

## Medical Journal Withdraws Article About Januvia And Byetta After It Gets Letters From Two Drug Companies

### April 2011 Edition Of *BMJ* Breaks News And Provides Insight From One Who Saw An Increased Risk Of Pancreatitis

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on March 3, 2011; see <http://bit.ly/ldLAB9>)

According to a news item published April 11, 2011 by *The British Medical Journal* (*BMJ*), letters written by Merck and Novo Nordisk to Anil Rustgi, the editor-in-chief of *Gastroenterology*, resulted in that journal withdrawing an article which it had posted on its website about how Januvia (sitagliptin) and Byetta (exenatide) have been associated with an increased risk of pancreatitis as well as several cancers.

From this April 2011 *BMJ* piece, ["Journal withdraws article after complaints from drug manufacturers"](#):

In the disputed paper the team responsible... used the FDA database of adverse events from 2004 to 2009 to compare the number of cases of disease reported by users of the two drugs with the number reported by users of four other antidiabetes drugs.

They concluded that the risk of pancreatitis was increased by 6.8 times in users of sitagliptin (95% confidence interval 4.7 to 10.2) and by 11.8 times (8.5 to 16.6) in users of exenatide. For pancreatic cancer the risk ratios were 2.4 and 2.0, respectively, and for thyroid cancer 3.4 and 7.6....

The "disputed paper" was put on the *Gastroenterology* journal's web site on or about February 21, 2011. About two weeks later, the two drug companies took their actions which resulted in getting this article removed:

The companies wrote letters to Anil Rustgi, the journal's editor in chief, after the paper appeared online. They expressed concern that the analysis, which used data derived from the US Food and Drug Administration's adverse event reporting system, reached conclusions that could not be justified. Merck warned that the paper could have a negative effect on the care of patients, while Novo Nordisk claimed that it could spark an unnecessary health scare.

One of the authors of the paper, Peter Butler, of the David Geffen School of Medicine at the University of California at Los Angeles (UCLA), said that the drug companies wanted the paper deleted. *Gastroenterology's* website initially recorded the paper as "retracted," which might imply that the authors themselves had chosen to remove it. This was not the case, Dr

Butler said: the decision had been taken by the editors. The journal has since changed the paper's status from "retracted" to "withdrawn."...

Dr Butler said he was pleased that the two drug companies had not achieved "complete deletion" of the paper.

We have been monitoring developments concerning the pancreatitis 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](#)

As for the 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 will continue to watch for reports of pancreatitis that may have been caused by Januvia or Byetta.

If you are aware of such a case, you may want to share your information by leaving a Comment below or, if interested in a possible legal case, by you can [submit a Byetta Case Evaluation form](#).

**P.S.** The diabetes drug Januvia is marketed by Merck.

Byetta is marketed by Amylin Pharmaceuticals and Eli Lilly.

Novo Nordisk has a relatively new diabetes drug, Victoza (approved by FDA in 2010) which is in the same class of drugs as Byetta. Victoza (liraglutide) has been linked to pancreatitis, also. See "[Acute Pancreatitis Associated with Liraglutide](#)", *The Annals of Pharmacotherapy*, April 2011.

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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>