never determined that [Byetta] actually caused these effects, or that the incidence was any greater than might be expected in a diabetic population.

- Bloomgren cited one recent study that found the risk of acute pancreatitis among type 2 diabetics is about three times that of nondiabetic individuals, across all treatments.
- Exenatide [*i.e.*, Byetta] is a synthetic GLP-1 mimic, while sitagliptin [*i.e.*, Januvia] inhibits the dipeptidyl dipeptidase-4 (DPP-4) enzyme that degrades GLP-1, thereby making the peptide more available.
- Another DPP-4 inhibitor was reported here to have no association with acute pancreatitis in a review of controlled clinical trial data involving nearly 12,000 patients.
- The drug was vildagliptin, marketed in Europe as Galvus but not available in the U.S.

As you can see, the findings from these two recent medical studies about the diabetes drugs Januvia and Byetta are mixed as regards the issue of whether Januvia causes an increased risk of pancreatitis.

We welcome any and all feedback or guidance as regards this emerging drug safety issue concerning Januvia. Please participate in the conversation by submitting a Comment, below.

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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