

[New Extensively Documented Case Report About Patient With Probable Byetta-Induced Pancreatitis](#)

Numerous Factors, Including Temporal Relation Of Symptoms To Drug Use Dates And A Naranjo Scale Score Of 7/9, Strongly Suggest Byetta Caused This Case Of Acute Pancreatitis

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 26, 2010; see <http://bit.ly/a0N8rD>)

On March 25, 2010 an article from *Endocrine Practice* -- 2010;16(1):80-83. © 2010 American Association of Clinical Endocrinologists -- titled "[Exenatide-induced Acute Pancreatitis](#)" was posted on the Medscape web site (access requires free registration). This article provides a thoroughly documented case report concerning a woman with non-insulin-dependent diabetes (NIDDM) receiving Byetta (exenatide) who developed acute pancreatitis.

As background, the active ingredient in Byetta, exenatide, is a 39-amino acid synthetic version of exendin-4, a naturally occurring component of Gila monster saliva. The FDA approved Byetta in 2005 as adjunctive therapy for non-insulin-dependent diabetes mellitus (NIDDM).

From this 2010 report about a possible case of Byetta-related pancreatitis we get these relevant facts about the subject patient:

A 64-year-old white woman presented with 1 month of epigastric pain aggravated by food and unrelieved by movements, melena, or rectal bleeding. Medical history included NIDDM, hypertension, hyperlipidemia, and cholecystectomy. She did not smoke cigarettes, had no history of recent trauma or endoscopic retrograde cholangiopancreatography, and did not drink alcohol. Her medications included metformin, 1000 mg twice daily; lovastatin, 40 mg daily; glipizide, 20 mg twice daily; lisinopril, 10 mg daily; furosemide, 40 mg daily; sertraline, 50 mg daily; aspirin, 325 mg daily; calcium carbonate, 1250 mg daily; multivitamin tablet, once daily; and pantoprazole, 40 mg daily. One month before hospital admission, she was prescribed exenatide, 5 mcg twice daily, because of poor glycemic control. This was stopped 10 days before admission because of symptoms that began 2 days after initiation of exenatide therapy.

The authors of this Byetta case report then set forth their analysis, which includes these three parts:

- 1)** The most common cause of acute pancreatitis is gallstone disease (accounting for 30% to 60% of cases), followed by alcohol (5% to 30%), and hypertriglyceridemia (1.3% to 3.8%). The serum triglyceride levels are usually greater than 1000 mg/dL when hypertriglyceridemia is the etiology.[6] Because this patient had a cholecystectomy, had no evidence of intrahepatic or extrahepatic duct obstruction, had no history of trauma or endoscopic retrograde cholangiopancreatography, did not drink alcohol, and had a normal lipid profile, we explored other etiologies. The commencement of exenatide treatment just before the onset of symptoms was striking. [footnotes omitted]
- 2)** We believe the patient we describe represents the most thoroughly documented case of probable exenatide-induced pancreatitis and is supported by a Naranjo score of 7/9, signifying a probable association.[10] The Naranjo scale consists of a 10-item, yes or no questionnaire used to estimate the probability of a change in clinical status being due to an adverse drug reaction. A score of 9 or greater indicates that an adverse drug reaction is "highly probable"; 5–8 indicates "probable"; 1–4 indicates "possible"; and 0 or less indicates "doubtful." For a quarter of a century, the Naranjo scale has been widely accepted in the pharmacologic literature to assess the probability of an adverse drug reaction. [footnotes omitted]
- 3)** Obviously, an occult etiology for the patient's pancreatitis cannot be entirely discounted without rechallenging with exenatide, an unethical intervention in this circumstance. Although pancreatitis has been reported with furosemide, lisinopril, lovastatin, sertraline, and metformin, their protracted use in the described patient without change in dosage militates against their being the etiologic agent.[12] To our knowledge, there has been no report of glipizide causing pancreatitis, although single case reports of the association of pancreatitis and glimepiride and gliclazide do exist.[13,14] Reinstitution of these

medications, with the exception of glipizide and exenatide, at the same dosages did not result in recrudescence of symptoms, abnormal serum lipase concentration, or radiographic evidence of pancreatitis in our patient. [footnotes omitted]

The authors conclude their article with the advice that where there is a diabetic patient with pancreatitis, "exenatide must be ruled out as the cause and its use discontinued."

As we reported previously, [in October 2009 the FDA said in a letter to Amilyn that the agency wants studies done on the safety of Byetta](#), with a focus on pancreatitis and pancreatic cancer as well as some other possible side effects.

We are [currently investigating cases of pancreatitis -- acute, hemorrhagic, and, necrotizing pancreatitis -- kidney failure, and renal insufficiency](#) involving patients who have used Byetta.

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>