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FDA Alerts Doctors About Diabetes Drug Byetta And Acute Pancreatitis Reports

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POSTED: Friday, October 19, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Package Insert Will Be Changed To Include Stronger Warning About This Potentially Fatal Side Effect

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On October 16, 2007 the FDA issued an alert to doctors informing them that the agency had reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta (exenatide), a drug used to treat adults with type 2 diabetes.

From this October 2007 FDA document, "[Information for Healthcare Professionals - Exenatide \(marketed as Byetta\)](#)", we get some breakdown of those 30 adverse reaction reports:

- FDA said there is evidence that suggests an association between Byetta and acute pancreatitis "in some of these cases."
- In six patients the pancreatitis symptoms began or worsened soon after Byetta dose was increased from 5 mcg twice daily to 10 mcg twice daily.
- 22 of the 30 reports indicated that the patients improved after discontinuing exenatide, *i.e.*, "de-challenge".
- Details in three reports indicated that the symptoms of acute pancreatitis returned when exenatide was restarted, *i.e.*, a "re-challenge".
- 21 of the 30 patients were hospitalized.
- Five patients developed serious complications including dehydration and renal failure, suspected ileus, phlegmon, or ascites.
- 27 of the 30 patients had at least one other risk factor for acute pancreatitis such as gallstones, severe hypertriglyceridemia, and alcohol use.
- The package insert, or label, will be changed to include information about pancreatitis in the "Precautions" section.

According to an October 17, 2007 article, "[FDA Says Diabetes Drug May Cause Pancreatitis](#)", by Jennifer Corbett Dooren:

Byetta is co-marketed by Amylin Pharmaceuticals Inc., based in San

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Diego, and Eli Lilly & Co., of Indianapolis. It was approved in 2005....

Alice Bahner Izzo, an Amylin spokeswoman, said information about pancreatitis is already on Byetta's label, but that it's being updated to give clear advice on what signs and symptoms doctors should look for.

"It's a rare but serious event," Ms. Izzo said of pancreatitis. Byetta has been used by 700,000 patients in the U.S. since the drug was introduced.

The FDA recommends that patients taking Byetta who experience unexplained severe abdominal pain, perhaps accompanied by vomiting, should seek immediate medical care.

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